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THE OFFICIAL TECHNICAL MAGAZINE OF ISPE

JANUARY/FEBRUARY 2014 VOLUME 34, NUMBER 1

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ISPE Announces Annual Meeting to be held on Mars; Katy Perry Joins ISPE!

by Roger Nosal, Chair, Pharmaceutical Engineering Committee

There is nothing like a vivid or startling headline, albeit completely phony, to draw a reader to a story. Even when strained with bias or vaguely misleading, tabloids and newspapers use headlines to grab attention, provoke a reaction and "sell copy." However, technical publications, like this one, tend to strive for a loftier, more altruistic goal – scientific integrity and respect. While scientific integrity and content quality are critically important to *Pharmaceutical Engineering's* success, highly technical and esoteric topics can render articles in a technical magazine or journal as dry as a piece of toast. As pharmaceutical supply chains become increasingly global and complex and the regulatory environment concomitantly challenging, a multitude of important issues have emerged. While the editors of *Pharmaceutical Engineering* will guard against overtly sensational headlines, in the coming issues, we will begin to confront contemporary topics with a challenging and provocative approach.

I have the privilege of serving as Chair of the Pharmaceutical Engineering Committee (PEC) which oversees the content, style and publication of this technical publication. The PEC is committed to improving the relationship between ISPE members and the publication. In addition, we intend to expand readership of *Pharmaceutical Engineering*, by introducing an auspicious and uninhibited forum for tackling compelling issues facing the pharmaceutical industry. Toward that end, we plan to establish a progressive voice for *Pharmaceutical Engineering* that stimulates ISPE member interest and provokes responses to articles, opinions/editorials and industry perspectives. While *Pharmaceutical Engineering* will continue to publish articles of specific technical interest to ISPE members and constituents, we will also introduce unconventional, innovative, inspiring, provocative, useful and contemporary perspectives that we hope will stimulate visceral reactions and prompt thoughtful responses from our readers. In future issues, we expect to focus on a variety of topics, including drug shortages, supply chain complexity, global harmonization, regulatory divergence, post-consumer environmental fate, manufacturing challenges of antibiotic, cytotoxic and vaccine development, quality risk management, quality metrics, modular manufacturing and continuous processing, green chemistry, extemporaneous clinical supplies, modernizing ICH, sustainability, regulatory risk tolerance, and many more.

> *"The dissemination of technology in a free market cannot proceed very effectively if each manufacturer works in total disregard of all others."*
>
> *H. Petroski, Invention by Design*

During 2014, the PEC will conduct a brief survey to canvas ISPE members to improve our understanding of readership interest. Please tell us why you read *Pharmaceutical Engineering* and what topics you would like us to address? We certainly don't want to rely on catchy headlines. We want to publish articles and perspectives that are meaningful to you and perhaps provoke a response. We want *Pharmaceutical Engineering* to serve as a forum for feedback and dialog on contemporary issues that face our industry. I look forward to hearing from you in the future.

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ISPE Stretches its Reach in new Opportunities while Building on its Traditions

Berg shares new opportunities to lead, build and enhance valuable Member benefits and increase the Society visibility among Members, companies and executives.

I guess I was a funny kid. As a teenager, I remember attending a county fair and winning a game that required especially good hand to eye coordination. The game's prize was my choice of a collectible pin or button featuring the names of rock bands like the Rolling Stones, popular phrases like "faaaar out" and "stay cool," sports logos and political characters. As I passed over the music and sports options, my eyes focused intently on a simple black and white pin that was to be my selection. It read: **When things are out of reach; *s-t-r-e-t-c-h.*** This pin has been with me ever since as a reminder to set big goals.

Stretch goals have been my mantra for ISPE. When the Society engaged me in 2011, it was at a crossroads–it needed to s-t-r-e-t-c-h or reach for opportunities to better serve the Membership by leading, building and enhancing valuable Member benefits and increasing the Society's visibility among Members, companies and executives. Since 2011, ISPE has *stretched*–taking on extraordinary opportunities including leadership in global drug shortage initiatives, quality metrics and other high profile issues. Last year ISPE led its first patient survey focused on experiences with clinical trial materials; launched several new events including Pharma EXPO, a new global exhibition (2-5 November, Chicago, IL, USA) and formed groups to attract involvement of new and inactive Members. In case you missed us, last year ISPE was mentioned more than 8,000 times in trade journals, newspapers, websites, tv, radio and other media outlets and more senior executives were involved in Society projects than ever before.

While ISPE is leading new initiatives, it is also enriching tradition. In 2014, meetings will take place among long-serving Members, Society groups and the ISPE Board of Directors to determine ways to enhance Member experiences. One discussion series will engage leaders from every ISPE Affiliate and Chapter worldwide around how to best present the ISPE global and local brands and leverage all ISPE knowledge and talent in support of the Society mission.

We will also continue to invest in annual programs such as ISPE's 23rd Annual Conference on Barrier Isolation, RABS and Aseptic Processing Technology scheduled for 24-25 March in Washington, DC. This year's program will again address the latest technologies and approaches to ensuring the quality of injectable drugs. Congratulations to Member leaders like Jack Lysfjord who has been a member of the planning team since its inception, making this one of ISPE's most respected and information-packed experiences.

A new programming approach in Europe will debut with the ISPE Europe Annual Conference, 28-30 April in Frankfurt, Germany. An expert Member team has planned this program which includes participation of more than two dozen European regulators. The conference theme is Driving Effectiveness in Pharmaceutical Operations within the New Quality Culture with conference tracks on QbD, Quality Risk Management and Facilities of the Future.

Register for all ISPE programs at www.ispe.org/events. I would love to hear your ideas for strengthening ISPE. We are also seeking blog writers to share thoughts and wisdom. Write me at nberg@ispe.org for more info.

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Application of Single-Use Equipment for Buffer Storage and Distribution in Medium Size mAb Production Facility

by Wilfried Kappel, Bhimasen Vadavi, Sanjay Lodha, and Daniel Karrer

This article presents a hybrid system approach in which stainless steel equipment and single-use equipment have been combined in the best possible manner for buffer preparation and buffer storage systems at a 2,000 L mammalian cell culture CMO production facility.

Biopharmaceutical processes are operated in aqueous systems using large quantities of WFI or Purified Water (PW). In the upstream process (USP), WFI is required for media preparation and feed solutions. In the downstream process (DSP), large quantities of PW or WFI are required for buffers, with buffer preparation, buffer storage, and distribution systems representing a significant portion of the process equipment used for the downstream purification in monoclonal antibody (mAb) production facilities.

However, the overall required volumes for buffer storage as well as the complexity for buffer distribution are often underestimated. This is especially the case for multi product facilities, which need a high degree of flexibility and short time intervals for product changeover.

In large scale production facilities of 10,000 L and more working volume, stainless steel systems have been installed traditionally using large buffer tank farms for buffer storage and complex transfer line configurations for buffer distribution.

In small scale production facilities, single-use systems with bags for buffer storage and flexible hoses for buffer distribution are widely used; however, size limitations and a higher degree of manual operations in regulated cGMP production environments must be taken into consideration.

This article describes an intelligent hybrid system approach in which both technologies – stainless steel systems and single-use systems – have been combined in the best possible manner in consideration of the pros and cons of each individual technology. The system described for buffer storage and buffer distribution has been realized for a 2,000 L mammalian cell culture production facility at Kemwell Biopharma Pvt. Ltd., India (a Contract Manufacturing Organization (CMO)).

The article will discuss the basic concepts and the selection criteria for utilizing single-use or stainless steel systems. Furthermore, practical examples will be provided for novel process designs as well as for novel equipment design details, such as interfacing flexible hoses with stainless steel piping that need SIP/CIP capabilities. Finally, the level of flexibility achieved by still keeping the systems simple and safe will be highlighted.

Buffer Demands

In most cases, current production strategies for manufactur-

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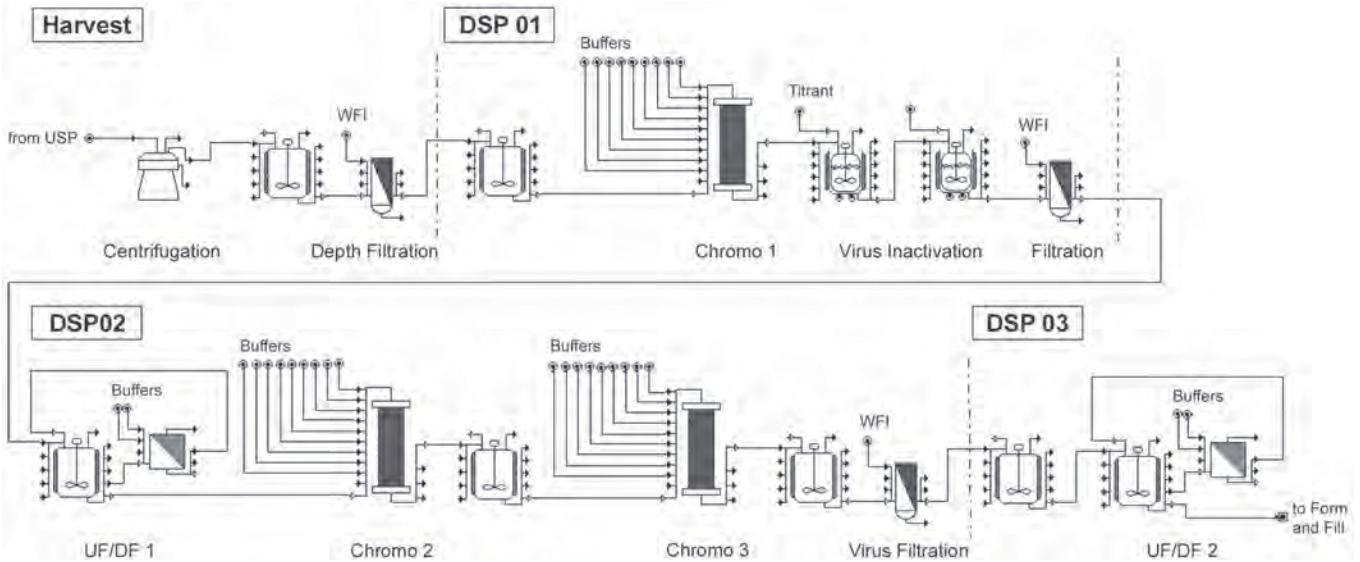

Figure 1. Process flow diagram for downstream process steps of a mAb platform process.

ing of protein therapeutics, such as monoclonal antibodies (mAbs), are based on platform processes[1] that need to allow easy adaption for multiple products in CMO facilities, if different product titers in upstream can be handled with the available buffer volumes in downstream. As a consequence, for flexibility the downstream process has to be designed for the expected titer range in the upstream process such as a cell culture titer of 3 to 5 g/L.

Figure 1 shows the downstream unit operations for the process steps of a typical mAb platform technology. After harvesting the bioreactor by disc stack centrifuge, further clarification is carried out by using depth and membrane filters.

The first purification step usually is a Protein A affinity chromatography (Chromo 1), in which the monoclonal antibody is selectively captured and purified from other host cell proteins and media components with a purity of up to 95%.

Two additional chromatography polishing steps are typically used for further purifications, most commonly a cation exchange chromatography (Chromo 2) for removal of aggregates and an anion exchange chromatography (Chromo 3) for removal of DNA.

In order to achieve sufficient viral clearance, a low pH virus inactivation step after the Protein A chromatography and a virus filtration step after the anion exchange chromatography step is foreseen in the purification process.

Additional dead-end filtration steps for removal of impurities and ultrafiltration/diafiltration steps (UF/DF 1) for product concentration and buffer exchange may be required for mAb processes.

Lastly, a final ultrafiltration/diafiltration step (UF/DF 2) is used for concentration and formulation before the bulk drug substance is frozen for storage.

Each individual purification step as described above

Process Step	WFI	Buffer A	Buffer B	Buffer C	Buffer D	Buffer E	Buffer F	Buffer G	Buffer H	Total
Depth Filtration	800 L									800 L
Chromatography 1	700 L	2,000 L	2,000 L	1,300 L	1,500 L	1,300 L	200 L	300 L	100 L	9,400 L
Virus Inactivation		100 L	100 L	50 L						250 L
Chromatography 2	800 L	1,000 L	600 L	600 L	1,100 L	600 L	300 L	500 L		5,500 L
UF/DF 1		1,400 L	100 L	200 L	200 L					1,900 L
Chromatography 3	800 L	1,000 L	1,000 L	1,600 L	1,000 L	600 L	300 L	300 L		6,600 L
Nanofiltration	500 L	200 L								700 L
UF/DF 2		1,600 L	100 L	200 L	200 L					2,100 L

Table A. Typical buffer volumes for a 2,000 L mAb downstream process with a product titer of 5 g/L.

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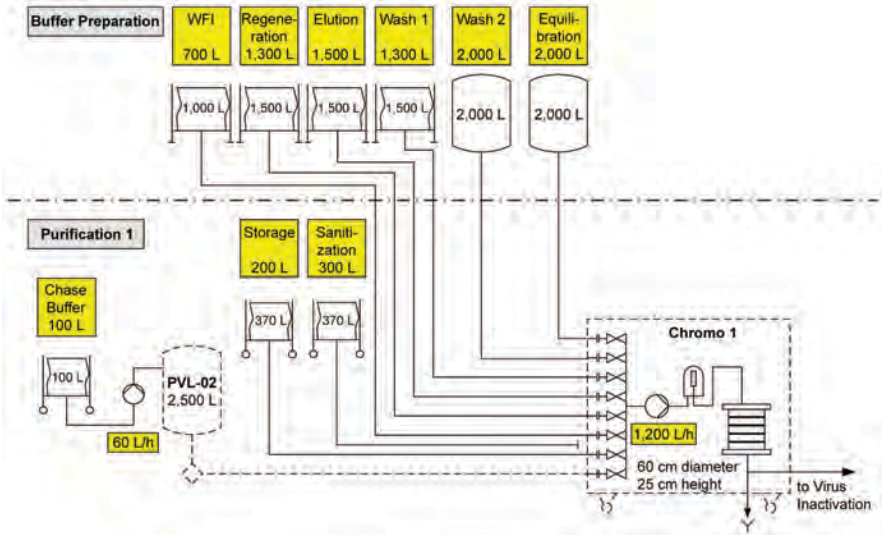

Figure 2. Buffer usage diagram for protein A chromatography step.

requires a number of specific buffers with different volumes. Those buffers are normally prepared in buffer preparation vessels or buffer mixing bags, then transferred for intermediate storage into buffer storage vessels or buffer storage bags and finally distributed to the point of use for the required process step. The processes for buffer preparation, buffer storage and buffer distribution run concurrently with the purification process steps and require sufficient process equipment and a proper process scheduling to make sure to have the right buffer at the right time at the right point of use in the DSP area.

The volumes of the different buffers that are required for a mAb purification process and the logistics behind for preparation, storage and distribution are often underestimated. Table A provides data on the required buffer volumes for a typical 2,000 L mAb downstream process with a product titer of 5 g/L.

As shown in Table A, the purification of 2,000 L of cell culture broth yielding less than 200 L of final bulk drug substance requires a number of different buffers with a total volume of more than 25,000 L; individual volumes are between 50 L and 2,000 L.

The buffer volumes required for each process step have been evaluated by modeling using mass balance calculations at different product titers. In the second step, buffer usage diagrams have been prepared for each process step. Figure 2 shows an example of a buffer usage diagram for the Protein A chromatography step (Chromo 1).

The buffer usage diagrams helped to further optimize the concepts and designs for buffer storage and buffer distribution such as:

- Number of the required buffers
- Volumes of each buffer
- Buffer storage system (stainless steel vessel or single-use bag)
- Location of the buffer storage systems (buffer preparation room or process rooms)

Utilization of Single-Use Bags for Buffer Storage

Single-use bags for buffer storage offer a number of advantages compared to stainless steel systems.[2] The main advantage is the high degree of flexibility, because the bag size can easily be changed if new processes will require this. Further advantages are that SIP and CIP are not required, and small size bags can be directly carried to the point of use without the need for transfer systems.

Figure 3. 2D-bags and 3D-bags for buffer storage, 2D-bags are installed on trays, 3D-bags are installed in palletanks.

Single-use bags are available either as pillow-style 2D-bags for small volumes (1 L to 50 L) and as box-shaped 3D-bags for larger volumes (50 L to 2,000 L).[3,4] 3D-bags are installed in bag containers which are either cylindrical (drum bags) or rectangular (palletank bags). Figure 3 shows a 2D-bag and a 3D-bag which is installed in a bag container (palletank).

However, regarding the utilization of single-use bags for buffer storage there are technical limitations that must be considered. Currently, the maximum size of 3D-bags is 2,000 L, and the flexible hoses that come with the bag are limited to 1" inner diameter which results in a

maximum flow of approximately 1.8 m³/h.

Also operational requirements should not be ignored while using single-use bags for buffer storage and buffer distribution, which have been considered in this project based on practical experiences from other projects.

- 2D-bags should be limited in size that they can be transported in filled state without using additional trays or trolleys. A suitable maximum bag size is 20 L.
- 3D-bags in bag containers which are located in the process rooms should be limited in size that they can be moved by trolleys in filled state without using fork lifts.[2] Forklifts are recommended for bag sizes ≥ 500 L.
- 3D-bags in the process rooms should utilize a small footprint as the required space in the purification rooms should be minimal for keeping flexibility in the set-up of the process equipment.
- Buffer bags which are located in the process area also should be filled in the process area via suitable buffer distribution systems in order to avoid too much traffic between the buffer preparation room and the process rooms.
- Large size buffer hold bags in the buffer preparation area should be installed into stationary bag containers (palletanks) with easy connection of the flexible hoses to headers for filling and buffer distribution.

Under consideration of the technical limitations and the operational requirements mentioned above, bag selection criteria have been set up in the beginning of the project with the following objectives:

- Large buffer volumes (> 1,500 L) that also need high flow rates are supplied from 2,000L stainless steel buffer storage vessels.
- For all buffers that are required in smaller volumes, single-use bags are used for buffer storage.
- 2D-bags are used only up to 20 L.
- 3D-bags for movement are used only up to 200 L.
- The maximum bag size in process rooms is limited to 500 L.
- Buffer volumes from 500 L to 1,500 L are stored in stationary bag containers (palletanks).

Clear bag selection criteria helped to minimize the number of different bag types and to standardize on the connection methods. More detailed information is provided in Table B, which shows the type of bags related to the buffer volume,

the location where the bag will be filled with buffer, the method for distribution of the buffer to the point of use, and the method for supplying the buffer to the process equipment.

Buffer Preparation and Storage

The initial concept for buffer preparation and buffer storage, which utilized buffer preparation vessels with 100 L, 500 L, 1,000 L and 2,000 L working volume had provisions for buffer storage up to 1,000L in bags in the process rooms and two large volume 2,000 L buffer storage vessels in the buffer preparation room. During the course of the project; however, it became clear that the designated 1,000 L palletanks for buffer storage in the process room would occupy too much space. Even more critical, the large volume buffer storage capacity with just two 2,000 L buffer storage vessels only was not sufficient for the buffer demands of different CMO processes.

A solution to both problems was found by installing additional palletanks in the buffer preparation room. With this simple extension, the large volume buffer storage capacity was increased to 1 × 1,000 L and 3 × 1,500 L in single-use bags plus 2 × 2,000 L in stainless steel vessels.

Buffer preparation takes place in a 1,000 L or a 2,000 L stainless steel vessel. Buffers are transferred from the buffer preparation vessels via sterile filters to the buffer storage vessels with filling of the buffer storage vessel from bottom. The transfer line and filter will be steamed in place (SIP) before buffer filling and rinsed or cleaned in place (CIP) after buffer filling.

Transfer to the buffer storage bags is also done via sterile filters using two stainless steel headers, one header assigned to the 1,000 L buffer preparation vessel, and the other header assigned to the 2,000 L buffer preparation vessel. The gamma-irradiated bags are connected via short flexible tubing with steam-to valves[5] to one of the two filling headers. With the steam-to valves, which are connected at minimum distance to tri-clamps at the filling header piping, a sanitary connection between the single-use tubing and the stainless steel piping could be realized. As for the transfer lines to the buffer storage vessels, the filling lines to the buffer storage bags also will be steamed in place before buffer transfer and rinsed or cleaned in place after buffer transfer, by this providing closed sanitary systems for the filling of the buffer bags. The process flow diagram for buffer preparation and buffer storage as seen in Figure 4 shows the connection between the stainless steel buffer preparation vessels and the single-use buffer storage bags via the fill header.

The additional four palletanks had to fit into the infrastructure of the buffer preparation room which was dominated by the stainless steel buffer preparation equipment and its appropriate design principles. For seamless integration of the single-use equipment, the four palletanks have been mounted on a small skid with one stainless steel piping header for filling of the buffer storage bags from the buffer preparation vessels, and another stainless steel piping header for buffer transfers from the buffer storage bags to the process rooms as seen in Figure 5. The palletank skid containing four 1,000 L/1,500 L bags occupied a footprint of 5.5 m × 1.0 m only. Inserting of the single-use bags can easily be done from the front. The integration of the palletank skid for the buffer storage bags, with its piping headers into the existing piping systems and automation structure could be realized in a consistent manner.

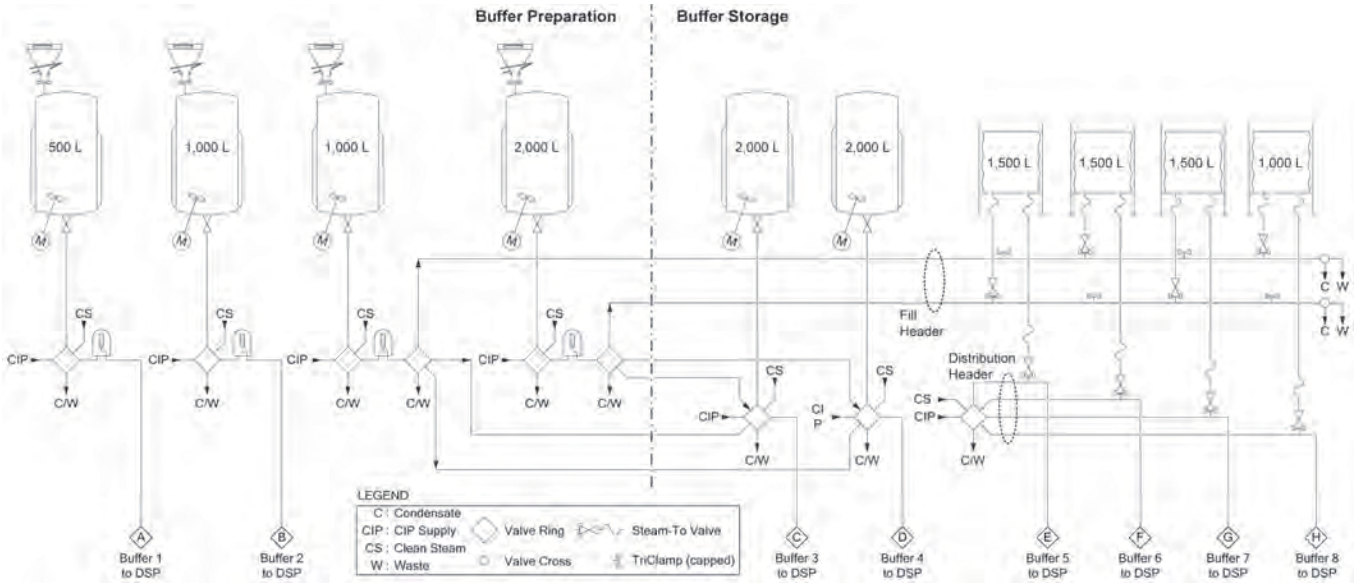

Figure 4. Process flow diagram for buffer preparation and buffer storage. Connecting points <A> to <H> refer to P&I-diagram in Figure 6.

Figure 5. Palletank skid for buffer storage with stainless steel piping headers for filling and distribution, located in buffer preparation room.

Buffer Transfer and Distribution

For transferring the buffers from the buffer storage bags over long distance to the process rooms, the gamma-irradiated bags also are connected via short flexible tubing with steam-to valve to a dedicated stainless steel buffer distribution line for each buffer storage bag. By using the same sanitary connection method – steam-to valves to tri-clamps at the piping header – as for the filling lines, the buffer distribution lines also can be steamed in place prior to buffer transfer and rinsed/cleaned in place after buffer transfer, thus providing a closed sanitary system.

Both flexible hoses at the buffer storage bags for buffer filling and buffer distribution provide 1"-ID tube sizing in order to allow fast filling and high flow rates for buffer delivery, which are required at certain process steps (e.g., Protein A Chromatography).

Further buffer distribution from the buffer preparation room to the process rooms for DSP purification is performed via a simple transfer line system. As the buffer preparation room is in the second floor, and the process rooms Purification 1, Purification 2, and Purification 3 are at the ground floor, stainless steel transfer lines[6] are used for buffer distribution to the point of use or for filling bags in the process rooms.

Table B identifies which buffer volumes (> 500 L to ≤ 1,500 L) will be directly transferred from bags in the buffer preparation room to the point of use in the process rooms, and which buffer volumes (> 50 L to ≤ 500 L) will be filled into bags in the process room from the buffer preparation vessels which are located in the buffer preparation room.

The buffer transfer from the buffer preparation room to the process rooms is done by gravity flow which is a well established method for stainless steel systems because it doesn't require pumps or pressurized vessels for transfer and it provides the necessary pressure head which is required for robust operation of the chromo systems at higher flow rates. The advantages of gravity flow have been adapted to buffer transfer out of bags within this project.

Figure 6 shows a simplified P&I diagram for the routing of the buffer transfer lines from the buffer preparation room via a mezzanine floor above the process rooms to the three process rooms at the ground floor. Only a few automated valves are needed for flow path selection for each of the eight buffer transfer lines. Based on the buffer demand in the individual process rooms, all eight buffer transfer lines are routed to Purification 1 and Purification 2, but only three buffer transfer lines are required for Purification 3.

While the sending side of the buffer transfer lines is assigned to either buffer preparation vessels, buffer stor-

Buffer Volume	Buffer Bag Type	Buffer Filling	Buffer Distribution	Buffer Usage
> 5 L to ≤ 20 L	2 D-Bags mobile	At buffer filling station in Buffer Prep. Room	Carry from Buffer Prep Room to Process Room	Connect bag to process equipment
> 20 L to ≤ 50 L	3 D-Drum Bags mobile	At buffer filling station in Buffer Prep. Room	Carry from Buffer Prep Room to Process Room	Connect bag to process equipment
> 50 L to ≤ 200 L	3 D-Drum Bags mobile	At buffer distribution skid in Process Room	Move to point of use within Process Room	Connect bag to process equipment
> 200 L to ≤ 500 L	3 D-Palletank Bags stationary	At buffer distribution skid in Process Room	Stationary Palletank in Process Room	Connect bag to process equipment
> 500 L to ≤ 1,500 L	3 D-Palletank Bags stationary	Via buffer filling header in Buffer Prep. Room	Buffer distribution skid in Process Room	Connect process equipment to buffer distribution skid
> 1,500 L to ≤ 2,000 L	Buffer Storage Vessels stainless steel	Via buffer filling header in Buffer Prep. Room	Buffer distribution skid in Process Room	Connect process equipment to buffer distribution skid

Table B. Bag selection criteria for buffer bags.

age vessels or buffer storage bags, the receiving side of the buffer transfer lines should allow flexible assignment for either filling of buffer storage bags in the process rooms or for supplying buffers directly to the process equipment, e.g., chromatography systems or UF/DF skids. As a general target, it should be possible to supply each buffer from the buffer preparation room to each point of use in the purification process rooms.

This approach for maximum flexibility has been realized by installing three buffer distribution skids in Purification 1, Purification 2, and Purification 3 room. The buffer distribution skids are the termination points of the buffer transfer lines in the process rooms with all required valves and instruments for SIP and CIP of the transfer lines (Figure 7). From the buffer distribution skids, the final connection for filling of buffer storage bags or supplying buffers to the process equipment is always done by short flexible hoses, which provides the targeted flexibility for supplying each buffer to each point of use.

The sanitary interface between the stainless steel buffer distribution skid and the single use bags or plastic transfer hoses is also done via steam-to valves at minimum distance to tri-clamps at the buffer distribution skid piping. Reusable steam-to valves have been used in this project which are autoclaved together with the transfer hose and then connected to the gamma irradiated bags by sterile tube welding (for tubes up to ¾" inner diameter), by this maintaining a closed sanitary system.

After connection of the steam-to valve to the selected buffer line at the buffer distribution skid via tri-clamp, the buffer transfer line will be steamed in place in order to provide a sanitary connection. For supplying buffer to the bag or process equipment, the steam-to valve must be opened manually. After transferring the buffer to the point of use, the steam-to valve will be closed again and the buffer transfer line will be rinsed with WFI or cleaned in place from the CIP unit.

The connection of the steam-to valve at the buffer distribution skid is done via a standard 1½" tri-clamp port (50.4 mm flange diameter). This tri-clamp port is suitable for connection of a small steam-to valve for ½" ID flexible hoses or a large steam-to valve for connection of 1" ID flexible hoses. This again provides a high degree of flexibility for buffer demand changes at new processes in the CMO facility.
As the entire mAb production facility is fully automated by a PLC/SCADA system, precautions must be taken for safe operation during connection and disconnection of the individual flexible hoses to the tri-clamp ports at the Buffer

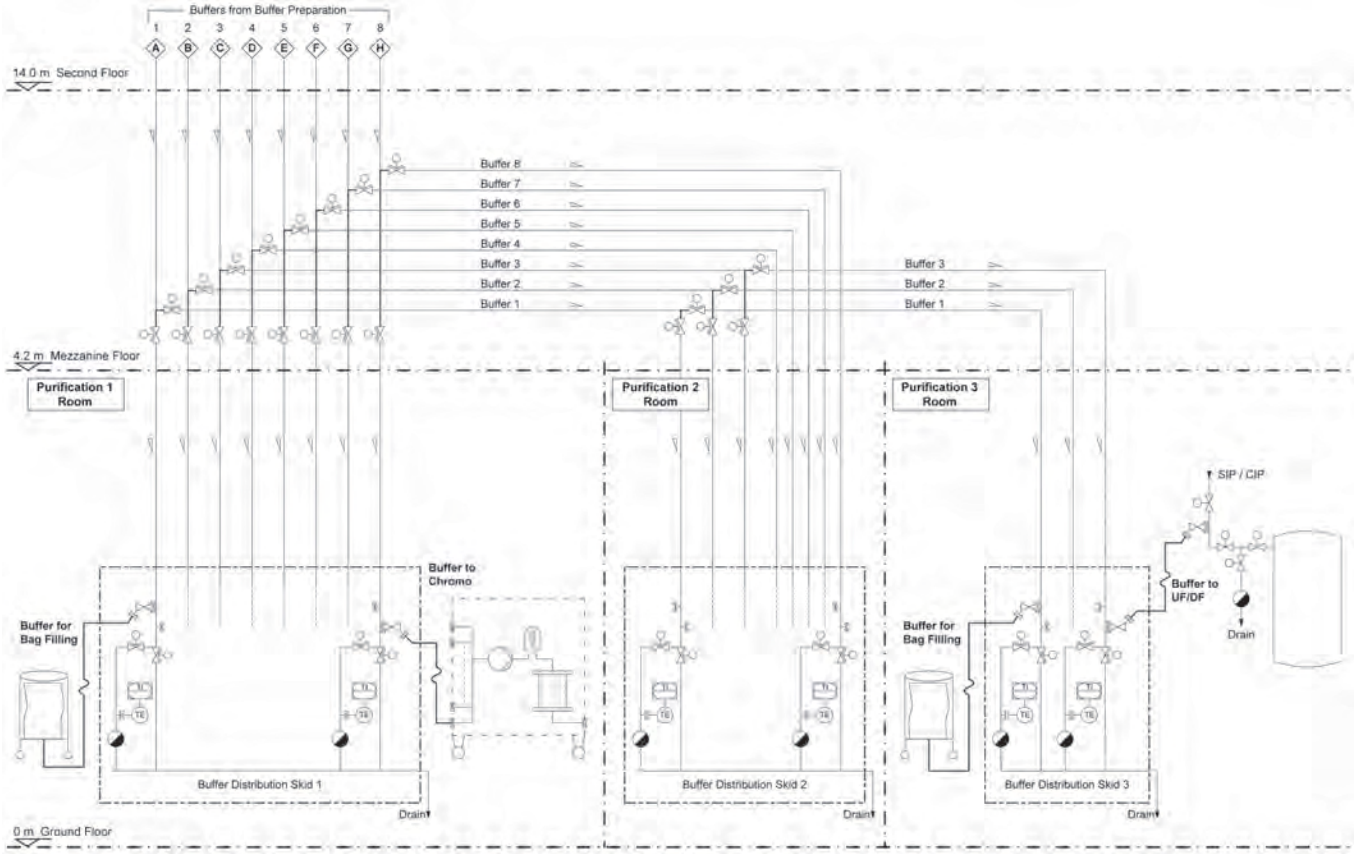

Figure 6. Simplified P&I-diagram for buffer distribution. Connecting points <A> to <H> refer to process flow diagram in Figure 4.

Figure 7. Buffer distribution skid in process room, with flexible hoses directly connected to chromo system and to drum bag for filling.

Distribution Skid. For that purpose, each buffer distribution skids is equipped with a small human-machine-interface (HMI) panel. The HMI panel shows the current status of all buffer transfer lines, which can be idle, SIP, transfer or CIP mode. Furthermore, operator prompts are given to guide the operators on the necessary manual operations that must be performed. Each manual operation must be acknowledged explicitly by the operator, in order to proceed with the automated functions. All those activities are part of the audit trail in order to achieve 21 CFR Part 11 compliance.

SIP/CIP Strategy for Hybrid Systems

Because the hybrid systems for buffer storage and buffer distribution, which are described in this article consist of stainless steel systems and single-use systems, Steam in Place (SIP) and Clean in Place (CIP) will be required for the stainless steel part according to the following general strategies for process execution:

a. Buffer storage vessels
   - SIP before buffer filling
   - Hot water rinse after buffer delivery
   - CIP in regular intervals, e.g., weekly intervals

b. Buffer storage bags
   - No SIP required, bags come gamma irradiated
   - No CIP required, bags will be disposed after use

c. Transfer lines for buffer filling to vessels or bags
   - SIP before buffer transfer to vessel/bag
   - Hot water rinse after buffer transfer
   - CIP in regular intervals, e.g., weekly intervals

d. Transfer lines for buffer distribution to process rooms
   - SIP before buffer transfer to buffer distribution skids
   - Hot water rinse after buffer transfer
   - CIP in regular intervals, e.g., weekly intervals

As it can be seen, the stainless steel parts of the hybrid systems (buffer preparation vessels) need full SIP and CIP with high CIP fluid consumptions and long CIP cycle times which are known from those kinds of systems. On the other hand, the single-use part of the hybrid systems needs SIP and rinse/CIP for the transfer lines only. By using steam-to valves as a consistent and simple interface between the pre-sterilized single-use bags and the stainless steel piping with connection to a simple tri clamp only, SIP and CIP is limited to SIP and CIP for a straight pipe only with low CIP fluid consumption and short CIP cycle time.

Conclusion

The hybrid systems, ideal for medium size mAb production plants, combining stainless steel equipment with single-use technology for buffer storage and buffer distribution, as described in this article provide the following features and benefits:

- Clear concept for the utilization of the buffer storage bags, which results in freed up process clean rooms.
- The installed buffer storage capacity in conjunction with the simple and flexible buffer distribution concept provides the necessary flexibility for running different low and high titer processes in a CMO facility.
- The buffer storage and buffer distribution systems, combining stainless steel equipment and single-use technology could be realized as closed sanitary systems in order to be prepared for future requirements from the regulatory authorities.
- The well established gravity flow method known from stainless steel systems for buffer transfers has been realized also in combination with single-use buffer storage bags.
- The single-use systems have been fully integrated into the plant-wide PLC/SCADA automation system with special functionality added for guiding and tracking of manual operations.
- The single-use systems with their transfer lines use a simplified concept for CIP/SIP with low CIP fluid consumption and short CIP cycle time, by this reducing cost and

process time and help to increase throughput
- The same principles as described in this article also can be applied to media preparation and storage.

Single use concepts and components are getting more and more mature and sophisticated,[7] helping to overcome current limitations and enabling further optimization of the concepts and designs described in this article. Basic designs for new projects did already consider an extended usage of single-use buffer storage bags, with still maintaining the advantages of closed buffer transfer systems.

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Evaluation of Controlled Manufacturing Environments following an Air Handling Unit Shutdown

by Catherine E. Anderson and Brian J. Lloyd, PhD

This article provides a methodology to evaluate the environmental impact of an air handling unit shutdown in a GMP manufacturing environment.

Environmental control within the biopharmaceutical and medical device industries usually involves a continual cycle of steady state activities interrupted by maintenance and recovery measures. Systems and practices, such as air temperature and humidity control, number of air exchanges, and room cleaning practices, are in place to maintain the overall environmental control. When the environment is challenged or breached, recovery measures are in place to ensure the controlled classified area returns to the qualified state with minimal impact to the environment and product. In many cases, the recovery measures may involve significant cleanings, limited access, and additional environmental monitoring which can reduce manufacturing time and increase cost. This case study evaluated the impact of a short term breach to a biopharmaceutical controlled classified manufacturing cleanroom areas and determined how long it would take these areas to recover with minimal recovery measures and intervention.

Introduction

Air Handling Units (AHUs) are the primary engineering control for classified controlled environments. They provide humidity/temperature control as well as the filtration and air exchanges necessary to ensure an environment meets its classified requirements. These units must be shut down periodically to allow routine maintenance, calibration activities, or planned construction. An example of the activities required to shut down a GMP AHU are listed in Table A.

The average costs associated with AHU shutdowns include two to four planned events annually per unit with an estimated annual cost of $2000 to $4000 per unit for parts and labor. The disruptive impact to the environment can be even longer for unplanned outages caused from mechanical or power failures. An average AHU also has one to two unplanned outages annually. The frequent disruption to the environment, whether planned or unplanned, can have a significant impact to production. These disruptions cause

Activity	Time
AHU Shutdown (Power down)	10 – 15 min
Routine Maintenance Work Performed	30 min – 4 hours
AHU Operation Resumed (Restart)	15 – 30 min
Classified Area Cleaning	2 – 4 hours
Additional Environmental Monitoring	2 – 4 hours
Overall Potential Delay	**Up to 12 hours per AHU Shutdown**

Table A. Typical planned AHU shutdown activities.

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delays in the production schedule due to required area cleanings, additional environmental monitoring, and time and resources necessary to assess product impact if the environmental disruption occurred during manufacturing operations. The degree of the appropriate response to an environmental disruption, especially a short duration of less than a few hours, is needed and data should be generated. This article presents a methodology that evaluated the impact of a temporary AHU shutdown on a classified environment and the potential for an AHU recovery period to minimize recovery efforts, specifically re-cleaning and monitoring of classified rooms.

Case Study Design

Along with climate control, AHUs utilize High Efficiency Particulate Air (HEPA) filters to control the level of particulates, both viable and non-viable, in the environment. An AHU shutdown increases the potential to reach or exceed allowable particulate levels in a controlled environment. To evaluate the potential impact and determine how long it takes for an area to recover with minimal intervention, a study was designed to shut down full scale AHUs for a prescribed amount of time, collect samples, then return to operation and allow the classified environment to recover for a prescribed amount of time. Samples would be collected again following the recovery period. No additional area cleaning would be performed as part of the recovery. The intention was to utilize the study results to temporary AHU shutdowns, whether planned or unplanned.

Industry Requirements

Controlled environments are used to protect products from contamination by greatly reducing the probability that airborne contamination will come in contact with the product or product intermediates or components. Controlled environments are classified based upon their potential impact on product quality. The general industry classifications and criteria[1,2,3,4] utilized for this case study are listed in Table B through Table D.

Classified Manufacturing Rooms

Two different GMP AHUs were selected for the study because they encompassed a range of air classifications (EU Grade B, Grade C, and Grade D) and support both processing and support (non-product) activities. One AHU primarily services Grade D rooms, with an air exchange rate of approximately 20 Air Changes per Hour (ACH), while the other primarily services

EU Grade	ISO Classification	US Designation
A	5	100
B	7	10,000
C	8	100,000
D	Undefined	Undefined

Table B. Area classification.

Classification	Static Conditions[Note A]		Dynamic Conditions[NoteA]	
	≥ 0.5 µm particle/meter^3	≥ 5.0 µm particle/meter^3	≥ 0.5 µm particle/meter^3	≥ 0.5 µm particle/meter^3
EU Grade A	NMT 3,520	NMT 20	NMT 3,520	NMT 20
EU Grade B	NMT 3,520	NMT 29	NMT 352,000	NMT 2,900
EU Grade C	NMT 352,000	NMT 2900	NMT 3,520,000	NMT 29,000
EU Grade D	NMT 3,520,000	NMT 29,000	Undefined	Undefined
Class 100/ ISO 5	NMT 3,520	NMT 29	NMT 3,520	NMT 29
Class 10,000/ ISO 7	NMT 352,000	NMT 2,930	NMT 352,000	NMT 2,930
Class 100,000/ ISO 8	NMT 3,520,000	NMT 29,300	NMT 3,520,000	NMT 29,300
A. No more than (NMT).				

Table C. Particles/non-viable environmental criteria.

Classification	Active Air Sample[Note A]	Settling Plates[Note A]
EU Grade A	LT 1 CFU/meter^3	LT 1 CFU/4 hours
EU Grade B	NMT 10 CFU/meter^3	NMT 5 CFU/4 hours
EU Grade C	NMT 100 CFU/meter^3	NMT 50 CFU/4 hours
EU Grade D	NMT 200 CFU/meter^3	NMT 100 CFU/4 hours
Class 100/ISO 5	LT 0.1 CFU/foot^3	LT 1 CFU/4 hours
Class 10,000/ ISO 7	NMT 0.5 CFU/foot^3	NMT 5 CFU/4 hours
Class 100,000/ISO 8	NMT 2.5 CFU/foot^3	NMT 50 CFU/4 hours
A. No more than (NMT), less than (LT).		

Table D. Particles/viable environmental criteria.

Grade C rooms, with an approximate air exchange rate of 25 ACH. There was one Grade B room located within the Grade C suite. There are no AHUs that provide environmental control for Grade A areas; these environments are controlled through laminar flow hoods. Therefore, testing of Grade A areas were excluded in this case study as this area was still under control during the AHU shutdown. The two AHUs selected for the study are serviced by HEPA filters with a standard 99.97% efficiency rating at 0.3micron.

The AHUs selected for the study contained rooms representing various configurations: rooms adjacent to unclassified areas, rooms adjacent to lower grade air classifications, rooms considered high traffic areas, rooms where direct product processing occurs and rooms where no processing occurs. The test areas were in an idle state during study execution, whereby the areas were still considered GMP and under control, but no open or closed processing would occur during testing. At the onset of the AHU shutdown, all doors to unclassified and lower classification areas were opened and remained open throughout the shutdown period to simulate worst case reverse air flow. While opening the doors to the unclassified areas is not routine and would be considered a disruption to the controlled environment, there is the possibility that a door separating unclassified and classified areas could be inadvertently opened. When the adjacent unclassified areas maintain air pressure during a classified AHU shutdown, reverse air flow would occur from the unclassified area into the classified area. This is a worst case scenario. Personnel flowed throughout the testing area and simulated routine dynamic activities.

The AHUs were shut down for a duration of approximately three hours. At the end of the shutdown period, with the units still powered off, the shutdown samples were collected. Once the shutdown sampling was complete, the units were powered back on and all doors to the unclassified/adjacent areas were closed. The test areas were allowed to recover for approximately one hour, whereby the AHUs were in operation and limited personnel flow was allowed through the areas. No additional area cleaning was performed as part of the recovery. The second round of sampling, recovery sampling, was performed at the end of the one hour recovery period. There were 140 samples collected during each sample period: 62 air viable samples and 78 surface viable samples. The shutdown and recovery sample sets were duplicate sets of samples taken from different sites at the same relative sample location.

Sampling Methodology and Acceptance Criteria

Sample collection included surface viable sampling and active air viable sampling at routine environmental monitoring locations. The routine locations were identified as worst case locations during the initial facility cleaning validation. The study collected the same number of samples at each sampling period as during routine environmental monitoring. Passive air viable sampling could not be performed within the confines of the study because the AHU shutdown period (three hours) was not long enough to accommodate the continuous sampling period required for passive air viable sampling method <USP 1116>. Thus active air viable results represent dynamic air conditions for a greater air volume than passive air viable results, and as such, active air viable samples were collected at the routine passive air viable sampling locations. Non-viable sampling was not performed as viable sampling would represent worst case particulate and microorganism levels in the environment. Surface viable samples were taken using Tryptic Soy Agar (TSA) contact agar plates. Air viable samples were taken using an electric volumetric sampling device (100 L/min) at 1 m^3 with TSA media.

The viable limits were based on criteria outlined in environmental classifications per <USP1116> and EU cGMP Guidelines Annex 1 (2008), Table D. The acceptance criteria for the shutdown samples could not exceed the routine action limit while recovery samples could not exceed the routine alert limit. The shutdown acceptance criteria were intended to evaluate how much of an environmental disruption a temporary AHU shutdown would create, while the recovery acceptance criteria showed that the environment had returned to a controlled classified state. This case study itself was considered a planned environmental disruption; whereby any alert or action level results would be considered part of the disruption and addressed in the case study.

Results

All samples were submitted for growth determination (CFU/plate). All samples met their respective acceptance criteria. The results based on *growth* verses *no growth* were evaluated to determine the impact of the shutdown and the recovery periods. The overall percentage of shutdown and recovery samples with any microbial growth is shown in Figure 1.

The number of samples, both surface and dynamic air, exhibiting any level of growth was reduced significantly with the post recovery period. This comparison illustrates that

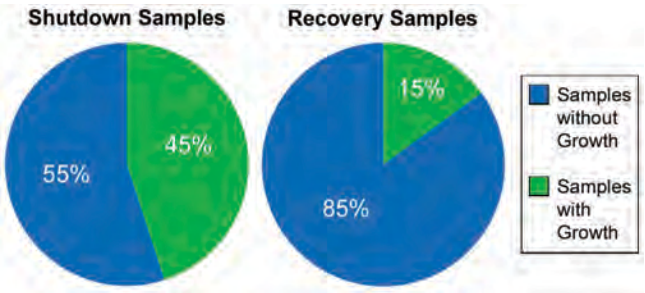

Figure 1. Samples with growth during shutdown and post recovery.

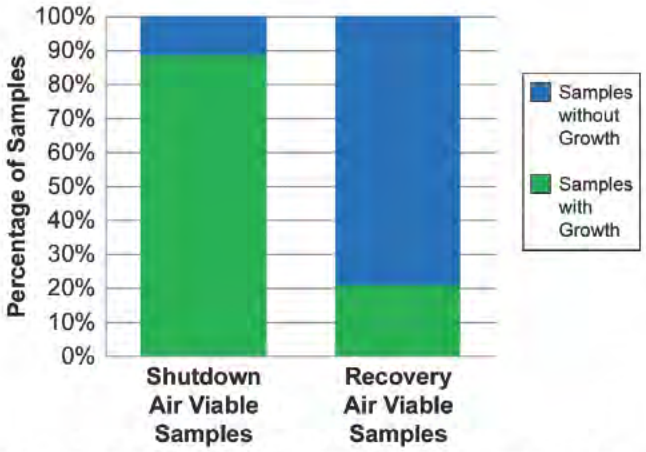

Figure 2. Air viable samples for shutdown and recovery samples.

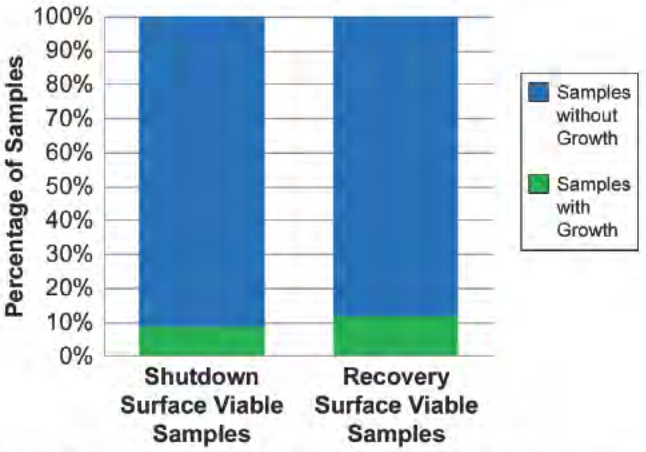

Figure 3. Surface viable samples for shutdown and recovery samples.

AHU operation alone decreases the overall number of microorganisms in the environment. For the recovery samples, the percentage of samples with growth (15%) was consistent with historical air viable and surface viable levels for the test areas. It also should be noted that all of the shutdown samples with growth were below the action levels of <10 CFU/m³ for Grade B, <100 CFU/m³ for Grade C, and <200 CFU/m³ for Grade D.

An assessment of each type of sample, air viable and surface viable, also was performed. The percentage of air viable samples with growth by sample period is shown in Figure 2. The percentage of surface viable samples with growth by sample period is shown in Figure 3.

As shown in Figure 2, the number of air viable samples with microbial growth was significantly reduced from the shutdown sample period to the recovery sample period (89% to 21%). For the surface viable samples in Figure 3, growth during the shutdown and recovery sample periods was basically equivalent (9% and 12%). Surface viables would not be expected to increase during a temporary AHU shutdown at the same rate as air viable because air contaminants are more directly controlled by HEPA filtration. The recovery air viable and surface viable results support not performing additional area cleaning (surface cleaning) for a temporary AHU shutdown. In addition, the results further demonstrate that AHU operation, as a singular measure, decreases air viable levels below acceptance criteria for classified environments.

The samples with growth were further reviewed based on their relative location within the test area: adjacent to unclassified areas, high traffic areas, processing rooms, non-processing rooms, etc. The majority (89%) of shutdown air

Room Grade	Sample Description	Relative Location and Type				
		Adjacent to Unclassified	Adjacent to Lower Grade Level	High Traffic	Non-Processing	Processing
C	Surface Viables					X
D	Surface Viables	X		X	X	

Table E. Shutdown results and relative room location and type.

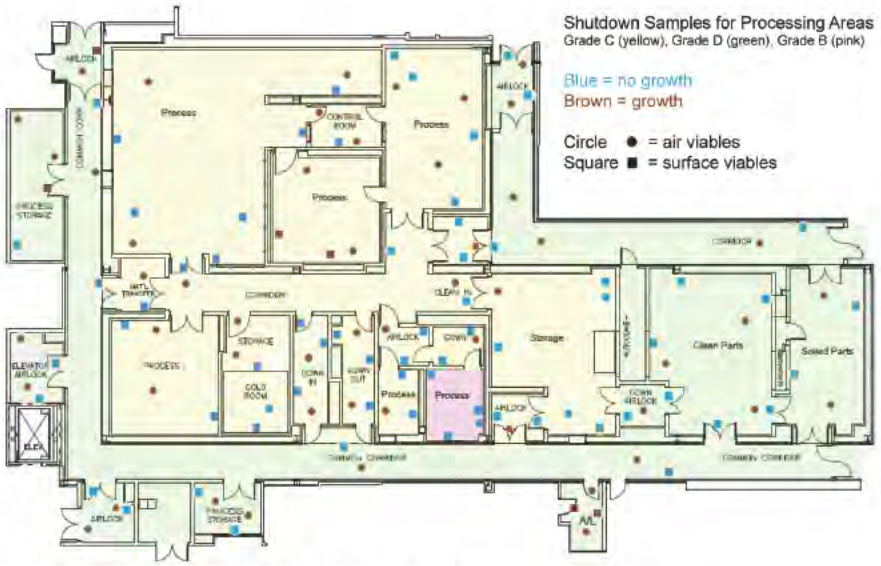

Figure 4. Location of shutdown samples and results.

viable results showed some level of viable growth; therefore, only shutdown surface viable samples were evaluated based on relative location within the test area. A summary of the shutdown results and relative room location are shown in Table E while detailed locations of each shutdown sample and result are shown in Figure 4.

The location of surface samples with growth showed a random distribution of samples with growth based on relative location and type. It was expected that room locations adjacent to unclassified areas or lower grade levels and rooms (or corridors) with higher traffic flows would have an increased potential for microbial growth. However, the shutdown surface results with growth occurred in both processing and non-processing rooms and were located throughout the test areas as opposed to being grouped in certain locations. Based on this comparison, no correlation was identified between room type or relative location and microbial growth during the shutdown sample period.

Both air and surface viable samples exhibiting growth were evaluated from the recovery sample period. The recovery results compared with the relative room locations and type are shown in Table F. Detailed locations for the recovery samples and results are shown in Figure 5.

Similarly, recovery samples with growth occurred mostly in non-processing rooms, but were located throughout both test areas including interior rooms, high traffic rooms and rooms that are adjacent to unclassified or lower grade level areas. The minimum volumetric turnover rate, room changes per minute (RCM), is >30 for Grade B and >20 for Grade C and D. Most GMP facilities operate with Grade C turnover rates between 27 to 28 RCM and Grade D turnover rates between 22 to 24 RCM in order to meet the recommended RCM rates. The lower RCM was speculated to cause the majority of the recovery samples with growth to be located in Grade D rooms. Based on this evaluation, there was no identified correlation between room type or relative location and microbial growth during the recovery sample period.

Room Grade	Sample Description	Relative Location and Type				
		Adjacent to Unclassified	Adjacent to Lower Grade Level	High Traffic	Non-Processing	Processing
C	Surface Viables				X	X
	Air Viables			X	X	X
D	Surface Viables	X		X	X	X
	Air Viables	X	X	X	X	

Table F. Recovery results and relative room location and type.

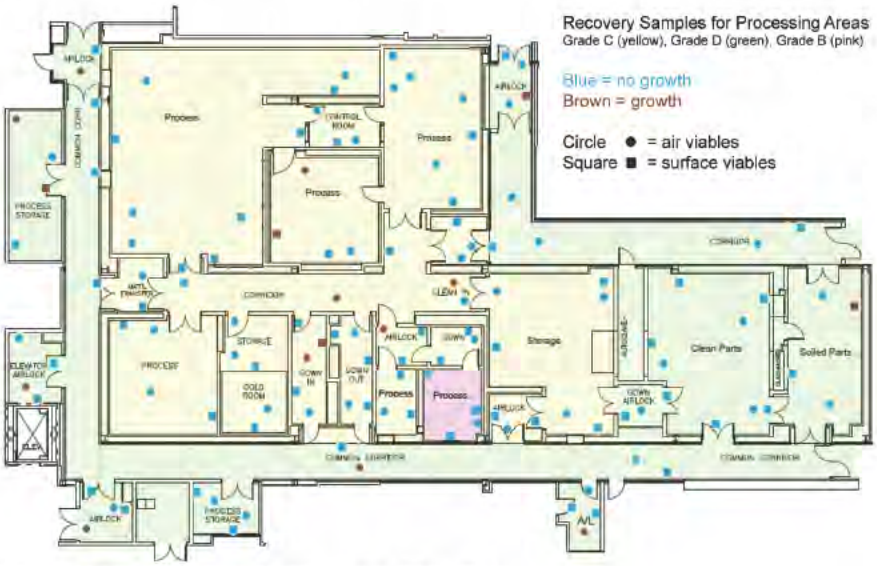

Figure 5. Location of recovery samples and results.

Conclusion

The environmental sampling results met all acceptance criteria for surface and air viable testing during the AHU shutdown sampling and recovery sampling events. These results demonstrated that environmental microbial levels increase during an AHU shutdown, and following an AHU recovery period of the classified environment, will return to acceptable environmental levels. Based on this study, it was recommended that a controlled GMP manufacturing environment would recover from a temporary AHU shutdown, whether planned or unplanned, of Not More Than (NMT) *three* hours by following the shutdown with Not Less Than (NLT) *two* hours of AHU operation; no additional area cleaning or environmental monitoring should be performed. A key aspect of this conclusion is that regardless of the type of shutdown, it is required that open processing should not occur during both the shutdown and recovery periods. If open processing occurs during any type of AHU shutdown, the routine required recovery response should be followed.

This case study demonstrated that when one key piece of environmental

control such as power to the AHU has been temporary lost, a full recovery to regain control within the environment can still be achieved without surface cleaning and environmental monitoring. When conditions permit, area surface cleaning may be eliminated when responding to an AHU shutdown, whether planned or unplanned. The data from this study does support that a recovery response that does not include area surface cleaning can return an area to its qualified state with minimal impact to the environment and product. The manufacturer should additionally perform a formal risk assessment prior to implementation to ensure all of the potential negative events are identified and mitigated to maintain product quality.

> *"...a standardized recovery that does not require physical cleaning and monitoring has the potential for meaningful savings.*

Cost Savings

The conclusions of the case study to evaluate a recovery period following AHU shutdowns with no additional area cleaning projected potential hard and soft cost savings. It was estimated that approximately 56 man hours and $2,500 in supplies could be saved per AHU annually by reducing cleaning and recovery operation costs associated with AHU shutdown and recovery. Savings include reduced or eliminated environmental monitoring and administrative efforts. Finally, resuming manufacturing operations in a timely manner without waiting for room cleaning and monitoring activities additionally benefits the manufacturing schedule. Considerable time and coordination goes into scheduling any maintenance activity, combined with additional time and coordination to release a classified area back into GMP production; therefore, a standardized recovery that does not require physical cleaning and monitoring has the potential for meaningful savings.

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Electron Beam: An Emerging Practical Technology for Sterilization of Pharmaceutical Products in an Innovation-Driven Industry

by Jorge A. Sugranes and Anne F. Booth

This article presents an overview of the potential use of electron beam (e-beam) ionizing radiation as a versatile and innovative technology for sterilization in the pharmaceuticals manufacturing industry.

Historically, the pharmaceutical manufacturing industry has been a leader in financial performance and value creation. However, a different direction has been observed in recent years and stock market records have raised doubts about the sustainability of that history. From December 2000 to February 2008, the top 15 pharmaceutical companies lost approximately $850 billion in shareholder value mainly due to the rise of generics, pricing pressures, and regulatory requirements. The past few years have seen enormous changes in many manufacturing industries, and pharmaceuticals are not the exception. History has demonstrated significant evolution and transformation in the manufacturing sector, especially in the pharmaceutical industry. A transition from simple family-owned companies managed by people to highly complex mega-mergers managed by sophisticated systems. This transformation has been impacting our society, economy, and labor force in multiple dimensions. Mergers big and small have spawned plans to decrease costs as well as many jobs. These highly technological companies are under continuous threat and pressure from a competitive global market, strong regulations, and incremental financial performance expectations from stockholders and investors. Business differentiation and sustainability are the biggest challenges.

There are many situations in which innovation has been the basis for sustainable results. Electron beam (e-beam) technology for sterilization in the life sciences industry is an example. The practical application of electron beam sterilization in the medical device and pharmaceutical industry has been commercially well established over the last several decades. Today, the electron beam technology is fundamentally similar to what it was in the 1950s. During the last six decades; however, this sterilization technology went through significant reengineering and process improvements that resulted in an enhanced and robust technology. Today's electron beam systems are more compact and efficient with improved reliability, automated control systems, computer-based operations, improved safety, and better quality at lower cost.

Before embracing any innovation, reengineering, or continuous improvement initiative, three fundamental concepts, their implications, and their differences must be clearly understood. Operational innovation should not be confused with operational improvement or operational excellence. Those terms refer to achieving high performance via existing modes of operation without fundamentally changing how that work is accomplished. Operational innovation means coming up with entirely new ways of doing any activity that an enterprise performs. For example, a change in sterilization method from gamma to electron beam or from aseptic

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process to terminal sterilization, demonstrating that process improvement is great, excellence in operations is better, but innovation is best. Electron beam technology, when properly implemented as a process innovation, can yield a true competitive advantage by reducing sterilization costs, providing faster throughput, decreasing inventory, and improving the supply chain. From the cost perspective, based on analysis performed by the authors, electron beam can be up to 40% to 60% less expensive (sterilization cost per unit) and significantly faster than other traditional radiation sterilization methods such as gamma. A typical electron beam sterilization exposure time can be few minutes, while gamma irradiation may require several hours to reach similar dose delivery, when using the appropriate electron beam accelerator's power (e.g., 10 mega-electron volts [MeV]). Another advantage is that modern electron beam accelerators can be installed on-site and can irradiate on production line, reducing transportation costs.

E-Beam Technology and Its Application

Radiation processing may be defined as the technology of producing useful and desirable changes in the properties, structure, microbiological organisms count, or decontamination level of materials and products by treatment with ionizing radiation. Radiation sterilization is used for sterilization of heat-sensitive materials, liquid-filled products, combination drug/devices, and tissue based products when other industrial methods, such as steam and ethylene oxide, are inappropriate. Many pharmaceutical products and some materials are radiation-sensitive, so this method is permissible only when the absence of deleterious effects on the product has been confirmed experimentally. Radiation sterilization can be achieved with gamma rays, electron beams, and X-rays.

The lethal effect of radiation on microorganisms is well understood and extensively documented in the literature. The Sterility Assurance Level (SAL) of a drug product is defined in probabilistic terms, where the likelihood of a contaminated unit or article is acceptably remote (a 10^{-6} Probability of Nonsterility (PNS) or a maximum of 1 nonsterile unit in a total of 1 million units is considered to be the minimally acceptable PNS). While achieving the desired SAL, electron beam processing produces less product degradation; penetrates all types of product packaging; causes no damage to sterile seals; allows control of temperature during processing; delivers well-controlled (narrow) dose range; and most importantly, is FDA recognized, and accepted by regulatory organizations.

Many of the early studies of the effect of radiation on pharmaceutical products were conducted at very high doses, typically over 25 kilogray (kGy). Electron beam dose is measured in gray (Gy), where 1 Gy of absorbed dose equals 1 joule per kilogram (J/kg). An absorbed dose of 1 Gy means that each kilogram of product material has absorbed 1 J of energy (1 Gy = 1 J/kg). Radiation quantities and the units used to measure them were initially defined by the International Commission of Radiation Units and Measurements (ICRU) and updated in the International System of Units (SI).

The irradiation dose of 25 kGy is no longer considered the standard sterilization dose in the pharmaceutical and medical devices industries. Sterilization can be effectively validated at lower doses if the biological load (bioburden) on or in the target product is well known and controlled. The main advantages of electron beam technology over other radiation methods are operational cost savings, higher throughput rate, and reduced product degradation. Electron beam processing is accomplished through accelerated electrical energy and not via radioactive isotopes such as Cobalt-60; therefore, the facility does not need to be out of service for any period of time in order to reintroduce the sterility source into the operation. Productions remain in an electron beam cell for a matter of seconds as compared with several hours in a gamma cell. Faster turnaround time requires less product to be held in inventory. In addition, because of the shorter exposure time to the irradiation source, electron beam processing reduces the oxidation effects on products and thus reduces material degradation and minimizes sensory changes. Because electron beam systems run from the normal electrical power distribution grid, they can be inactivated by simply shutting off the power. There are no radioactive materials issues or residuals to handle.

As the pharmaceutical technology advances and sensitive drug formulations or materials demand ever-greater stability, radiation processing is likely to be the only alternative for sterilizing thermo-labile pharmaceutical products or components. Some practical applications of electron beam in the pharmaceutical industry is the sterilization of:

- Caps
- Bottles
- Vials
- Plugs
- Syringes (prefilled or empty)
- Chemical raw materials
- Ancillary equipment such as trays, totes, etc.
- Devices such as cardiac catheters, stents, wound care products, and dialyzers
- Single use disposable technology parts (plastic bags, disposable fill needles, valves, aseptic connectors, hoses, etc.)
- Transfer system into a barrier isolator

Treatment with electron radiation is becoming a common process for the sterilization of the packages used in the aseptic processing of pharmaceuticals, most of which are

made of natural or synthetic plastics. In order to design and develop appropriate packaging configurations and sterilization processes, the effects of irradiation on these packaging materials must be known and validated.

Terminal sterilization of pharmaceutical products using electron beam is a novel application that can result in elimination of the traditional and costly aseptic fill practice. Regulatory pressures from the FDA encourage manufacturers to adopt terminal sterilization where possible as an alternative to aseptic manufacturing. Terminally sterilized products represent the lowest risk category of sterile pharmaceutical products. Unlike products aseptically manufactured in a microbiologically controlled environment, terminally sterilized products are subjected to a sterilization process the microbiological lethality of which can be quantified.

Pharmaceutical manufacturing companies that are considering switching from traditional sterilization methods, such as dry heat, moist heat, ethylene oxide gas, filtration, or gamma irradiation, to the electron beam sterilization method are confronted with numerous questions including:

- What pharmaceutical products and packaging materials are compatible with electron beam irradiation? How much irradiation energy and dose is required to consistently achieve sterilization conditions?
- How is dose measured or controlled?
- What is the impact of electron beam irradiation on the product quality attributes?
- What will electron beam sterilization technology cost and how do I justify the investment?
- What is the impact of single unit versus batch sterilization approach on the efficiency of manufacturing production lines?
- Should I sterilize the product in-line, off-line, or off-site contract?

The pharmaceutical manufacturing industry have had limited success in answering these questions.

Type of E-Beam Systems

Industrial electron accelerators can be classified as low-energy, medium-energy, and high-energy machines, based on the energies of the electrons they produce. Accelerators producing electrons with energies that are less than 1 MeV are typically classified as low-energy, and medium-energy machines produce electrons with energies in the region 1 to 5 MeV and high-energy accelerators produce electrons with energies that are greater than 5 MeV. Traditional industrial applica-

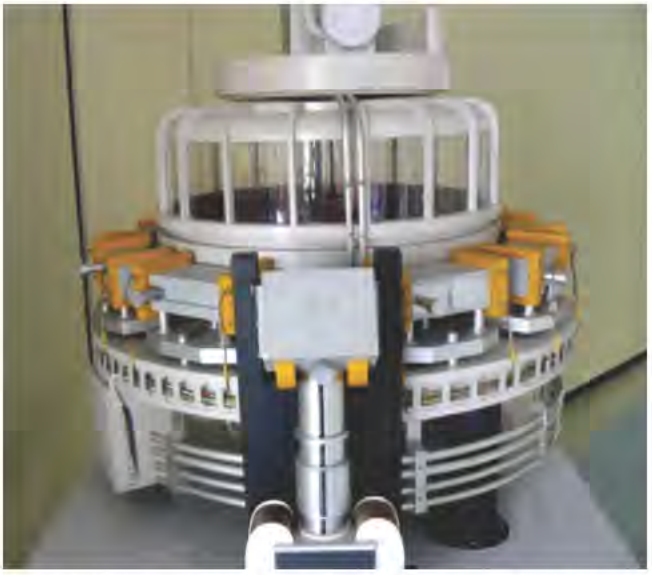

Figure 1. High energy "Rhodotron" accelerator model (courtesy of Ion-Med, Spain).

Figure 2. Materials passing under the e-beam scan horn (courtesy of Ion-Med, Spain).

tions for batch sterilization involve the use of high-energy electrons with energies ranging from 5 to 10 MeV - *Figure 1*.

Accelerators are machines that use electrical energy to generate free electrons, accelerate them to high speeds, and then direct them at materials passing by the accelerator on a conveyor or in another type of flow-through system - *Figure 2*. The electrons penetrate the material, which can be gaseous, liquid, or solid, and initiate chemical reactions that alter the properties of either the material or specific components in or on the material. The types of chemical reactions produced depend upon the nature of the material being treated. The reaction can vary from *polymerization* (plastics and composites) to *degradation* (chemical materials) to *sterilization* by disrupting the microorganism's DNA chain.

Accelerators generate the electrons, which operate in a pulse or continuous beam mode. High energy levels are required to penetrate the product material. Electrons with energy higher than 10 MeV can be achieved by using accelerators that employ multiple stages of acceleration. Typically, accelerators producing electrons with energies up to 10 MeV are used in the industrial applications.

As the beam is scanned through the product, the electrons interact with materials and may create secondary energetic species, such as electrons, ion pairs and free radicals. Free radicals also may affect lipid and protein functions by ionizing covalent bonds and producing reactive intermediates that propagate through the intracellular medium. These secondary energetic species are responsible for the inactivation of the microorganisms as they disrupt the DNA chain of the microorganism, thus rendering the product sterile.

Most significant process parameters to be considered for sterilization applications are energy (volts), power (Watts), exposure time (conveyor speed), dose or energy deposited by the radiation in the unit of mass (J/kg), and penetration (mass density). The appropriate combination of these parameters will determine the electron penetration. These characteristics are defined and validated during installation and operational qualification studies to ensure reproducibility.

Some of the most recognized by the author e-beam academic research centers that work with electron beam technology and its application are:

- The Research Center for Advanced Manufacturing (RCAM) at SMU University in Dallas, Texas
- The National Center for Electron Beam Research at Texas A&M University in College Station, Texas

E-Beam Energy vs. Penetration

There is a general tendency to believe that electron beam technology is more appropriate for surface sanitization. The real answer to this myth is no. The fact is that modern electron beam systems, when using the appropriate emission power and radiation process, can deliver sufficient kinetic energy to penetrate dense materials in liquid or solid form. Mathematical analysis using National Institute of Standards and Technology (NIST) modeling tools to calculate electrons stopping power, and controlled experimental studies conducted by the author confirmed that electron beam can successfully penetrate a box of more than 2 square feet containing empty polypropylene bottles, when irradiate using a high power 10 MeV accelerator and dual pass or double side processing. Table A presents approximate penetration results at different energy levels, material densities, and exposure path (single and double). Table B present electrons

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stopping power calculations using NIST models for polypropylene material. This data and the bi-dimensional concept shown on Figure 4 give a good perspective on how the penetration of energized electrons varies at different process conditions.

Be aware that the electrons "penetration" range is essentially the total path length traveled by an electron along its (scattered) path, not the real depth of penetration. Electrons are relatively light particles and suffer significant angular scattering, so that between the effects of angular deflections and fluctuations in energy loss, their depth of penetration can be a relatively wide distribution - *Figure 3*. And this distribution can be affected by the irradiation angle and surface geometry. There are rough rules of thumb that predict some average penetration depths. For example, the projected range is (often) defined as the extrapolation (to the depth axis) of the fairly straight-line portion of the descending depth-dose distribution. It turns out that for electrons normally incident with kinetic energies below some few MeV, the ratio of the projected range to the predicted range is fairly constant. Quantitative examples of predicted penetration are illustrated in Tables A and B. These theoretical penetration and range values are based on NIST electrons stopping power modeling.

It is important to understand that the electron-beam radiation model has two-dimensional components that

Energy	Density g/cm^3	Single Side	Double Side
200 KeV	1	200 µm	---
3 MeV	1	0.4 in.	0.9 in.
3 MeV	0.1	3.9 in.	9.4 in.
10 MeV	1	1.3 in.	3.3 in.
10 MeV	0.1	13.4 in.	33.1 in

Table A. Penetration at different energy levels.

Kinetic Energy (MeV)	Penetration Depth (Inches)	
	Single Side	Double Path
1	0.2	0.4
2	0.4	0.8
3	0.6	1.3
4	0.9	1.7
5	1.1	2.1
10	2.1	4.2

Table B. Electron beam theoretical penetration for polypropylene material (based on NIST electrons stopping power modeling).

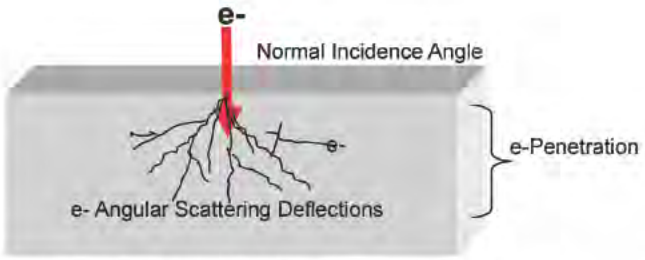

Figure 3. Electrons angular scattering.

will determine effectiveness of electron penetration and the sterilization process. These are kinetic energy and dose delivered. The kinetic energy driven by emission power dictates the path length traveled by an electron in the material, also known as stopping power. Penetration is a function of material density as well. On the other hand, the dose determines the accumulative energy absorbed and is correlated to lethality of the sterilization process. Low-energy emitter systems are appropriate for surface sanitization, while high-energy systems are effective for sterilization. This concept is illustrated in Figure 4.

One of the typical mistakes is the analysis of e-beam from a single dimensional perspective. Compatibility of the material or product to be irradiated is important too. Some common materials compatible with e-beam are

- Polyethylene terephthalate (PET)
- Polypropylene (PP)
- Polyethylene (PE)
- High Density Polyethylene (HDPE)
- Vinyl acetate polymer (PVAC)
- Polyvinyl Chloride (PVC)
- Polyvinyl Fluoride (PVDF)
- Polytetrafluoroethylene (PTFE)
- Other elastomers

With radiation sterilization, the objective of validation is to demonstrate that the required lethal dose is delivered to the entire batch of material or product, taking into consideration the loading pattern of product within relation to the radiation source, and using calibrated dosimeters. Radiation dose-setting methods are based on inactivation of the contamination present on the product, not by assessing the resistance of a biological indicator.

The Regulatory Requirements for Radiation Sterilization

An integral part of a device manufacturer's statement to regulatory authorities when requesting marketing approval for a sterile product is proof of safety and efficacy. Two elements of that proof are 1. the demonstration of a compliant quality system program following ISO 13485 and pertinent FDA regulations (21 CFR Part 820 and Parts 210-211) and 2. a vali-

Dose: Lethality (Y)	Energy: Penetration (X)			
	Energy Source/ Dose	Low Energy (Less Than 1 MeV)	Medium Energy (1 – 5 MeV)	High Energy (6 – 10 MeV)
	Low Dose (less than 25 kGy)	Surface Sanitization, Lowest Penetration, Lowest Lethality, Lowest Impact on Product Surface.	Surface Sanitization or Surface Sterilization.	Surface Sanitization or Sterilization, Higher Penetration, Lower Lethality, Lower Impact on Product Surface.
	Medium Dose (25 – 50 kGy)	Surface Sterilization	Product Sterilization	Product Sterilization
	High Dose (>50 kGy)	Surface Sterilization, Higher Lethality, Lower Penetration, Higher Impact on Product Surface.	Product Sterilization	Highest penetration, Highest lethality, Highest impact on product. Over kill zone.

Figure 4. E-beam 2D concept.

dated sterilization method that is appropriate for the intended product. Consensus standards have been developed and accepted by both the USFDA and other international regulatory bodies as evidence that a product manufactured and sterilized according to these standards can support a reasonable assurance of sterility. As such, the ISO 11137 series of standards outline acceptable validation steps, ensuring sterility requirements meet US and international regulatory standards.

The initial validation activities are generally performed by or at the sterilization contractor (and confirmed by the user company) where the operation of the equipment is defined and validated:

1. Audit of the irradiator's installation for GMP/regulatory compliance
2. Installation qualification of the irradiator system (qualification of the electron accelerator unit with emphasis on control systems, automation, software, hardware):
   a. Equipment documentation
   b. Equipment tests
   c. Equipment calibrations
   d. Irradiator dose mapping
3. Process qualification using a specific product or simulated product
4. Definition and calibration of the dosimetry system
5. Administrative certification procedure to review and approve documentation of previous validation elements. Information gathered or produced while conducting validation exercises should be documented and reviewed for acceptability by a designated individual or group with appropriate knowledge and expertise.
6. Activities performed to support maintenance of irradiator system and validation:
   a. Requalification program (frequency of requalification depends on whether there have been any significant process or equipment changes, and whether there have been any adverse or unusual sterility or functional test results
   b. Change control program
   c. Calibration program
   d. Preventive maintenance program
   e. Sterilization dose auditing
   f. Standard operating procedures
   g. Well-defined operational and safety training per the company training program
   h. Operator training

The microbiological validation of an irradiation-based sterilization method is based on the sensitivity of the natural bioburden population present on the product just prior to exposure to a specific radiation dose. Therefore, knowledge of the types of organisms found on or in the product is required. The number of organisms inactivated by a given radiation dose is a statistical phenomenon, which depends on the sensitivity of the microorganism to alterations of biologically active molecules and their ability to repair the alterations. Microorganisms are inactivated by first-order kinetics, which can be represented by a dose/survival curve where the fractional survival is plotted on a semilog scale. The probability of survival then can be predicted assuming this exponential relationship as seen in Table C.

Review of historical microbial data has resulted in development of a theoretical population with defined levels or resistance. Using computational methods and the standard distribution of resistances for this population, individual doses required to achieve stipulated sterility assurance levels were calculated for levels of bioburden on product just prior to irradiation. These values are the basis of the dose tables documented in ISO 11137. The validation experiment is per-

D10 kGy	1	1.5	2	2.5	2.8	3.1	3.4	3.7	4	4.2
Probability	0.65487	0.22493	0.06302	0.03179	0.01213	0.00786	0.0035	0.00111	0.00072	0.00007

Table C. Standard Distribution of Resistances (SDR) D10 Values (ISO 11137) for population C.

formed to ensure that this relationship is confirmed. After successful completion of this test, selection of the dose for sterilization is used during routine processing.

Validation of an E-Beam Radiation Process

The basic requirements and guidance for validation of any radiation sterilization process can be found in ISO 11137-1:2006, "Sterilization of Health Care Products – Radiation – Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices" and ISO 11137-2:2006, "Sterilization of Health Care Products – Radiation – Part 2: Establishing the Sterilization Dose." These standards cover radiation processes employing irradiators using

- The radionuclide 60Co or 137Cs
- A beam from an electron generator or
- A beam from an X-ray generator

The microbiological validation process to be performed by a qualified contractor or in-house consists of the following elements:

1. Choice of product's desired SAL
2. Confirmation of distribution of dose through the product (dose mapping) and assessment of maximum acceptable dose
3. Determination of product bioburden
4. Selection of a validation method and verification of the dose
5. Selection of routine dose
6. Activities performed to support maintenance of the validation

Four approaches to selection of the dose can be used depending on the batch size and device bioburden level:

1. Method 1 – determination of the bioburden, then used to select and test at the 10^{-2} verification dose (a probability of 1 in 100 survival)
2. Method 2A and 2B – incremental dosing of product samples to determine the lowest effective dose
3. Method VD_{max} [25] – substantiation of a sterilization dose; appropriate for devices with less than 1000 organisms per product (other VD_{max} dose levels can be validated from 15 kGy to 35 kGy in 2.5 kGy increment as defined in AAMI TIR 33:2006)

	Method 1	Method 2 A and B	VD_{max}
Rationale	Estimate dose for SAL = 10^{-2} Extrapolate to required SAL	Determine dose by incremental dosing Calculate dose required for SAL	Assume 25 (or 15, or 20) kGy produces SAL = 10^{-6}
Production Lot Size	All	Medium-Large	All
Production Rate	Any	Frequent	Any
Bioburden Limit	1,000,000	None	≤1000
Samples for Testing	130 units	Method 2A-840 Method 2B-780 (200 can be returned to inventory)	40

Table D. Comparison of the dose setting methods.

Table D shows a comparison of the dose setting methods. Method 1 is generally a reliable and safe method of dose setting although it tends to be less discriminating with small population sizes and requires more samples. In the United States, Method VD_{max} is more commonly used than Method 1 because it can be applied to any type of product that uses Method 1 and it is widely accepted by the FDA.

Step 1: Choice of Product's desired SAL

Microbiologists are familiar with the concept that bacteria subjected to a sterilizing agent will, in theory, die exponentially with time at a uniform rate. A constant percentage of the microbial population is inactivated with each successive dose interval. The absorbed dose required to destroy 90%, or 1 log, of the microbial population is defined as the D_{10} value, or decimal reduction value. Therefore, a semilog plot as seen in Figure 5 will yield a straight-line relationship. Note that when the line crosses below 10^{0}, resulting in less than one survivor, it is expressed as a probability of survival. Assuming an initial bioburden of 1 million, a 10^{-6} survivor level or SAL or a 12 log reduction (SLR) represents a one in 1 million probability of one microorganism surviving the process; for an initial bioburden of 100, an 8 log reduction would yield an SAL of 10^{-6}.

In the past, for terminally sterilized products to be labeled "sterile," the theoretical probability of a surviving organism present on the product could be either 10^{-3} (probability of one in 100,000 organisms surviving) or 10^{-6} (probability of one in 1 million organisms surviving), depending on the intended use of the product. Most recently, however, manufacturers have the ability to select an alternate SAL, such as 10^{-5} or 10^{-4}, for those types of products that are sensitive to 10^{-6} sterilization processes (i.e., biologics and drug/device combination products). AAMI ST 67: 2011, "Sterilization of Medical Devices –Requirements for Products Labeled 'Sterile'" requires the use of the most rigorous SAL that the

product can withstand, as well as a risk assessment in order to select an alternate SAL. This focus on risk assessment aligns with other regulatory documents.

Step 2: Confirmation of Product Density (Dose Mapping) and Asssessment of Product Safety and Efficacy at Elevated Doses

Dose mapping of products in a documented tote-loading pattern is conducted to determine the minimum and maximum dose zones, the dose uniformity, and the processing rate. (The dose is determined using dosimeters.) In general, when performing the dose map, the product loads are first established and documented so that the amount and density of product within each carton will reflect those used in typical irradiation runs. If at the end of a product batch a partially filled irradiation container results, a dose map of this situation should be performed. The key objectives of the dose map are to locate the maximum and minimum internal doses within the product (load) and relate them to the dose at the reference point. Once determined, the internal minimum/maximum can be predicted simply by measuring the reference point.

If the effect of irradiation on certain product materials is not known, samples of these products should be exposed to a maximum dose (40 to 50 kGy), and evaluated for functionality and efficacy. Because radiation doses are cumulative, if product is exposed twice for whatever reason, there must be data to show the product is safe and effective. An accelerated aging approach can be used to predict material degradation over time, but results must be supported at some point by testing real-time aged products.

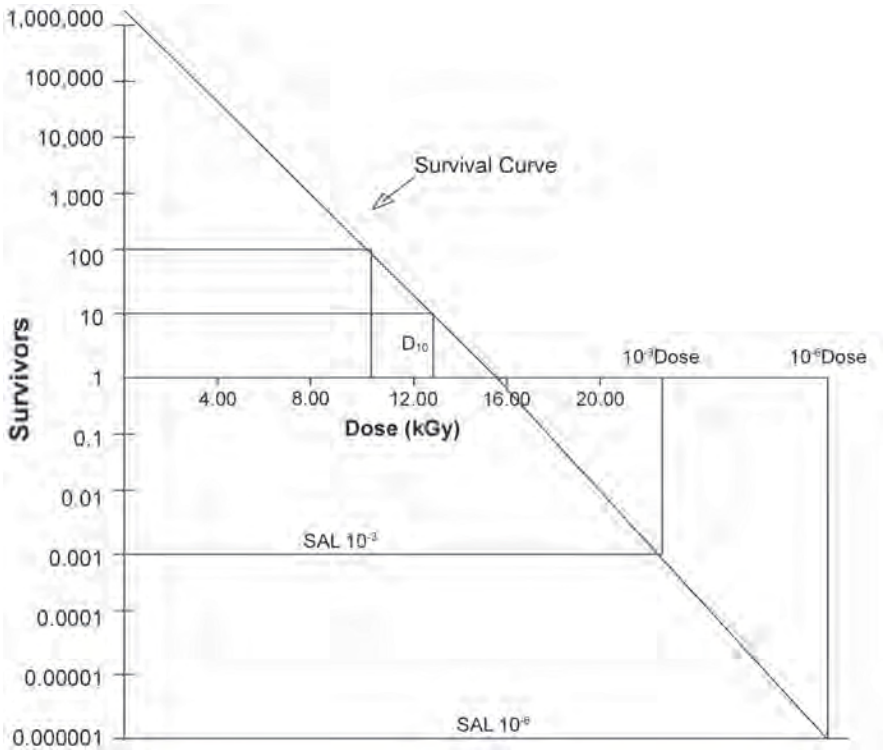

Figure 5. Theoretical microorganism survival curve.

Step 3: Determination of Product Bioburden

An understanding of the viable microorganisms on a finished device is necessary and required to support the validation process. Bioburden data are important because the extent of the treatment of a sterilization process is a function of the bioburden on the product, the resistance of the bioburden, and the SAL required. The assessment of the bioburden needs to include the number of microorganisms with their identities. Information for proper bioburden determination can be obtained from competent microbiological laboratory services following guidance in accordance with ISO 11737, Parts 1, 2, 3.

- For each of the methods, perform the bioburden evaluation (see ISO 11737-1:2006, "Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Product") by selecting 10 individually packaged products randomly from three different lots of recently manufactured product. If products are costly, decrease the number sampled to five. Do not use expired or old product for bioburden evaluation because the organisms on such products may not represent those present on recently manufactured products. The frequency of the bioburden estimations, supported by documented evidence or rationale, should be established.
- The test method used must be validated because it only produces an estimate of the number of microorganisms. The validation will produce a correction factor.
- Once the bioburden data are obtained for all three lots, apply the correction factor, then calculate the overall batch average.

Step 4: Selection of a Validation Method and Verification of the Dose

Method 1

Sample requirements initially total 136 (100 for the dose experiment, 30 for bioburden determination, and 6 for bacteriostasis/fungistasis testing) and thereafter, 110 (100 for the dose experiment and 10 for bioburden determination) on each quarterly dose audit.

The sequence of steps required to validate a radiation process using Method 1 are:

1. Select the appropriate SAL and obtain samples of product units
2. Determine the bioburden levels
3. Determine the batch average of each of the three batches after applying the correction factor
4. Calculate the overall batch average
5. Select the verification dose from the dose table 4 in ISO 11137-2, using either highest batch average (if one or more batch average is greater than the overall batch average) or overall batch average
6. Send the 100 product samples from a single batch to the irradiator and perform the verification dose experiment. The samples can be selected from any of the three batches from which the bioburden samples were taken or from a fourth batch. The actual dose delivered can vary by +10%. If the dose does not meet specification, do not proceed to the sterility test. Repeat the verification dose using fresh samples.
7. Sterility test (USP <71>) the 100 units according to ISO 11737-2, using soybean-casein digest broth incubated at 30°C (±2°C) for 14 days (see ISO 11737-2:2009, "Sterilization of Medical Devices – Microbiological Methods – Part 2: Tests of Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process"). Record the number of positive tests. (Bacteriostatsis/fungistasis testing should be performed if this is the first time the product has been subjected to a sterility test).
8. Review results to assess the acceptability of the experiment:
   - 1 or 2 positive tests = acceptable
   - >2 positives with no deviations in the testing or dose delivery = dose method is not valid for the product and the alternative method (Method 2) should be used

Bioburden Range	Sterilization Dose (kGy)	VD_{max} Values
< 0.1 to 1.5	15.0	See Table A.1*
< 0.1 to 9.0	17.5	Table A.2
< 0.1 to 45	20.0	Table A.3
< 0.1 to 220	22.5	Table A.4
< 0.1 to 1000	25.0	Table A.5
1.0 to 5000	27.5	Table A.6
1.0 to 23,000	30.0	Table A.7
1.0 to 100,000	32.5	Table A.8
1.0 to 440,000	35.0	Table A.9

Table E. Sterilizing dose for each bioburden range.

9. Establish the sterilization dose if test is acceptable by finding the closest bioburden number in dose Table 5 equal to or greater than the average bioburden and the selected SAL level

Method 2A or 2B

(For a Method 2A dose establishment, 640 product units are required, and for a Method 2B dose establishment, 580 are required.)

Using Method 2A can result in a sterilization dose that is significantly less than the sterilization dose established through the use of either Method 1 or Method VD_{max}. This is important if the product is radiation sensitive (for complete details, see ISO 11137-2). A modified Method 2 as outlined in AAMI TIR 40: 2009, "Sterilization of Health Care Products – Radiation – Guidance on Dose Setting Utilizing a Modified Method 2" also can be used (AAMI TIRs are guidance only). The validation process is more complicated, but still intends to confirm inactivation of microorganisms at a specific dose.

1. Select SAL and obtain product samples from recently manufactured batches
2. Select 280 product samples randomly from each of three production lots (see Table 26 in the standard)
3. Perform incremental dose experiments irradiating 20 product units from each of the three lots at one of a series of not less than nine doses, increasing in 2 kGy increments. The delivered doses can vary from the nominal dose ±1.0 kGy or ±10%.
4. Sterility test the product units at 30°C (±2°C) for 14 days. Record the number of positive and negative tests.

For each of the three lots, determine the lowest dose (FFP kGy) where at least one of the 20 tests is negative. Find the median value. For further details, consult the standard for equations used to calculate the sterilization dose.

Method VD_{max} (as an example, VD_{max}^{25} is discussed)

This method can be used for any size production batches with average bioburden of less than 1000 CFU per device. The method preserves the conservative aspects of Method 1, but is more accurate for low bioburden products. It is not limited to batch size or production frequency and the number of product samples (10) needed for the verification experiment is constant. In addition, the VD_{max} method can be used to substantiate a selected sterilization dose of 15, 17.5, 20, 22.5, 25, 27.5, 30, 32.5, or 35 kGy. Each dose has an associated unique range of applicable bioburden as shown in Table E. Guidance on performance of this method can be found in AAMI TIR 33: 2006, "Sterilization of Health Care Products – Radiation Sterilization – Substantiation of a Selected Sterilization Dose – Method VD_{max}."

1. Obtain at least 10 product units from each of three recently manufactured production batches
2. Determine the average bioburden on each product as outlined in ISO 11737-1 and average the bioburden values for each batch. Apply the correction factor based on the validation of bioburden recovery. Compare the three batch averages and select the grand average or one average if two or more times the overall average.
3. Obtain VD_{max}^{25} verification dose (10^{-1} level of probability) by finding closest bioburden value greater than or equal to the bioburden average in table 7 in ISO 11137-2.
4. Irradiate 10 product units from a single batch at the VD_{max} obtained in table 9 in ISO 11137-2, for VD_{max}^{25}. These may be selected from any one of the bioburden batches or a fourth batch. The actual dose may vary from the calculated dose by not more than +10%. If the delivered dose is less than 90% of the verification dose, the experiment may be repeated.
5. Sterility test the product units according to ISO 11737-2 using soybean-casein digest broth incubated at 30°C (±2°C) for 14 days. Record the number of positive tests.
6. Interpretation of results. If no more than one positive test is observed in the 10 tests, 25 kGy is substantiated as the sterilization dose to achieve at least a 10^{-6} SAL. If 2+/10 tests are observed, a confirmatory verification dose experiment shall be conducted. If 3+/10 tests are observed, 25 kGy is not substantiated and another dose setting method must be used.
7. Confirmatory verification dose experiment (if required). Randomly select 10 product units from a single batch (can be from the batches previously sampled or from a new batch). Use the same dose as determined initially and irradiate the 10 product units at the confirmatory verification dose. The same dose tolerances apply. Sterility testing results are evaluated as follows:

- 0 ±10 – 25 kGy is substantiated
- 1+/10 or 1-10+/10 – 25 kGy is not substantiated

Step 5: Selection of the Routine Dose (in ISO 11137-2)

If as a result of the sterility test, an acceptable result is obtained, the sterilization dose is validated. When the verification dose experiment is successful using the VD_{max}^{25} method, a 25 kGy sterilization dose is substantiated (or confirmed) and will be the minimum dose used for routine sterilization.

Step 6: Activities Performed to Support Maintenance of the Validation

Ongoing support of an e-beam radiation validation program must include:

- Established and documented environmental monitoring (ISO 14644 series and USP <1116>) and bioburden programs (ISO 11737-3) to ensure consistent and low contamination levels on products
- Audits are performed each quarter to demonstrate the ongoing applicability of the validated dose;
- Audit of the sterilization contractor and the test laboratory
- Maintenance of a quality systems program following ISO 13485

Conclusion

We are in a global era in which creative thinking, technological innovation, and doing things differently are necessary to compete in the international market. High quality, rapid production, and efficiency are no longer the secret weapons that bring competitive advantage to the manufacturing sector. Innovation, reengineering, and continuous improvement are at the forefront of bringing a sustainable competitive differentiation to the manufacturing industry. E-beam technology, when properly implemented as a process innovation, can yield a true competitive advantage by reducing sterilization costs, minimizing cycle time, increasing throughput, decreasing inventory, and improving supply chain. From the cost perspective, electron beam processing can be up to 40% to 60% less expensive and significantly faster than other traditional radiation sterilization methods such as gamma. It produces less product degradation and temperature rise during processing due to the fast rate of dose delivery. Because of the shorter exposure time to the irradiation source, electron beam processing reduces the oxidation effects on products and thus reduces material degradation and minimizes sensory changes. The validation exercises are well documented in ISO sterilization standards and are well received by regulatory reviewers. Electron beam accelerators can be installed on-site or can irradiate on production line, reducing transportation costs. Process qualification, routine process monitoring, changes control, periodic requalification, and equipment maintenance programs are necessary to ensure reliability and consistency of the sterilization process.

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Harmonizing USP <1058> and GAMP for Analytical Instrument Qualification

by Lorrie Vuolo-Schuessler, Mark E. Newton, Paul Smith, Christopher Burgess, and R.D. McDowall

This article presents a framework for harmonization of the approaches presented by the GAMP GPG on Compliant Laboratory Computerized Systems with the revised USP <1058>.

Recent years have seen an increase in the sophistication and complexity of computerized systems and software used for the automation of laboratory testing and data management operations. Widespread reliance on these new technologies and their potential impact on data integrity have increased the importance of the appropriate selection, implementation, control and maintenance of laboratory computerized systems. As any analytical instrument or computerized laboratory system used in a regulated GxP environment must be fit for its intended use,[1-6] there are various approaches to fulfill this requirement depending on the risk posed by the item, the use of the instrument, decisions to be made on the data obtained and complexity of the process it automates.

The challenge with implementing analytical instruments and computerized systems in a regulated laboratory is developing a quality approach to encompass the wide variety and complexity of systems. Two of the primary sources of guidance for the verification of analytical instruments and computerized systems in regulated laboratories are:

- The recently published ISPE GAMP® Good Practice Guide (GPG) Risk-Based Approach to GxP Compliant Laboratory Computerized Systems,[7] replacing the previous 2005 version.[8]
- United States Pharmacopoeia (USP) general chapter <1058> on analytical instrument qualification or AIQ.[9] Although this general chapter is currently under revision, the initial drafters of the revision are two authors of this article who were also actively involved with the writing of the GAMP Laboratory GPG above.

In addition, the warning letters issued by the Food and Drug Administration (FDA) provide an indication of how these guidance documents are interpreted by the inspectorate.

Both publications[7,9] strive for control of analytical instruments and laboratory computerized systems, but from different historical perspectives. The GAMP® 5 approach looks at the necessary controls for instruments and systems from the perspective of software; in contrast, USP <1058> controls instruments and systems from the perspective of instrument hardware.

This article will review the starting positions of the ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems (GAMP® 5)[6] and the second edition of the Laboratory GPG[7] and USP <1058>[9] for the control of laboratory computerized systems before looking at the approaches to harmonization. To define a computerized system, the following PIC/S *Good Practices for Computerised Systems in Regulated "GXP" Environments* definition will be used:[5]

> *A computerized system consists of the hardware, software, and network components, together with the*

controlled functions and associated documentation.

For the purpose of this article, the term laboratory computerized system refers to systems operating in a regulated GxP laboratory environment and may include:

- Configured and non-configured software products
- Custom additions to configurable software products
- Analytical instruments, i.e., devices used to carry out a measurement

Systems such as Laboratory Information Management Systems (LIMS) are not specifically addressed within the Lab Guide as the approach described in GAMP® 5 is directly applicable to those systems.

ISPE GAMP® GPG: A Risk-Based Approach to Compliant GxP Computerized Systems

ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems[6] presents four software categories in Appendix M4 to help focus effort where risk is greatest and to help select the appropriate system life cycle activities and deliverables. Using the GAMP® 5 software categorization, laboratory computerized systems fit into software categories 3 and 4 and to some degree Category 5, although it needs to be noted that Categories 3 to 5 are effectively a continuum with no absolute boundaries.[10] The categories are defined as follows:

- **Category 3** – Non-Configured Commercial Products: this category includes off-the-shelf products used for business purposes. It includes both systems that cannot be configured to conform to business processes and systems that are configurable but for which only the default configuration is used;
- **Category 4** – Configured Commercial Products: configurable software products provide standard interfaces and functions that enable configuration of user specific business processes;
- **Category 5** – Custom Applications: these systems or subsystems are developed to meet the specific needs of the regulated company. The risk inherent with custom software is high. The life cycle approach and scaling decisions should take into account this increased risk, because there is no user experience or system reliability information available.

The recently published second edition of the GAMP® GPG for laboratory systems is aligned with the concepts and terminology of GAMP® 5 as well as recent regulatory and industry developments. The GPG builds upon the framework presented in GAMP® 5 to define a rational, scalable, risk-based approach to ensure that laboratory computerized systems are fit for intended use, meet current GxP regulatory requirements, are operated in a controlled manner and produce correct and accurate results.

The Laboratory GPG addresses laboratory computerized systems used within the regulated life science industries, including pharmaceutical, biological, and medical devices. Systems within the scope of the Guide support a wide range of processes, including but not limited to analysis of drug products, in-process materials, Active Pharmaceutical Ingredient (API), excipients, environmental samples, clinical samples, or toxicology samples used within the regulated life science industries, including pharmaceutical, biological, and medical devices.

Owing to the wide diversity of laboratory systems and how those systems are used, a single prescriptive approach would be neither practical nor cost-effective. The revision of the Guide presents a continuum of activities based upon risks incurred when operating a laboratory computerized system in the business environment, rather than discreet subcategories with prescribed activities, as in the first version. The aim is to achieve compliance, efficiency, and effectiveness – within a reasonable budget and timeline – for a wide variety of systems. The scalable, risk-based approach is aligned with industry trends and enables regulated companies to select the appropriate life cycle activities.

This approach requires thorough knowledge of the business process and intended system use, and focuses on the most critical activities to use resources more effectively. As a Subject Matter Expert (SME), the laboratory scientist must understand the business process and the risks to the integrity of their data based upon intended use. The revision emphasizes the leveraging of supplier documentation and knowledge, whenever possible, to avoid unnecessary duplication of efforts.

GAMP® 5 and the Laboratory GPG are aligned with the ASTM E2500 life cycle approach.[11] The life cycle approach defines and performs activities in a systematic way from concept, through development, operational use, to retirement.

Many laboratory computerized systems are now configurable products consisting of closely integrated hardware and software that are best verified as an integrated unit. For Category 3 (Non-Configured Product) systems, the amount of information available at the time of the initial risk assessment may be sufficient for all relevant risks to be identified, assessed and controlled without the need for further assessments. For Category 4 (Configured Product), it may be necessary to carry out additional detailed risk assessments on the specific configuration to support the business process. Controls should be traceable to relevant risks and verified. Verification should demonstrate that the controls achieve the expected risk mitigation. Furthermore, the software associated with an instrument can vary from basic firmware to

servers, workstations and configurable software for multi-user networked data systems.

United States Pharmacopoeia <1058> on AIQ

The USP General Chapter <1058> on Analytical Instrument Qualification became effective in August 2008.[9] Analytical Instrument Qualification (AIQ) describes the framework and general activities necessary to ensure the suitability of an analytical instrument for its intended use.

Before looking at the contents, it is important to understand the general chapter numbering of the USP. Analytical general chapters between <1> and <999> are mandatory (i.e., enforceable) and general chapters numbered between <1000> and <1999> are informational (i.e., strong guidance).[12] However, in the current USP revision cycle (2010 – 2015), USP plans to revise the majority of general chapters into two chapters per analytical technique: one mandatory and one informational. Each mandatory general chapter will contain a section on the analytical parameters to verify and the corresponding informational general chapter will offer guidance. The stimuli to the revision process and drafts of the general chapters are published in Pharmacopoeial Forum, available on the usp.org web site.

Therefore the proposed revision of USP <1058> needs to be seen in the context of the overall picture of updating the USP general chapters. The revised USP <1058> will contain the general principles for qualification and validation of analytical instruments and laboratory computerized systems under which the mandatory chapters will operate. Therefore, it is important for harmonization between USP <1058> and the GAMP GPG for laboratory computerized systems to provide a consistent message to analytical scientists working in regulated GxP laboratories.

USP <1058> manages risk in the AIQ process by classifying laboratory items into one of three general groups as follows:

- **Group A** – standard laboratory apparatus with no measurement capability or usual requirement for calibration.
- **Group B** – standard instruments providing measured values as well as equipment controlling physical parameters (such as temperature, pressure, or flow) that need calibration.
- **Group C** – computerized laboratory systems that typically consist of an analytical instrument that is controlled by a separate workstation running instrument control and data acquisition, and processing software.

The actual group that a laboratory items are assigned to is dependent on its intended use; however, one of the limitations of <1058> is that it only provides general guidance.

In Group A, there is no validation impact as there is no software in this group; therefore, this group will not be discussed further.

Group B software is firmware used to control the instrument with little data storage capability. It corresponds to the GAMP® 5 software Categories 3, 4, or even 5, depending upon the nature of the embedded software. However, the scope of Group B instruments ranges from firmware control only, firmware with the ability to perform calculations that are required to be verified and firmware with the capability for users to write their own programs using a language developed by the supplier. The breadth of this firmware category highlights the need for a structured approach to categorization based on use and consideration of sub-categories. The current USP approach is to qualify the instrument for the expected operating range, thereby implicitly verifying the firmware. This is an acceptable approach for firmware for instrument control, but verifying calculations and controlling user defined programs are not mentioned in USP <1058>.

In Group C, the software can vary from GAMP® 5 Category 3 to 4, sometimes with the ability to write custom modules (Category 4 plus Category 5 modules), e.g., macros or have additional code added to enhance functionality of the laboratory computerized system. However, USP <1058> assumes that the vendor has done all of the validation work and all the laboratory needs to do is to leverage this work, which can leave a laboratory exposed with the more complex software systems if they follow this approach.

USP <1058> introduces a quality triangle which highlights the critical components involved in the generation of quality data. The current data quality triangle consists of four layers: AIQ, method validation, system suitability and quality control checks. However, in the revised general chapter, the proposed data quality triangle is reduced to three layers and expanded in scope as shown in Figure 1. The fundamental principles of this triangle apply to all laboratories as it did in the current general chapter. The foundation layer is analytical instrument qualification which is instrument centric. The other two layers of the data quality triangle are method validation and holistic tests including system suitability tests and process performance verification tests. What has been added is the role of the manufacturer/supplier which was not included in the current version and the expansion of the AIQ layer into the component parts of the 4Qs model. In the AIQ layer and supplier addition, the roles of each are made more explicit. Both method validation and holistic tests are based on a specific analytical method. This reinforces the fact that effective AIQ is vital for ensuring fitness for purpose because if the instrument is not fit for purpose the rest of the effort in the triangle is wasted.

USP <1058> uses a single system life cycle, in both the current and proposed update, that is based upon the 4Q's model:

- **Design Qualification (DQ):** defines the functional and operational specifications of the instrument and is the responsibility of the manufacturers and developers.
- **Installation Qualification (IQ):** establishes that an instrument is properly installed and that the environment is suitable for the instrument.
- **Operational Qualification (OQ):** documents that the system functions according to its operational specification in the user's environment after installation or major repairs. The system is released for regulated use after the successful completion of the OQ.
- **Performance Qualification (PQ):** demonstrates that an instrument in operational use consistently performs according to the specifications defined by the user using established practices to address operation, calibration, maintenance and change control.

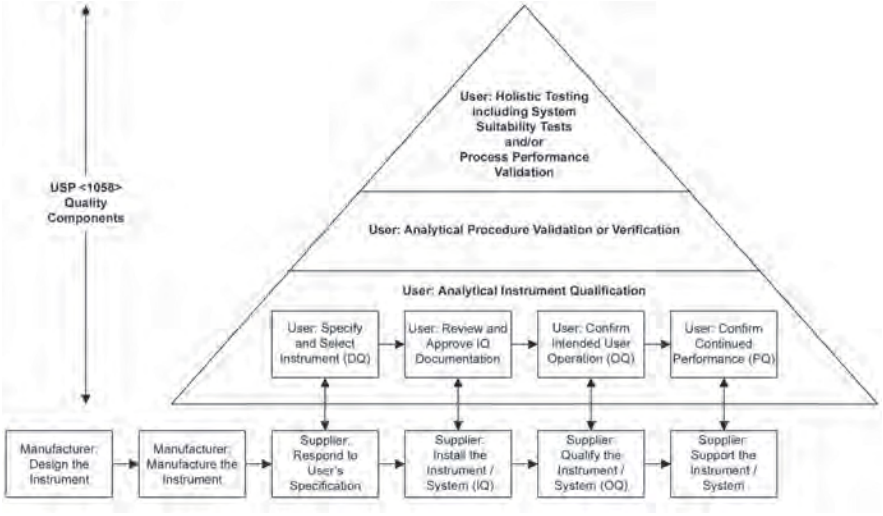

Figure 1. The Proposed USP <1058> Data Quality Triangle.

In the proposed draft, the data quality triangle is expanded to include more detail and the responsibilities of the user with respect to the 4Qs model plus also the responsibility of the instrument manufacturer and supplier - *Figure 1.*

Comparison between GAMP® 5 and USP <1058>

Both the GAMP® 5/Laboratory GPG and USP<1058> present a risk-based approach (using categorization) for compliant laboratory computerized systems (one based on software and one on hardware) and are designed to ensure that laboratory computerized systems are fit for purpose and operated in a controlled manner to produce the expected results.

While different terminology is used in the two publications, both aim to control computerized instruments and systems used in a regulated laboratory. Therefore, it is possible to map the two to determine the activities and approach to documentation as shown in Figure 2. Note that the sub division of instruments and systems shown in the figure will be discussed in more detail below under the section dealing with the revision of USP <1058>.

It is important to note key points from Figure 2 that establish the scope of harmonizing the USP and GAMP® 5 approaches.

1. GAMP® 5 exercises control of laboratory computerized systems through verification (software-driven) in contrast to USP <1058> which exercises control by qualification (hardware-driven).
2. Comparison between GAMP® 5 categories and USP <1058> groups are for illustrative purposes and it must be remembered that the GAMP® 5 categories represent a continuum.

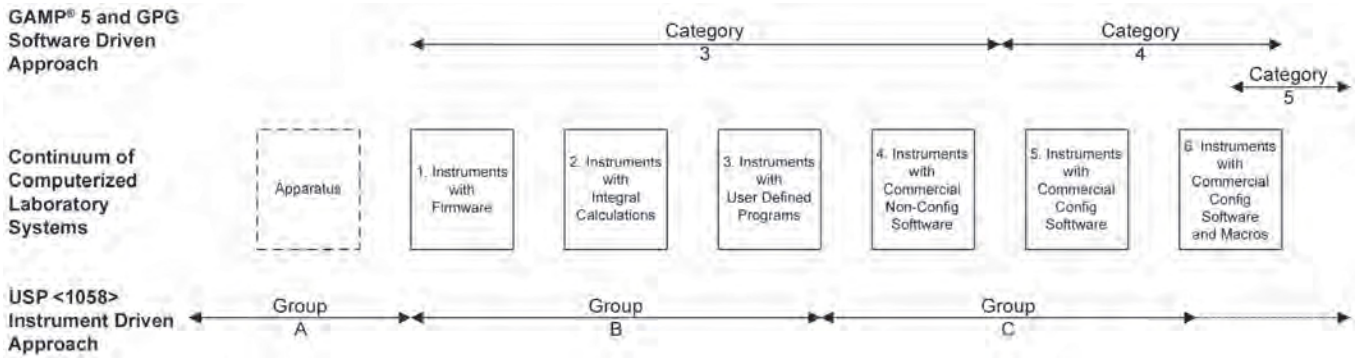

Figure 2. Mapping USP <1058> Instrument Groups and GAMP® 5 Software Categories.

DR CONGO. Millions of people are injured and infected through unsafe injections every year. WHO, UNICEF and UNFPA have a joint policy to use auto-disabled syringes when administering vaccines.

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3. USP<1058> Group A apparatus is not represented with the GAMP® 5 software categories as there is no software component nor any calibration requirement for these items.
4. USP <1058> groups B instruments and group C systems overlap with GAMP® 5 software Categories 3 and 4. However, USP<1058> does not include configurable and custom software elements described in GAMP® 5 Categories 4 and 5.
5. USP <1058> Group B items are essentially instruments controlled by firmware. GAMP® 5 Category 3 software covers a wide variety of instruments and systems, e.g., pH meters and analytical balances to chromatography and spectrometry data systems and consequently, requires a very efficient risk-based approach to identify the proposed use of the system, criticality of the records generated and the nature of the software used in the system to avoid wasting validation resources.
6. USP <1058> refers to the FDA guidance, General Principles of Software Validation13 for guidance on configurable and custom software elements. However, this guide is written principally for medical devices which are not customized (e.g., additional software code is written) or configured so that the business process automated remains the same. Therefore, there is a lack of guidance in USP <1058> for more complex software with or without custom modules.
7. The current USP <1058> recommends the use of qualification phases for analytical instruments while GAMP® 5 refers to specification and verification activities as described in ASTM E2500.[11] Though this represents a difference in terminology, the required activities are equivalent with the same outcome of demonstrating fitness for intended use against written specifications.

USP <1058> Term	Description	GAMP® 5 Verification Activity
Design Qualification	Documented Verification that the proposed design of system (specifications) and equipment is suitable for the intended purpose.	The Design Review is the assessment of this information to determine if the selected system matches their user requirements.
Installation Qualification	Documented verification that a system is installed according to written and pre-approved specifications.	Checking, testing, or other verification to demonstrate correct: • installation of software and hardware • configuration of software and hardware (See GAMP® 5 Appendix D5 for details)
Operational Qualification	Documented verification that a system operates according to written and pre-approved specifications throughout specified operating ranges.	Testing or other verification of the system against specifications to demonstrate correct operation of functionality that supports the specific business process throughout all specified operating ranges. (See GAMP® 5 Appendix D5 for details) Testing or other verification of the system to demonstrate fitness for intended use and to allow acceptance of the system against specified requirements. (See GAMP® 5 Appendix D5 for details)
Operational Release of Instrument of Laboratory Computerised System		
Performance Qualification	Documented verification that a system is capable of performing the activities of the processes it is required to perform, according to written and pre-approved specifications, within the scope of the business process and operating environment.	Operational controls Periodic reviews

Table A. Comparison of the USP <1058> 4Qs model versus GAMP verification activities.

A more detailed comparison of the two approaches can be seen in Table A which demonstrates equivalent activities of USP <1058> and GAMP® 5. It is presented from USP <1058> 4Qs model with the GAMP verification activities mapped. Note that under USP <1058> the operational qualification phase is equivalent to user acceptance testing and performance qualification is an activity when the system is operational compared with the traditional performance qualification for validation of laboratory computerized systems which equates to user acceptance testing. Therefore, a row in Table A indicating operational release of the instrument or system has been added to demonstrate equivalence between the two approaches.

An Integrated and Harmonized Approach – GAMP® Laboratory GPG and USP <1058>

In parallel to the second edition of the Laboratory Good Practice Guide, a stimulus to the revision process for USP <1058> chapter was submitted. The roots of this stimulus process can be traced back to the "round table discussion" on USP <1058> that took place

at the New Orleans AAPS meeting in November 2010. The authors of the <1058> stimulus paper were also invited to participate in the development of the GPG, creating the possibility of stronger alignment and harmonization of approach. The proposed <1058> stimulus paper included a new risk assessment and accompanying flow chart that is comprised of 16 questions, aligning the chapter with the principles of GAMP® 5.[14] This proposal is to provide a means of:

1. Differentiating Group A apparatus and Group B instruments based on their functionality and intended use
2. Incorporating risk assessment of the software elements contained in Group B instruments and Group C systems by identifying sub groups within groups B and C

The proposed risk assessment model[14] has been updated and published recently.[15] The risk assessment subdivides USP <1058> Groups B and C into the 3 categories each allowing greater granularity and flexibility in the approach to overall verification of function as shown below:

USP <1058> AIQ Inst Group	GAMP® 5 SW Category	Computerised Laboratory System Description	Verification Approach for Instrument	Verification Approach for Software
B	3	1. Instrument with firmware	• Define operating ranges of the instrument • Install and qualify the instrument over predefined ranges	• Implicitly validate the software functions of the instrument during instrument qualification
		2. Firmware instrument with in-built calculations	• Define operating ranges of the instrument • Install and qualify the instrument over predefined ranges	• Identify calculations used and input and output ranges • Implicitly validate the software functions of the instrument during instrument qualification • Check accuracy of the calculations during qualification
		3. Firmware instrument with ability for users to define routines	• Define operating ranges of the instrument • Install and qualify the instrument over predefined ranges	• Implicitly validate the software functions of the instrument during instrument qualification • Control user defined routines by SOP including specification of the routine, review of written code and testing against specification before release • Place under change control
C	4	4. Instrument controlled by non-configurable software	• Define operating ranges of the instrument • Install and qualify the instrument over predefined ranges	• Define user functions • Install and qualify software • Test whole system and software against user requirements • Place under change control
		5. Instrument controlled by configurable software	• Define operating ranges of the instrument • Install and qualify the instrument over predefined ranges	• Define user functions • Install and qualify software • Configure software • Test whole system and software against user requirements • Place under change control
	4+5	6. Instrument controlled by configurable software with custom additions	• Define operating ranges of the instrument • Install and qualify the instrument over predefined ranges	• Define user functions • Install and qualify software • Configure software • Specify, code and test custom elements • Integrate with application software • Test whole system and software user requirements • Place under change control

Table B. Harmonization of approach between GAMP® 5 and USP <1058>.

- Group A (apparatus) – no qualification impact (the risk assessment model also identifies instruments and systems with no GXP impact).
- Group B (instruments)
  1. Type 1 – Instrument firmware – requiring instrument qualification
  2. Type 2 – Instrument with software containing calculations – qualification required and calculations verified
  3. Type 3 – Instrument with software that is capable of end-user programs – qualification required plus control of user defined programs
- Group C (systems)
  1. Type 1 – Instrument with non-configurable software
  2. Type 2 – Instrument with configurable software
  3. Type 3 – Instrument with configurable software and customized macros

The reduced validation suggested by the stimulus paper is based on a risk-based approach for category 3 software using a single document to accomplish the complete validation.[16, 17]

Therefore, to harmonize the approach between GAMP® 5 and USP <1058>, there must be a mapping of GAMP® 5 software categories 3 to 5 with the proposed sub groups contained within Groups B and C. This is shown in Table B where the first two columns are the USP <1058> groups and the GAMP® 5 software categories respectively. The types of laboratory computerized systems possible are presented in the third column and the proposed verification approach that should be taken (contingent on the outcome of a risk assessment on the use of the system, process automated and the risk posed) is presented in the two right columns. These are split into instrument and software components of system. It is important to include two columns as the focus of GAMP® 5 is on software, but the analytical instrument functionality also must be tested.

Conclusion

Historically, there has been a tendency for people to align strongly with either USP <1058> or the GAMP® 5 Good Practice Guide. The different perspectives and approach of these two documents contributed toward this, but belied a commonality of intent and approach that may not have always been fully appreciated. Both publications strive to provide a guidance framework to support the activities necessary to ensure laboratory computerized systems are suitable for their intended use in GxP regulated environment, including the integrity of the data generated. Taking this commonality of approach further and mapping high level GAMP® 5 activities against USP <1058> provides a framework for understanding the inherent harmonization which already exists.

The updated ISPE GAMP® Good Practice Guide (GPG) Risk-Based Approach to GxP Compliant Laboratory Computerized Systems[7] has already been published. At the time the GPG was being finalized for publication, a stimulus to the revision process for USP <1058> chapter had been submitted, indicating the start of a revision cycle to <1058>. Prior to publication, expansion of the special interest group supporting the GPG development occurred, to include the authors of the <1058> stimulus paper which resulted in additional rich collaboration which contributed toward the development of the GPG.

“Taking this commonality of approach further and mapping high level GAMP® 5 activities against USP <1058> provides a framework for understanding the inherent harmonization which already exists.

The <1058> revision process will ultimately result in changes in its content and because of this, for pragmatic reasons, there were limits to how much information could be included in the GPG about <1058> at the time of publication (because of uncertainty over the extent to which it would change). The proposed expansion of <1058> defined in the stimulus paper and summarized in this document provides a further mechanism for even stronger harmonization of approach between USP <1058> and the GPG. The harmonization of these two approaches is important as they provide a consistent message and consistent guidance to users of computer laboratory systems in the GxP regulated environment. This reduces complexity and ultimately, well implemented harmonization can reduce compliance risks (because it reduces the diversity of approach/interpretation) and importantly in the current economic climate, reduce overall costs. As a comparison example, where pharmaceutical manufacturing validation has focused on reducing the cost of validation, the single biggest cost saving, approximately 30%, came from adopting standardized practices.[18]

The revision process for <1058> is on-going and changes will be made to the content of <1058> before the updated chapter is finalized and published. However, the sub categories contained in the current draft are based on practical experience of applying <1058>. Although the content of <1058> may change in the final version, the information contained within the draft and represented in this publication is of fundamental interest to achieving a harmonized

approach between GAMP and <1058>. Additionally, members of the GAMP community and readers of *Pharmaceutical Engineering* are encouraged to participate in the review process, when the proposed draft is published in Pharmacopeial Forum. This will help drive greater alignment.

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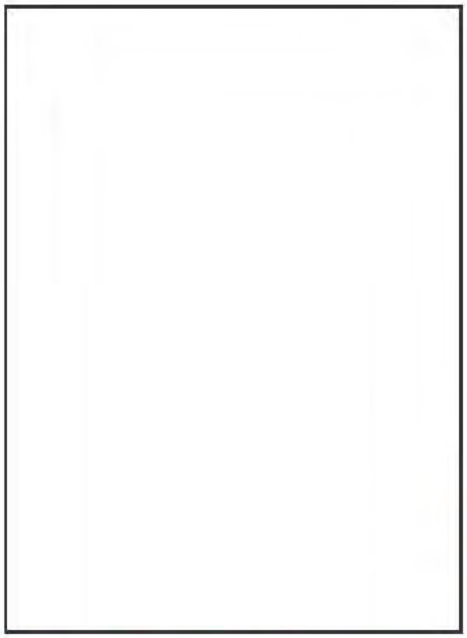

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Cloud Computing in a GxP Environment: The Promise, the Reality and the Path to Clarity

by the GAMP Cloud Computing Special Interest Group (SIG)

This article presents the current issues facing adoption of cloud computing, paradigm shifted needed and a strategy for establishing guidance within the pharmaceutical industry.

We are in a challenging time for most traditional pharmaceutical companies; the competiveness of the market place, loss of patents, increasing international regulatory requirements, downward pressure on health care costs. These are just a few of the factors that are driving pharmaceutical companies to adopt strategies of previously never seen cutting of resources and costs that have been present in other manufacturing sectors for some time.

At the same time, IT needs to support the challenges the businesses are facing and are consequently being asked to deliver effective solutions, while cutting costs without compromising quality, compliance, agility and flexibility.

More recently there has been a new term introduced into our IT vocabulary that is causing a great deal of discussion and debate throughout much of the business world - cloud computing. The promises of cloud computing are certainly considerable: extremely fast and flexible solution delivery, on-demand scalability, high-demand business continuity services with easy solutions for backup and archiving. All this, and at a cost which is considerably lower than the traditional internal setup. Is the dream becoming reality? Are IT managers able to meet the speed of delivery and cost pressures of their businesses? Will cloud computing provide the capabilities and adoption levels, while simultaneously meeting the regulatory compliance needs that are core to the pharmaceutical sector?

The dream is not attractive to IT departments alone. IT cloud providers are directly accessible to the pharmaceutical end user. Privately we store our lives on the cloud, our music, our pleasure reading, and our family photos. The next step of embracing the technology in our professional lives is a small one conceptually, but massive if compliance, security and integrity are to be maintained. An end user can engage a cloud provider with a credit card and fix a problem that needs resolving with little or no guidance on how the cloud IT world is different from the environment within their corporate network.

The Reality

Despite the promises of efficiencies and flexibility, there is a very slow adoption of cloud solutions at an enterprise level in the regulated environment. On evaluation of this remarkable phenomenon, we believe the reason is simple – the everlasting dilemma of innovation versus compliance. Our understanding of how to operate today has been shaped in the relatively recent past based on regulations, such as FDA Part 11, EU Annex 11, and industry forums like ISPE GAMP®. As an industry we are holding our breath and waiting for specific guidance around a technology which is still evolving. The longer we wait, the further we seem to fall behind. The absence of specific regulatory guidelines for the cloud, in combination with a very conservative mindset and a historically risk-adverse culture is once again slowing down the pharmaceutical

industry in the adoption of new technology.

So, what is stopping us from simply taking the well-established industry guidance – such as GAMP® 5 and shaping it to fit the cloud computing model? After all, as IT delivery departments, we have adapted GAMP® 5 to ensure our own internal infrastructure and applications are compliant. Would it not make sense to simply create parallel processes for an IAAS, PAAS or SAAS provider like we also did for specific areas such as manufacturing execution systems or laboratory equipment? Can regulated companies accept less than traditional execution of IT controls when considering a cloud provider?

The answer to this question has to be sought in the fact that cloud providers have diverse customer bases – ranging from individual users that simply want to save some files on a central internet location to large multinational companies in a wide range of industries. The representation and importance of the pharmaceutical market in a cloud provider's overall customer base is limited. The limited presence results in limited power to dictate how the quality aspects of the cloud businesses are run. One of the best examples of such a limitation is the fact that some of the larger cloud providers (and the more cost effective ones) are unwilling to open up their companies and processes for scrutiny by multiple teams of auditors. Vendors that do open their doors to audits do not always understand the need for individual regulated companies to audit and would prefer that they could provide these regulated companies a "GxP certification." However, such certifications do not exist.

A second reason that holds us back from embracing cloud systems in the same way as any other computer system is the fact that some of the quality related processes used by the cloud service providers are a little "different," in other words, a bit more risk-tolerant than what we are used to in the conservative pharmaceutical world. The differences can be found in all parts of a provider's organization. What does a "proper" Quality Management System (QMS) look like? If the QMS has all the right elements, is it okay that the QMS is posted on a Wiki and not in an electronic document management system? Do we need to see paper to demonstrate hardware and software is qualified? Does the paper make a server more reliable? Is the QMS on a Wiki, although different from what we have traditionally seen, inferior in any way? The answer is neither no nor yes, but rather 'it depends.' It depends on what the corresponding risk is, how the risk is related to the overall process, and how we can manage and even mitigate the risk on the side of the pharmaceutical company if warranted.

If processes are different at a cloud provider, those responsible for the assuring processes are sufficient (for example Internal quality units, auditors, health authorities) need to partner with the IT departments and providers to understand the fundamentals before making judgments on

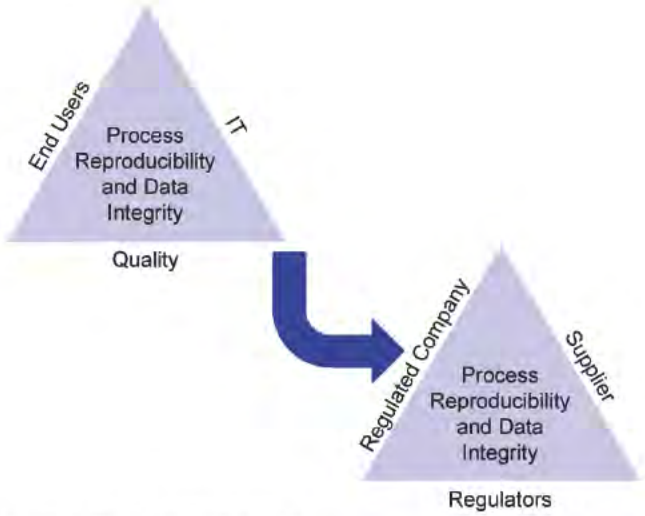

Figure 1. Quality paradigm shift.

the quality of the processes. Quality units need to assess why, where and by whom controls are established and then examine what those controls are. Quality professionals will need to understand the difference between formal elements of control and controls that may impact the data and how

this relates to processes being operated at a cloud provider (the difference between what and how). This will likely result in a shift from quality processes contained within a regulated company to a model where quality is achieved as a result of partnership between the regulated company, service providers and regulators - *Figure 1*.

Figure 2 represents a starting point for how one can visualize the partnership that a regulated company and a service provider must prepare. In this arrangement, we must be willing to view controls in a way that they are meaningful, not the same controls moved wholesale to the provider.

As is typical with any change scenario, there will be a certain level of human resistance toward this less proven and unknown territory in which the pharmaceutical companies do not have the control they are used to having. Yet - if we are honest with ourselves – we all know it is the way to go. Think back to the desire to take advantage of advancing technology and avoid paper in the early 90s. The adoption of what we now consider "E-signature" was equally unclear. Industry together with regulators pushed forward and E-signature controls are now embedded into the fabric of regulated companies. So the question in front of us now is about how we can start to better understand and manage (not simply avoid) the risks which come with this technology.

What do we need to do to allow us to:

- Obtain the "promised" cost optimization without compromising the integrity of the data that impacts product quality and patient safety
- Realize the responsiveness the end user demands
- Identify and analyze the risks across and within an enterprise
- Create a framework to manage these risks both in house as well as part of our supplier management processes

The Path to Clarity

In late 2012, and based on an ongoing dialogue between ISPE GAMP Community of Practice (CoP), industry as well as the FDA, it became very clear that there was – and still is – a need to provide guidance on the usage of cloud technologies in the regulated (GxP) environment in order to accelerate adoption of this technology. The GAMP leadership reached out to the FDA, a selection of pharmaceutical companies, and cloud service providers with the request to collaborate on this topic.

The result of this was the formation of a new GAMP Special Interest Group (SIG) in early 2013. A small core team representing a cross section of large and small pharmaceutical companies and cloud service providers SMEs started working together in delivering the guidance to industry and regulators. While the team did not have any idea on the shape or form of this guidance, one thing was clear - the need was high.

The initial questions the team addressed were structured in a simple three-step process:

- What is the current existing guidance for management of computerized systems in a health authority regulated environment?
- What is different in the world of cloud computing? What characteristics force us to look at this differently?
- What is the corresponding framework to combine 1 and 2 into a pragmatic and risk-based approach which satis-

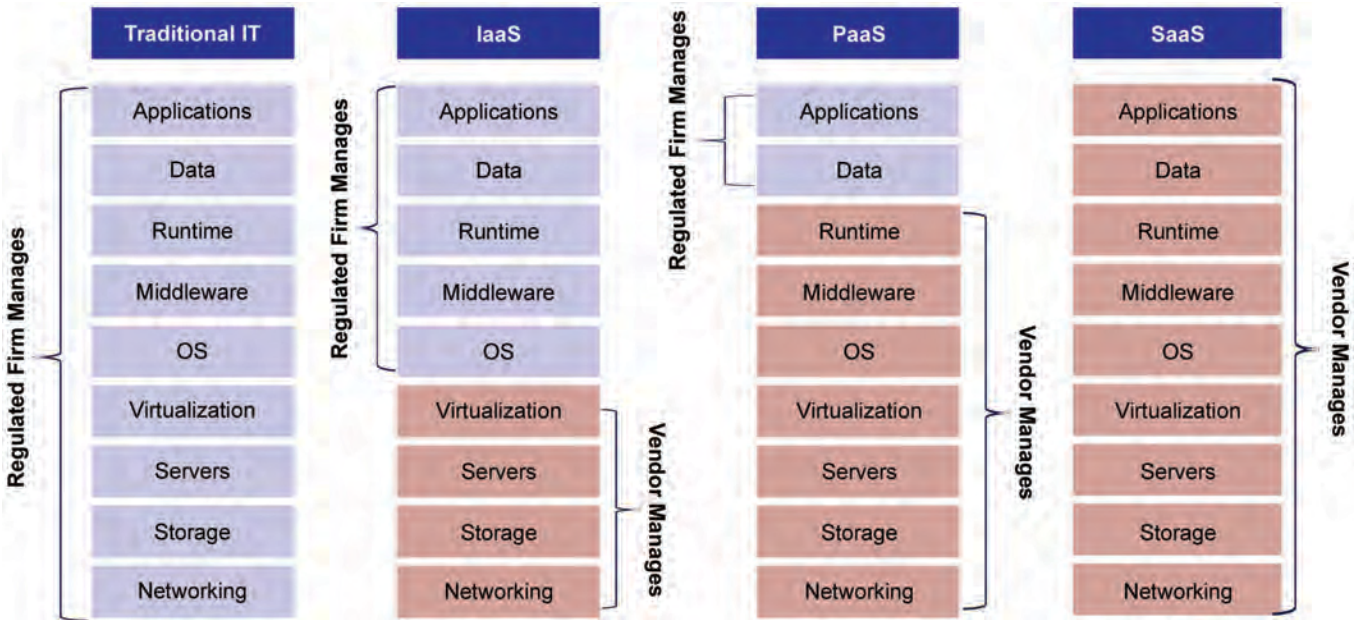

Figure 2. The partnership that a regulated company and a service provider must prepare.

fies the need of the regulator, regulated company and cloud service provider?

As a starting point, we looked at the following leading industry guidance's:

- The well recognized GAMP® 5 guidance, along with the GAMP® Good Practice Guide on IT Infrastructure Control and Compliance
- The National Institute of Standards and Technology (NIST) Definition of Cloud Computing (Special Publication 800-145)
- The Cloud Security Alliance documents, including the "Cloud Controls Matrix" and "Security Guidance for Critical Areas of Focus in Cloud Computing v3.0"

Once these documents were reviewed and digested, the team focused on the differences between the traditional computer systems and cloud computing services provided by external companies, and how these standards fit with the GAMP® documents listed above. In line with the items already highlighted in this article, the following drivers were identified:

- Shift of controls from the regulated company to the provider
- Presence of regulated companies as a cohesive block in the cloud
- Degree of flexibility and scaling possible

The first difference the group identified is that the use of cloud comes with a never-seen shift of controls across the lifecycle (hardware, applications, or data) from the pharmaceutical companies toward the cloud service provider. Many have seen outsourcing of infrastructure components in the past; occasionally application management is performed by a third party. Many have experienced that each outsourced application support was seen as an almost exotic setup, for which the compliance functions had to initiate intensive discussions with the service provider on how they should manage their application. Our experience has been that there is not even awareness that such transfers of operational activity could raise a compliance concern. Frequently, the individuals involved in such transfers were unaware of the differences and have not engaged a compliance department.

The current setup of a Software as a Service (SaaS) looks very much like those abnormal setups on steroids. It involves even greater movement of control toward the supplier, but still leaves the responsibility for the data and process with the regulated company supplier. Infrastructure as a Service (IaaS) on the surface appears like so much less of a compliance risk, but unless tight controls are established to guide what will be stored on top of that infrastructure, compliance concerns are as strong for SaaS. What do those controls look like and when in the lifecycle of information should they be applied? Platform as a Service (PaaS) and the interrelationship of controls between supplier and regulated company is perhaps the most complex. The compliance concerns are just as valid, on infrastructure, platform and even application level, with little or nothing that we as pharmaceutical companies can influence with regard to the providers management processes. Combine this with the fact that many of these cloud service providers are not even willing to open up their companies for audits, and it becomes clear why "cloud" is now one of the most instant "headache triggers" for our traditional quality teams.

The representation and importance of the pharmaceutical market in a cloud provider's overall customer base is limited."

Closely linked to the shift of controls, and as already highlighted in the introduction, is the second reason – the fact that the pharmaceutical companies only represent a small market share for the cloud providers, and hence have had little success in telling providers how to run their businesses. Sure, there are exceptions of smaller cloud providers who create an almost on demand setup, but it's no surprise that these are considerably more expensive, and thus less attractive from a pure economical point of view.

Returning to the bigger cloud service providers, it is clear that they do know what they are doing with an excellent track record of uptime and business continuity, and very few security incidents, operating with practices designed for a pure IT industry. There are a wide range of industries already using these services, including the more "conservative" industries such as the banking sector. So why are the processes sufficient for banking and not good enough for large regulated companies? Specialized certifications for companies are possible (CMMI, ISO, etc.). The certifications range from general controls across a provider to area specific certifications such as security. The pharmaceutical industry has occasionally considered a GxP certification for outsourced services, but this thought has never matured. Providers claim to be regulatory ready and some are; however, currently there is no recognized GxP certification process. The SIG is not proposing that one should be developed from new. Existing processes first need to be reviewed

objectively to understand the standards and where the differences between the standards and regulated companies expectations may be.

As a first step in mutual understanding, we can look at, for example, ISO 9003:2004 against which GAMP® 5 is aligned. It is a standard that that is frequently accepted as a reference when the pharmaceutical industry audits software providers. Table A demonstrates the fit between GAMP® 5 and ISO 90003 (just one of several controls which also include ISO/IEC 27001:2013 and ITIL®).

As a last difference, we must certainly mention the fact that cloud computing comes with a never before seen level of flexibility and scalability. Along with non-traditional processes for "keeping the lights on" comes the ability to react in minutes and hours to the needs of their customers rather than weeks and sometimes months. Cloud providers can provision space and applications to the end user without the need to assess the impact of such changes on existing systems. Their appeal is that they have what may be considered a narrow range of "products" or "services," but these can be delivered before most regulated companies have finished filling out their change form, not to mention assessing the impacts of those changes.

Clearly, there must be other forces at play. It is not just about the standards. Standards can be aligned. And this is exactly the question that providers are asking us.

A part of the question is answered by recognizing that regulated companies have specific controls that cover all of the classic software development standards and which are stricter than what we have seen in other industries. There are expectations of performing in-depth impact assessments toward product quality and patient safety when changes are made to any system. There is an expectation that during the development and operation of a system, a quality/validation "plan" is established to assure a system is delivered fit for use and can be maintained as well. Lastly, there is an expectation that the performance of activities, such as development, testing, release, etc., be formally documented. The expectation is that the process and the outcomes are reviewed, approved and preserved for future examination. The fact that we have historically executed some operational controls in a "different" way is not a good reason for not adopting innovative approaches, as long as quality, integrity and compliance are preserved.

Subject	ISO 90003:2004	GAMP® 5, Appendix
Basic Design	7.3.2, 7.3.3	D2/D3
Detailed Design		
Design Review	7.3.4	M5
Code Review	7.3.4, 7.3.5	D4
Module (unit) Test	7.3.6.2 a	D5
Integration/System Test	7.3.6.2 b	D5
IQ/OQ – System Test	7.3.6.2 c 7.5.1.5 7.5.1.6	D5/M7
PQ – Acceptance Test	7.3.6.2 d	D5/M7
Change Control	7.3.7	O6
Configuration Management	7.5.3.2	O6

Table A. The fit between GAMP® 5 and ISO 90003.

The First Steps on Our Journey

The fact that these processes in the cloud are different does not mean that they are inferior. It is up to the pharmaceutical industry to analyze these differences, identify resulting gaps, and manage the corresponding risks. The first step in this journey is to recognize the different cloud deployment models, the traditional IT controls and underlying actions, to understand who needs to execute the controls. To do so, controls, such as ISO/IEC 27001:2013, ITIL®, European Network and Information Security Agency (ENISA) also should be considered. If we are to operate in a new paradigm, we must look beyond the current practices of the pharmaceutical industry.

This first exercise will provide the SIG with a clear and detailed overview of the responsibilities between the cloud service provider and the regulated company. These traditional controls will have to be accounted for within a company's quality framework, and then we must step back in order to understand if this new model will require different or additional controls to ratify the rigor of the regulated industry.

Once this analysis is completed, the SIG will examine supplier management controls and how they may need to be re-considered. Additionally, we will further examine which IT controls are best performed by the service provider, as well as current certification programs commonly attained by providers. Only then with this analysis and dialogue between cloud providers, regulated companies and regulators can a framework be created that will satisfy the regulated industry.

The Future – What's Coming

In the coming months, the SIG will examine the ways in which the pharmaceutical industry is or would like to use the different services (IaaS, PaaS, SaaS), GAMP® vs. IT standard controls and providing recommendations on how to assess the risks, identify gaps and provide recommendations for the changing landscape of regulated IT controls.

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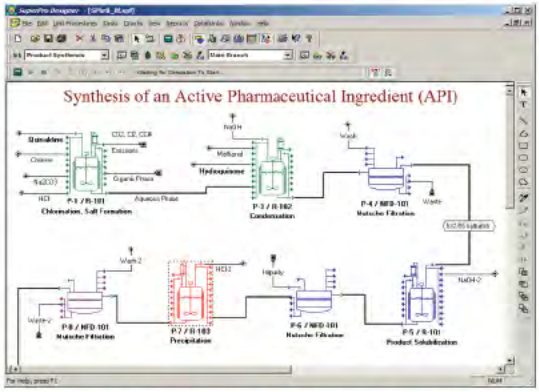

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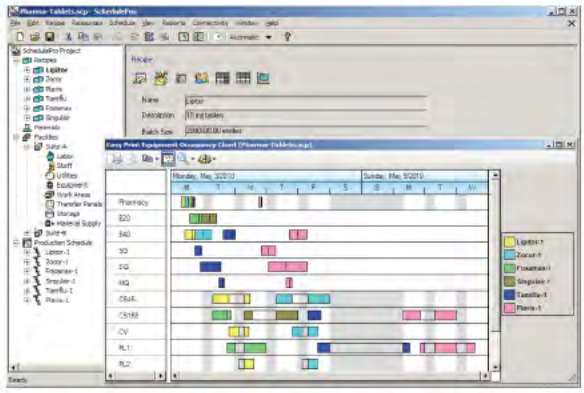

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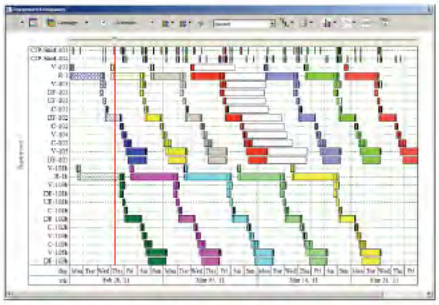

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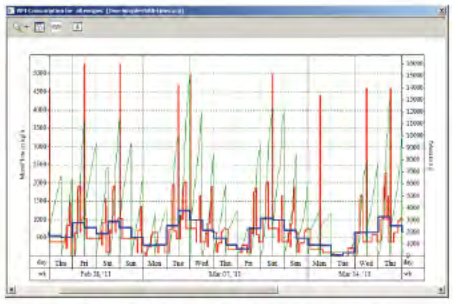
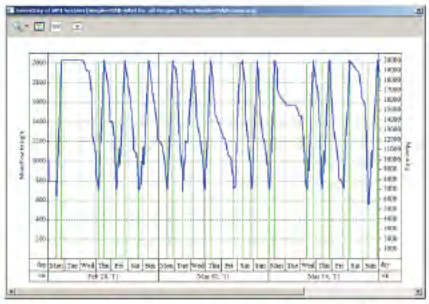


Tracking demand for resources (e.g., labor, materials, utilities, etc.)



Managing inventories for input, intermediate, and output materials

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SchedulePro is a versatile production planning, scheduling, and resource management tool. It generates feasible production schedules for multi-product facilities that do not violate constraints related to the limited availability of equipment, labor, utilities, and inventories of materials. It can be used in conjunction with SuperPro (by importing its recipes) or independently (by creating recipes directly in SchedulePro). Any industry that manufactures multiple products by sharing production lines and resources can benefit from the use of SchedulePro. Engineering companies use it as a modeling tool to size shared utilities, determine equipment requirements, reduce cycle times, and debottleneck facilities.

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The Blinding of Materials in Clinical Trials: Essential Processes for Ensuring the Integrity of Clinical Study Data

by Sandra Cook, Steven Yoder, Christina Owings, Barbara Campbell, and Charles Gentile

This article explores concepts for maintaining the blind throughout a trial and at various nodes in the clinical trial material supply chain.

The concept of blinding is foundational to the construct and execution of clinical trials associated with the drug development process. In its most simple form, blinding ensures that bias is not introduced into the trial or experiment by concealing the treatment to which a participant in the trial is assigned. Blinding is defined in Annex 13 (Manufacture of Investigational Medicinal Products) as, "A procedure in which one or more parties to the trial are kept unaware of the treatment assignments(s)." Single blinding usually refers to the subject or patient being unaware of the treatment assignment. Double blinding refers to extending the concealment of treatment group assignment to other participants including clinical site investigators, clinical monitors, and the various clinical operations personnel that support the trial.

Blinding introduces into the pharmaceutical clinical supply chain complexities, considerations, and controls that are not necessary in a commercial supply chain. During the very early trial design and planning, the clinical team has to consider how blinding will be established among the active, comparator, and placebo treatment arms. In some cases, blinding must be considered even earlier in the process, specifically during formulation development, device development and drug product manufacture. Once the clinical trial material manufacturing and packaging begins, controls must be in place to maintain the proper identity so that ultimately the patient to treatment group assignments are accurate and blinding is maintained.

Of course there are situations where breaking the blind, or intentionally disclosing treatment group assignment to one or more participants in a study, is required. For example, in the event of a medical emergency or other adverse reaction, the procedure for disclosing the treatment group assignment must be clear and easy to execute. The ability to intentionally unblind the participant, investigator, and health care provider may be a matter of life or death.

But in cases where the blind is broken unintentionally and in an uncontrolled way, the costs can be quite high. Patients may have to be dropped from the study. Data collected from those patients may be disqualified from consideration in an evaluation of meeting critical medical end points. In the most extreme case, the results of a study could be completely compromised and the sponsor forced to repeat the study. The sponsor's reputation could be tarnished causing reluctance by others to partner with them in future research. Product approval could be delayed, costing the innovator lost revenue and potentially prolonging the suffering of patients.

Clearly the stakes are high and this is an important topic for clinical supply professionals and those who operate in key functional adjacencies for several reasons. There is little

training and literature available on this topic and although most organizations provide basic training on these concepts, it is common for clinical supply managers to learn the hard way from situations where they may be involved in unintentionally revealing a treatment group to blinded participants.

This article explores concepts for maintaining the blind throughout the trial and at various nodes in the clinical trial material supply chain. It focuses on the blinding of clinical trial materials, strategies for ensuring the materials truly are blinded among treatment groups, important considerations for managing the clinical trial material supply chain, and other processes including change management, risk evaluation, and decision making.

Blinding Clinical Studies

Scientific method underpins all clinical research. The efficacy and side effect profiles of drugs need to be ascertained without any confounding variables, including those conceivably introduced by the materials themselves.

Within the disciplines of the clinical supply chain, blinding begins with the manufacturing of the drug product itself. Various strengths of a drug product and matching placebo need to be perceived as similar to one another. Creating these may be as simple as modifying the amount of active pharmaceutical ingredient or may require more elegant formulation techniques. For example, with tableted solid dosage forms, a common granulation would not necessarily permit units of the same size and shape, thus resulting in products that cannot be blinded to one another. Liquids of various concentrations may have different physical properties that can be distinguished, such as color and viscosity. As such, the pharmaceutical development functions play a key role quite early in the clinical supply chain. Furthermore, as the potential strengths required to support clinical trials are often a moving target as data is being gathered during the phases of clinical development, close and frequent communication between the functions is of paramount importance. This is often liaised through investigational products professionals and is one of the essential and most challenging of their responsibilities.

For both regulatory and commercial purposes, a growing number of clinical trials require direct comparison to existing marketed competitor products. To ensure that the clinical data yielded from a trial is free from bias, both the innovator products and the competitor products, or comparators, must be blinded to one another as well. This gives rise to an additional requisite that the key properties of the competitor product must not be altered in any way. Additionally, the competitor has generated stability data in their own primary barriers and as such subsequent blinded packaging for a comparative clinical trial must provide the same, if not greater, protection. It is necessary for adequate and robust stability programs to be designed and testing conducted.

When working with competitor solid dosage forms, for example, assuring the maintenance of product attributes would include the ability of the comparator to be absorbed into the bloodstream with the same pharmacokinetic profile. Therefore, any manipulations made to the comparator cannot alter the dissolution or ability to dissolve. This might seem easily achieved in a number of ways, such as de-inking or de-embossing, milling and filling; however, these methods frequently result in substantially altering the properties of the competitor product. Because of this, the most common, efficient and economical method is to over-encapsulate, often using an excipient backfill. By doing so, all products tested head-to-head to one another in a clinical trial can be made to appear similar. Here an interesting conundrum may result. Some patients may be tempted to break their capsules apart to examine the contents and possibly unblind themselves. So although over-encapsulation is the least likely method for altering the properties of a comparator, it inherently bares a degree of risk to the blind that needs to be considered. For more information, readers may find the "ISPE Good Practice Guide: Comparator Management" a useful reference.

So the goal in blinding is to ensure that a degree of sameness is brought to all of the materials utilized in a clinical

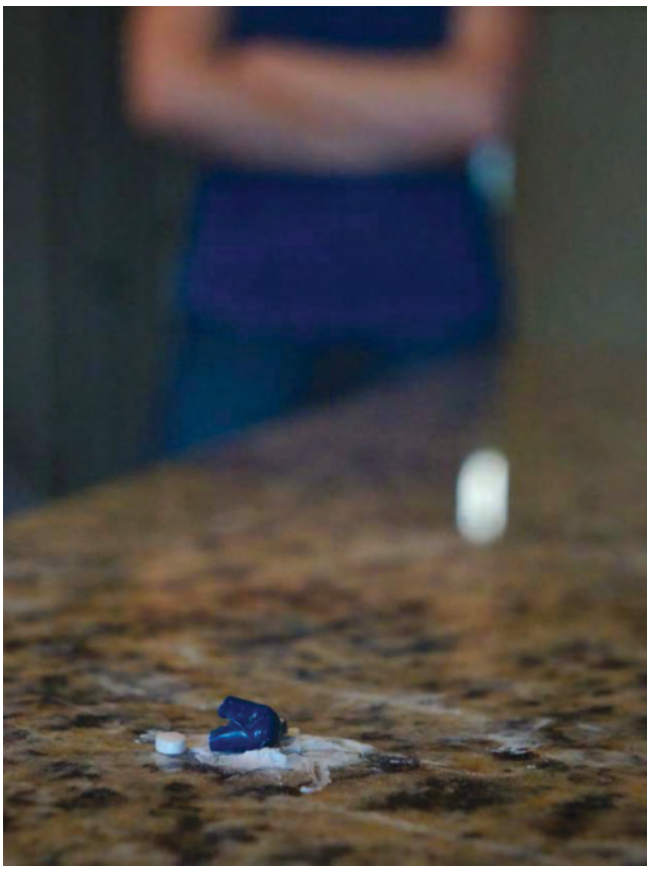

Figure 1. Over-encapsulation has powerful advantages and is used frequently, however a patient could reveal their treatment group through tampering (in this case by breaking open the capsule).

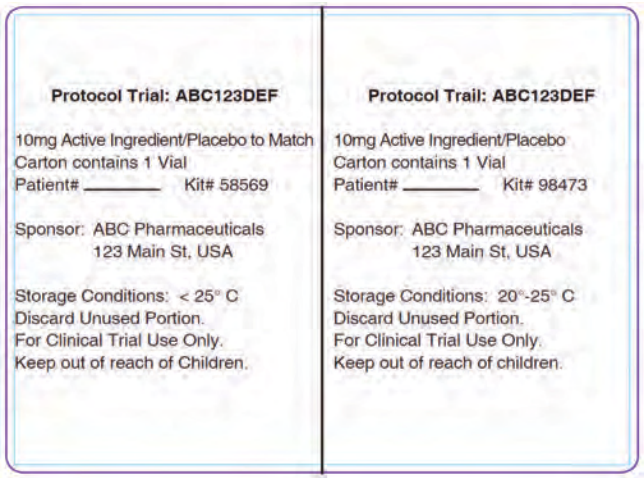

Figure 2. Label text differences can potentially distinguish one treatment group from another. Can you spot the differences between these labels?

a. trials versus trails/ b. placebo versus placebo to match/ c. storage conditions/ d. children versus Children. Note: The differing numerics for kit number are permissible as they designate the necessary unique identifier for each dispensing unit.

study. This not only involves the investigational products and comparators, but all components, too. The packaging professional must be diligent in every detail down to the component. When considering the blind, awareness needs to extend to bottles, caps, blister cards, inserts, labels and packing materials, to name a few.

As the discipline of supply chain continues to evolve and approaches shift to inventory management, the questions of "how much" and "how often" not only apply to product, but to associated packaging components, as well. Should you stock large quantities periodically or smaller volumes more frequently? There are pros and cons to both, and finding the optimal pivot point, although difficult, should at least be explored.

In making this assessment for your trials, also consider blinding implications. Acquiring a large volume ensures that minor changes in the components do not inadvertently unblind the trial if there are differences in a second purchase. It is possible, for example, that a second order of bottles might have a slightly different curvature to the bottom, or embossing, or seam despite being the same part. Should a subsequent packaging campaign for one treatment use these bottles, a risk of unblinding would be introduced.

Conversely, some properties of components can change or degrade over time so that it would be more beneficial to obtain smaller quantities more often. To illustrate, an order of dyed foam inserts might show a fading of color over time. A later campaign for one treatment using the foam inserts from the same, now older, lot also could potentially unblind the study. In this case, it would have been better to draw from a fresher inventory.

Therefore there isn't one default for the stock management of components when it comes to blinding. One should consider continuity of properties, such as appearance, as the key guidance in establishing a supply strategy.

The visual appearance of investigational materials is the most prevalent aspect considered in blinding; however, the other senses also need to be taken into account. What if there were differences in taste between products? What if they smelled different? It's possible that one formulation may sting upon injection, yet another may not. In these cases, returning to formulation development may be necessary to explore options that might allow all treatments to be perceived similarly. You may even hear differences that could compromise a blind. For example, comparing a competitor product over-encapsulated without a backfill to a powder in capsule for the innovator product would result in the primary product of one treatment to rattle when shaken, yet the other to create no audible sound. What about the sense of touch? Although the difference in weight between capsule types may be nominal, large volume kits supporting complex and long duration dosing periods may result in a cumulative effect where kit types can be distinguished by weight. What would you do if this occurred?

Strategies for Mitigation: Testing for Match

Ensuring the blind is maintained reaches back into the clinical supply chain to formulation and manufacture. Although as few changes as possible are made between active and placebo, between strengths, or with comparators, resulting materials can on some occasions be differentiated from one another. Discovering these differences early and making informed decisions regarding adequacy for use is essential. This is best accomplished with side by side comparison. Do samples appear the same?

Have two individuals conduct the review independently. Look from above and from the side. Evaluate attributes such as color, size, thickness, texture and gloss. You may even consider placing several sample units from each formulation together and determining if the units can be segregated back into two distinct groups. To do this for example with tablets, mark with a pen all the units of one formulation on one side, flip them over and scramble all the units together.

In the case of non-solid dosage forms, compare these formulations side by side as well. Are liquids the same hue? What about products requiring reconstitution? Do lyophilized powders seem similar? Does this hold true once reconstituted?

The testing for match should be required; however, the degree of formality and the actions if failure does occur must be agreed with consistent guidance in your organization.

Most important of all, though, is the timing for the testing of match. Why wait until the packaging job is scheduled to commence? Why even wait until delivery to the clinical sup-

plies function? Conduct your testing at the time of formulation manufacture.

Strategies for Mitigation: Reference Samples

What do you do in your company to communicate a common vision for packaged materials to everyone involved in assembling the clinical supplies? Creating a common reference can be a powerful tool to mitigate the potential for unblinding. Primary packaging, label placement, secondary assembly and kitting can be illustrated with schematics. Actual samples can be created and photographed. These schematics or photographs can then be referred to during operation activities as part of the packaging documentation. Some organizations create posters that are required to be displayed during job runs. Others might use the samples themselves as physical guides to match against. And some companies may inspect the reference samples as part of their batch release process.

Without these safeguards in place, it is possible for simple differences between treatments or campaigns to unblind a clinical trial. What if a square tamper seal with diagonal hash marks were placed in one direction in one instance and at a right angle in another? Wouldn't a label justified to the top edge of a carton on an active kit look different from the same label type centered on placebo kits? And with regard to labels themselves, the exact same thinking should apply to label text. Text, text placement, and font are just a few of the details to consider. Here the master label serves as the reference sample or standard.

Managing Blinded Clinical Supplies: Communications

Even when a drug product is formulated, packaged, and labeled with blinding intact, consideration also must be given to ensuring blinding integrity is maintained while interacting and communicating with clinical sites and other blinded study personnel. A single email to or conversation with blinded study personnel containing improperly blinded information may cause greater negative impact to a study more quickly than formulation or packaging errors, and quite often, there are fewer blinding integrity controls built into these communication processes. For example, attaching reports to emails, sharing documents on a collaboration space, and replying to or forwarding email chains are all high risk areas for potential unintentional unblinding if close attention is not paid to the content of the email or report and the intended recipients.

Preventing these aforementioned scenarios may seem straightforward; don't communicate patient or package numbers associated with treatment group descriptions to blinded study personnel. So why is study blinding so often compromised by improper communications with blinded personnel? One simple answer is that people naturally want to be helpful and want to provide information that they think

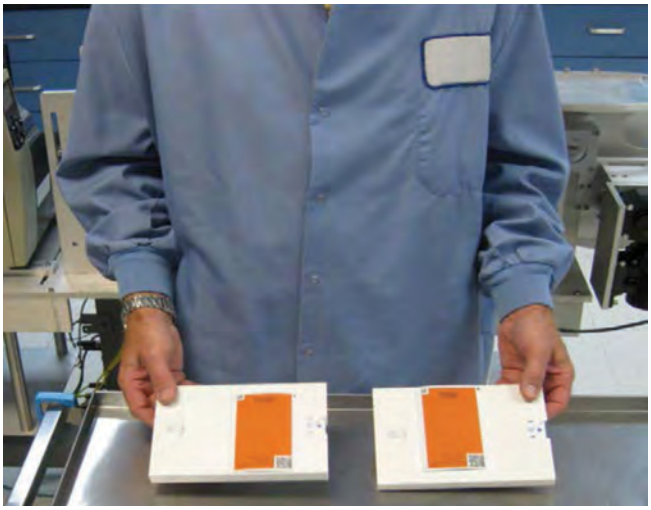

Figure 3. The blind can be compromised during packaging procedures. Here label placement is not consistent between two treatment groups.

will be of benefit to clients, clinical operations, site personnel and ultimately the patient. Another answer is that some of the individuals allowed to communicate with blinded personnel may not have proper training to be able to recognize

potential unblinding information or differentiate between blinded versus unblinded study personnel. Emails are easy to send, conversations among team members and interfaces occur, and communication processes are generally not as well defined or controlled as GMP processes, such as manufacturing, packaging, and labeling.

The first step to preventing unintentional unblinding during communications is to limit who can engage directly with blinded contacts. This includes defining roles and limiting both the number of roles and the number of individuals within a role that may engage in direct interaction with blinded personnel.

We suggest providing clear instruction to clinical sites and other blinded study personnel regarding contacts and the communication pathways for study related questions. For example, a clinical site may make contact to ask if they have the correct product available for a patient that is returning or if a shipment is en route to support that specific patient. They may call to state that an incorrect kit was given to a patient. A clinical site may bring in multiple patients in the same day and not have enough material to support all patients. In these cases, they should be kept unaware of the treatment assignments as well as the identity of the investigational product, be it active, placebo or comparator.

It is critical to provide specific guidance to all unblinded study personnel regarding what to do if or when they are contacted by blinded study personnel. Ensure all unblinded study personnel are aware of the roles and specific individuals that are intended to remain blinded to treatment group assignments. When communicating with the investigator, study coordinator, clinical operations, the contract management organization or sponsor, one should always assume that everyone is blinded. And when responding to queries it is important to provide only the information that has been requested without jeopardizing the blind.

Next, evaluate the computer software systems used in management of the trials and configure reports generated from these systems to default as blinded. Ensure that when unblinded reports are generated from these systems that they are clearly labeled as unblinded, including when they are exported to external software for additional manipulation, such as spreadsheets. Consider implementing an approval process for custom reports when unique information needs to be communicated to blinded study personnel that is not available in a standard, blinded report.

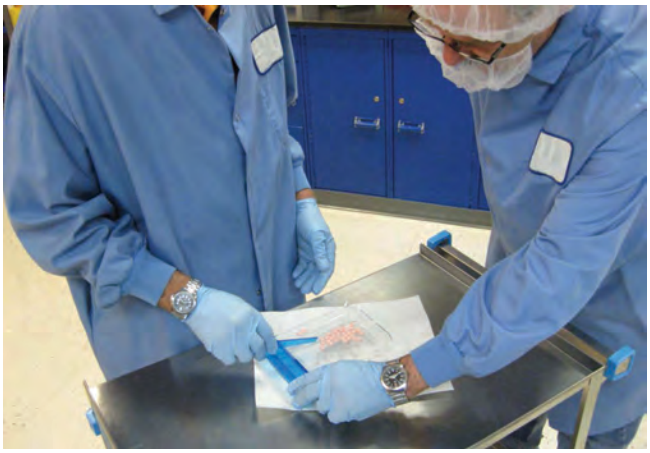

Figure 4. Conducting formal testing of match between dosage units can be a useful procedure in ensuring the blind.

Communication also includes the documentation that accompanies drug dispatch to clinical sites. While shipping documentation supporting clinical trials is not part of the clinical supply, it can play a significant role of potentially unblinding a subject or investigator. Information on the packing slip must not reveal any unblinding information. The distribution team is the last line of defense before the supplies are provided to the clinical sites and therefore their understanding of the blind is also paramount.

Establishing job title specific, unintentional unblinding awareness training for employees who may interact with or be contacted by blinded study personnel is a necessary preventive measure. The qualification program should include past examples of unintentional unblinding incidents which may have occurred or nearly occurred in one's organization. Identify the various risk areas for unintentional unblinding. Ensure the training includes a description of those parties potentially impacted by unintentional unblinding and the resulting implications. These may include the patient being dropped from the study, the loss of data from that patient, the study being delayed or suspended, trial personnel needing to be removed from the study, study delays, delayed submissions, financial impacts and ethical implications. Personnel also should be made aware of immediate actions that must be taken if and when unintentional unblinding occurs. Consider utilizing this article as a spring board for discussion.

Even when appropriate preventative measures are implemented and integrated into communication processes, unintentional unblinding can still occur. Time is of the essence when attempting to correct and justify an errant communication containing unintentional unblinding information. Upon identification of the incident, cease the communication and notify the appropriate parties. Attempt to recall the email communication, utilizing available email application functions if available. Reply all to the email, removing the unblinding information this time, and indicating "Do Not Open" or similar in the subject line. Immediately start a formal incident report to document these immediate control measure, the full root cause investigation, actions, and objective evidence.

As part of the investigation, utilize IT resources to ensure the email has been permanently deleted. Obtain objective evidence of this confirmation. Also, consider preparing a standard document for each potentially unblinded individual

stating that the individual did not open, read, forward, print, or otherwise disseminate the email and the email has been permanently deleted. Have each potentially unblinded individual sign the document. If unblinding information was shared via a collaboration site, obtain a list of all personnel with access to the collaboration site. Start gathering data on the roles of the potentially unblinded individuals within the study and the stage or phase of the study at the time of the unblinding incident.

Concurrently with or after these or similar immediate actions are completed, assemble a group of clinical supply management and quality personnel who are knowledgeable, capable, and empowered to make decisions about the future of the trial, enrolled patients, and involvement of participating clinical operations personnel. The group should review all of the data, including evidence of the success or failure of the immediate actions, the phase and design of the study, and the specific job roles of the impacted personnel within the study. Any decisions made by the group should be documented in the formal incident report, including any justification necessary to support that the integrity of the study blinding is still intact. The incident report also should be used as a mechanism to document root cause analysis results and the associated preventive actions.

Managing Blinded Clinical Supplies: Distribution

There is always a potential to unblind a site when it comes to distributing resupplies. Consideration must be given when setting up parameters for all treatment groups. If a site holds some inventory, but a shipment is still needed to provide availability of all material types, the risk of unblinding is high. The clinical site would be able to determine that the patient is receiving a different treatment than what is available and would therefore know that a future patient who receives any of the previously available materials would be on an opposing treatment. Some organizations see this as having a high likelihood of unblinding. They may consider establishing a resupply strategy to have all treatment groups resupplied at the same time, should stock permit. If a trial has randomization that is 1:1, one active drug to one placebo for example, it's particularly important to consider seeding centers with multiple kits per treatment and setting the parameters to resupply after dispensing to maintain these levels. This also provides a safety stock of each treatment to allow for increased enrollment or multiple patients returning on the same day. Although these types of distribution resupply strategies may leave more investigational product at the site than is ultimately consumed, they could aide in maintaining the blind.

Another aspect to consider is the unique medication ID or kit numbers on investigational products. If each treatment arm is given different but specific block ranges, this also could jeopardize the blind. It is essential to have all treatments blended numerically so that no numerical order would be given to each treatment group.

Managing Change

Throughout our manufacturing and packaging operations there exists the potential for changes in equipment, processes and materials. As most organizations concentrate on continually improving throughout the various sub functions in the supply chain, it is theoretically possible for what may appear to be a minor or innocuous change to miss an assessment of the impact on blinding.

Sometimes, although there may be recognition that a change could effect blinding, there is a potentially false assumption that all treatments will be equally effected as all treatments will be provided at a subsequent resupply.

Particular attention should be paid to those situations where the site of product manufacture changes or when some formulations are manufactured at one site and others at another. Consider the impact of a difference in sources or batches of excipients. What might be the result on the blind of the products to one another?

To ensure that your organization does not fall into a similar trap, take a close look at how you conduct your change control. When making any changes in equipment, processes and materials, is a robust group of individuals outside the immediate sub functions queried for their view on the potential to unblind? If not, than we recommend you require members of your pharmaceutical development, investigational products, project management and quality functions to review all changes, including those that may seem on the surface to be strictly operational in nature.

Risk Evaluation and Decision Making

Even in the most vigilant organization with all checks and controls in place, the potential for an unblinding event can still occur. As noted in examples above, batch to batch and between strength variations can be revealed in your product during formulation development and manufacture. Differences may be seen in components and in packaging configurations. Documentation and communications may put the blind at risk.

How should you move forward in the short-term and prevent long-term in the future? Assembling a team of experts to evaluate the immediate impact on the effected clinical trial or trials best ensures that all options have been explored and all implications have been fully considered. Gather the relevant trial specific clinical supplies technicians and operations area managers, clinical/client interfacing project manager, GMP QA, GCP QA, and clinical operations contact. The specific individuals may change from unblinding issue to unblinding issue, but the roles should have standard representation. Allow everyone to observe the materials together. Conduct a risk assessment of the potential severity of impact and the probability that an unblinding might occur.

For example, a minor difference in the color of a tablet may be deemed acceptable if it can be assumed through the trial design and planned conduct that the materials would never be together in the same place at the same time. The tablets would not be in the same blister card, would not be in the same set of bottles provided at a given visit to a patient to take home, nor would be together side by side with clinical site personnel or clinical monitors during patient compliance evaluations and final drug accountability processes.

> *"Clinical supply professionals play a key role in advancing pharmaceutical research by ensuring study related materials are available for patients at the right place and at the right time. But their responsibilities don't end there.*

Determine what activities would be required to replace the materials and their respective time and cost. Balance this against the risk and make an informed joint decision that can be fully supported and documented.

Once the short-term has been addressed, move from the tactical to the strategic to consider longer-term how this might be avoided in the future in a CAPA like approach. Utilize the specific team of experts along with functional managers and area experts to target which processes might be changed to mitigate the phenomenon from reoccurring and proceed with process improvement.

Conclusion

Clinical supply professionals play a key role in advancing pharmaceutical research by ensuring study related materials are available for patients at the right place and at the right time. But their responsibilities don't end there. In studies where material blinding is used to keep bias from being introduced into the results, they also are responsible for ensuring the supplies and the processes for managing those supplies preserve the blind. In order to achieve that objective, consideration must be given long before the supplies are packaged and delivered to the clinical trial site. Their involvement is required very early in the development of the clinical plan for a new drug entity and throughout the execution of that plan to make sure the right strategies and controls are being put into place so that at the conclusion of a trial there is a high degree of confidence in the integrity of the data being analyzed. The ultimate goal is product approval on innovative new therapies that improve the lives of patients.

This article has explored the concept of clinical trial material blinding and strategies for its management. The authors have attempted to cover some of the basic considerations, but understand there are even more scenarios and approaches related to this topic. They invite readers who have a particular interest or experience with this topic to reach out to them with further thoughts on clinical trial material blinding.

About the Authors

Sandra Cook, PhD, is a results oriented project management and training consultant with more than 25 years of experience in the pharmaceutical industry. The last half have been focused on investigational products where she has held both line management and senior level project management roles facilitating high performing teams in the delivery of worldwide clinical supplies, including materials supporting key priority blockbuster products for large pharma. Additionally, Dr. Cook has been instrumental in the design, development and implementation of several global process improvement projects for R&D clinical supply chain. An active member of ISPE, she also serves as Meetings Facilitator and Program Coordinator for the inter-company Equal Partners in Clinical Supplies forum. Dr. Cook holds a dual doctorate in pharmacology and toxicology and is a frequently invited speaker, facilitator and trainer recognized for her ability to communicate technical concepts while motivating audiences. She can be contacted by email: sc@scookconsulting.com.

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Christina Owings is a Quality Assurance Compliance Consultant with Fisher Clinical Services. She holds a BS in chemistry from Indiana State University and is currently pursuing her MS in regulatory science from Johns Hopkins University. For the past four and a half years of her career, Owings has provided quality assurance oversight and support for numerous investigational product development functions, including oral dry drug product manufacturing, clinical packaging, label printing, and clinical site inventory management. She is also proficient in training and instructional design and has developed and implemented training courses and procedures focused on awareness and prevention of unintentional unblinding incidents in investigational product production and support areas. She can be contacted by email: Christina.Owings@thermofisher.com.

Barbara Campbell is currently a Clinical Supply Chain Manager for Fisher Clinical Services. Campbell has moer than 15 years of experience with clinical trials and is responsible for the demand planning of investigational product needed to support clinical trials from first patient visit to last patient visit. Her previous roles throughout her career include study drug c oordinator and research study coordinator. Her expertise around supply and demand as well as site inventory management has helped provide insight into the unblinding risks associated with clinical trials. I 2012, she spoke at an ISPE Conference discussing the topic of Building a Supply Chain around a Protocol. She can be contacted by email: Barbara.Campbell@thermofisher.com.

Charles Gentile is currently the US Site Head, Clinical Supplies – Scientific Core Platform for Sanofi US, Great Valley, PA. In his current position, Gentile manages all aspects of the project management, packaging, labeling, assembly and distribution of investigational products at the Sanofi US Clinical Supplies site. He has held a variety of leadership positions in the approximately 25 years of clinical supplies experience in the pharmaceutical industry and has been with Sanofi since 2008. Prior to that, Gentile was with GlaxoSmithKline for 18 years. He earned a Bachelor's degree in organizational management from Cabrini College. He is a member of ISPE and has been selected to serve a three year term on the ISPE Investigational Products Community of Practice Steering Committee starting in 2014. He can be contacted by email: Charles.Gentile@sanofi.com.

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A Selected Comparison of 21 CFR Part 111 and USP General Chapter <2750> as Templates for Good Manufacturing Practices for Dietary Supplements

by Edward G. Malawer, PhD

This article presents a comparison of corresponding sections of 21 CFR Part 111 and USP <2750> using five dietary supplement GMP compliance issues each requiring some interpretation of the language provided by these documents.

Prior to 2008, a dietary supplement manufacturer wishing to operate in conformance with current Good Manufacturing Practices (cGMPs) in the US needed only to concern itself with GMPs required for foods under 21 Code of Federal Regulations (CFR) Part 110. This regulation was relatively simple as compared to those for the manufacture of drug products[1] since its main objective was to ensure that the food was being produced under clean and sanitary conditions. Although dietary supplement manufacturing sites were always subject to FDA inspections under the 1938 Food, Drug and Cosmetics Act, before 2007, the audit standard used was the same as for any other food manufacturer, namely 21 CFR Part 110.

With the passage by Congress of an amendment called the Dietary Supplement Health and Education Act (DSHEA[2]) of 1994, the federal government was given the authority to regulate dietary supplement firms according to more stringent cGMPs. Additional enforcement power was extended to the regulation of label claims. At the time DSHEA was passed by Congress, the corresponding regulations needed for enforcement had not yet been promulgated. The new regulations under 21 CFR Part 111[3] finally came into effect in 2007 and were phased in for dietary supplement firms of various sizes over a three year period from 2008 through 2010. The rationale behind this was to require large (and presumably well-staffed) firms to comply one year after publication of the final rule while allowing additional time for smaller firms to build the integral quality systems needed for compliance. From 2010 onward, all dietary supplement firms were expected to be fully compliant with the 21 CFR Part 111 regulations. All domestic and foreign companies that manufacture, package, label, or hold dietary supplements, including those involved with testing, quality control, and dietary supplement distribution in the U.S., must now comply.

This change represented a major paradigm shift in operation for the ownership of many such firms since the new regulations required that the same quality sub-systems be in place for them as those for a drug maker, namely quality management system, facility and equipment system, materials system, production system, packaging and labeling system, and laboratory controls system. A review of the inspection observations published by the FDA on its website in annual databases indicates that the industry, as a whole, continues to struggle to conform to the many elements of the Part 111 requirements.[4]

The FDA has published several subsequent guidances on the dietary supplement cGMP regulations in order to attempt to improve comprehension of 21 CFR Part 111.[5,6]

It should be noted that the United States Pharmacopeial Convention (commonly referred to as the USP) had long since published a general chapter describing (good) manufacturing practices for dietary supplements. In 1993, in the eighth Supplement to USP22-NF17, USP first published its official General Chapter <2750> *Manufacturing Practices for Dietary Supplements*. The most recent revisions to USP <2750> became official in 2008 (second Supplement USP31) and 2011 (second Supplement USP33) to incorporate requirements of the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 (AER law) and the FDA GMPs in 21 CFR Part 111, respectively. Even though USP <2750> had provided stringent quality requirements since its first publication in 1993, updates were necessary in order to clarify its equivalencies to and stringencies against new regulations that provided more general instructions. The current version can be found in USP36-NF31.[7]

Since the number of this USP general chapter <2750> is higher than 1000, it is, strictly speaking, only a guidance and not enforceable as a required standard by the FDA. (Conversely, USP general chapters with numbers lower than 1000 are enforced as standards by the Agency.) In reviewing the newly developed 21 CFR Part 111 regulations shortly after coming into effect, USP management published a review in which it was stated that the USP <2750>, in concert with published monographs for individual components and products, was able to control the quality of dietary supplements in a more rigorous and targeted way.[8] It was pointed out as an example that in 21 CFR Part 111 firms may request and be granted under certain conditions exemptions from the requirement to test every incoming lot of a dietary ingredient for identity. In contrast, USP <2750> requires makers to conduct identity testing for all components and in all cases. The USP's review provided examples of the harms suffered by consumers as a result of ingredient mix-ups or intentional adulteration.

It should be noted that non-US regulatory bodies do not cover "dietary supplement" regulations in a strict sense nor are the corresponding regulations as comprehensive as those contained in 21 CFR Part 111. In the European Union (EU), the European Directive 2002/46/EC covers "food supplements" which are currently limited to vitamins and minerals (and therefore exclude from EU regulatory consideration, such US dietary supplements as omega-3 fish oil, glucosamine/chondroitin, and lutein/zeaxanthin, as examples). In Canada, dietary supplements are covered under Natural Health Product (NHP) Regulations (SOR/2003-196) which also incorporate homeopathic medications not included under 21 CFR Part 111. The GMP sections of these Canadian "natural product" regulations are much more concise and less descriptive than those contained in the U.S. 21 CFR Part 111 counterpart.

Conformance to current GMPs requires firms to design their documented quality system elements to interpret the language in the various regulations in order to assure that dietary supplement products manufactured are pure, safe, and meet all label claims. Five specific examples of compliance issues are offered for consideration below since they require a certain amount of extrapolation of the existing regulations for the manufacture of dietary supplement products. These include the following: the use of wood pallets, the use of captive footwear, the weighing of full component containers, the frequency of production scale calibration verification, and the signature/countersignature of laboratory records.

Discussion

The examples of compliance issues discussed here are organized according to their corresponding FDA GMP quality sub-systems. These particular examples fall under three of the six sub-systems and are organized accordingly. The pertinent verbiage to be found in both 21 CFR Part 111 and USP general chapter <2750> is provided in each instance.

Facility and Equipment System

1. Use of Wood Pallets

The requirement to have an effective pest control system is clearly stated in 21 CFR Part 115.15(d): "*Pest Control* (2) You must take effective measures to exclude pests from the physical plant and to protect against contamination of components, dietary supplements, and contact surfaces on the premises by pests..." USP <2750> states in the section General Maintenance and Sanitation that "No pests shall be allowed in any area of a dietary ingredient manufacturing plant and a dietary supplement manufacturing plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against adulteration by pests of product on the premises..." Both documents include information on the proper handling of sanitizing agents and pesticides within a dietary supplement facility. Beyond this, for the most part, the specific elements of an effective pest control are left to judgment of the facility operators.

One word conspicuous for its absence in either of these documents is "pallet." Pallets are key pieces of equipment which allow the delivery, storage, and transitioning of components and packaging/labeling materials, in-process materials, and bulk finished goods throughout the plant, as well as the containment of packaged finished goods being readied for distribution or delivery. It is easy to overlook the potential for wood pallets to cause contamination of open component containers (in a sampling booth or a blending operation) or of open bulk product in a packaging suite. The possible types of contamination include wood particles as well as live or dead insects and microorganisms.

Heat treatment of pallets is only a partial solution to this problem at best. Pallets undergoing heat treatment must

be heated to achieve a minimum core temperature of 56°C (132.8°F) for at least 30 minutes. Pallets so treated are stamped with the letters "HT." (The heat treatment process is performed only at the time of original manufacture of such a pallet and is not intended to be repeated during the life of a pallet.) The end result is that such pallets can be regarded as being free of live insects and microorganisms provided that they are not stored outside a facility or in direct contact with non-heat treated pallets within the facility. While HT-pallets would not be expected to be re-infested by insects when stored properly within a facility, storage in wet or humid conditions could potentially encourage the growth of mold. However, they are fully capable of harboring dead insects, for example, and can therefore continue to act as a source of insect parts and wood particles contaminating products within otherwise controlled manufacturing or packaging suites. The act of moving or dropping a wood pallet may be all that is needed to cause such contamination to erupt. The HEPA filtration of such suites does nothing to prevent such contamination brought inside via a "Trojan horse" mode. In fact, the air movement due to such filtration systems within the facilities may keep such contamination airborne for longer distances.

In 2010, CBS News aired a television piece on a study which demonstrated that bacterial and insect contamination of wood pallets used in the food industry was common.[9] The dietary supplement industry would do well to emulate the well-accepted and established practice within the pharmaceutical industry which is to perform a transition from wood to plastic pallets prior to moving components into production suites, and the reverse when moving bulk finished goods out of packaging suites to the warehouse. This practice should include a prohibition of wood pallets inside sampling booths where component containers are opened (and their contents exposed to the air) in order to remove portions for identity testing and sample retention. The sampling booth should be regarded as an extension of a firm's controlled manufacturing/packaging environment.

Production System

2. Use of Captive Footwear

21 CFR Part 111.10 states that those working in a dietary supplement firm must prevent adulteration of components, dietary supplements, or contact surfaces. Sub-section 111.10(b) says that such individuals "must use hygienic practices to the extent necessary to protect against such contamination of components, dietary supplements, or contact surfaces." The section provides some specific requirements with regard to personal gowning, jewelry avoidance, and washing/sanitizing hands, and the wearing of hair nets, beard covers and other hair restraints; however, it does not provide all needed protocols to be followed in actual practice. In particular, there is no specific mention of footwear, either captive or disposable. The language contained in USP <2750> under Personnel Responsibilities is quite similar in these respects.

The drug product regulations in 21 CFR Part 211.28(a) specifically adds to the aforementioned gowning requirements the need for arm coverings in order to protect product from contamination. This practice in the drug industry also should be followed by dietary supplement firms. That is, sleeve covers, commonly disposable, should be worn by all workers whose job entails possible physical contact with components, in-process, or finished goods.

The drug product regulations are also devoid of any mention of footwear requirements. Nonetheless, the use of captive or "inside only" footwear for manufacturing personnel is a standard, accepted practice in the pharmaceutical industry, which has not gained widespread acceptance among dietary supplement manufacturers as a necessary element of gowning protocol. This is unfortunate as outside debris adhering to the soles of worker's street shoes can easily be introduced into a controlled, GMP manufacturing environment. The fact that worker's shoes may for the most part be below any open component/product levels in manufacturing or packaging suites does not prevent them from being contaminated by shoe-borne debris which can easily become airborne.

The required use of sticky mats or disinfectant baths for workers prior to entering the manufacturing corridor can be a useful, but not foolproof measure. Disposable shoe covers (sometimes called "booties") are not ideal because they compromise traction afforded by shoe soles being covered. Therefore, all dietary supplement firms should have a documented captive footwear policy. It is recommended that such shoes be purchased regularly for employees by the firm and that they possess steel toes in order to increase worker safety where heavy equipment or materials must be moved. Firms should keep in mind the general statement contained in 21 CFR Part 111.10(b)(1): "Wearing outer garments in a manner that protects against the contamination of components, dietary supplements, or any contact surface..." It is left to the discretion of the firms to eliminate all possible sources of contamination in their operations.

3. Weighing of Full Component Containers

The preparation step for any dietary supplement product includes the measuring out of the prescribed individual components required for a given batch in amounts dictated by both the formulation stated in the master record and consistent with the established product specification. Subpart I and specifically 21 CFR Part 111.260(e) of the regulations requires that "the identity and weight or measure of each component used" be documented within the executed batch record. It goes on to state in 21 CFR Part 111.260(j)(2)(i) that "the initials of the person responsible for weighing or measuring each component used in the batch" also must be documented. The apparent intention of Subpart I is for every full or partial container of raw materials to be incorporated into a batch to be weighed (or

otherwise measured as by volume, etc.) and for those weights to be recorded in the batch record. The language of USP <2750> under the section Production and Process Controls/ Charge-In of Raw Materials is even clearer: "Raw materials for product manufacturing should be weighed, measured, or subdivided as appropriate and the appropriate signatures recorded in the batch record." The phrase "should be weighed" requires a specific action on the part of the dietary supplement manufacturer itself.

When developing a protocol for manufacturing a given dietary supplement product, it is obvious to the firms' management teams that there is no way to avoid weighing partial container amounts required by the formula prior to blending, fill ingredient preparation, gelatin preparation or whatever the first production step happens to be. The temptation is great to simply rely upon the stated net weight of any full containers which are to be used in the preparation based upon the component manufacturer's declared net weight. In making a decision to do this (presumably to lower labor costs and speed production) firms may or may not have properly qualified the suppliers of such components (for example by administering quality questionnaires, performing on-site audits, performing expected weight checking of container contents, and/or testing quality parameters against provided specification results).

The end result is a significant risk of mischarging one or more components. This in turn could potentially result in not meeting quantitative label claims and/or adverse reactions in consumers. The problem here is that firms can take the position that the 21 CFR Part 111 regulations do not specifically require the physical weighing of all components, but rather merely the recording of the weights of the components which were added to the batch. Thus, it could be argued that for full containers, merely reporting the vendor-provided full container net weights in the executed batch record is sufficient to satisfy the regulations. This is an unfortunate outcome of the nebulous language in 21 CFR Part 111.260. It is also inconsistent with the FDA's philosophy of the need for Quality by Design (QbD) as opposed to testing into compliance. Therefore, in order to avoid potential mischarges and protect their customers and end-use consumers, dietary supplement firms are encouraged to follow the requirement outlined in USP <2750> to weigh all components used in a batch.

4. Frequency of Production Scale Calibration Verification

21 CFR Part 111.30 (c) requires that for any automated, mechanical, or electronic equipment, you must "Routinely calibrate, inspect, or check the equipment to ensure proper performance. Your quality control personnel must periodically review these calibrations, inspections, or checks…" USP <2750> states under Equipment and Utensils/Construction that "For any automated, mechanical, or electronic equipment that is used to manufacture, package, label, or hold a dietary ingredient, a dietary supplement, or both…the equipment must be routinely calibrated, inspected, or checked to ensure proper performance. The quality control unit must approve these calibrations, inspections, or checks…" Neither document offers any specific rule or even advice on an appropriate schedule for either the full calibration of production scales and balances or the regular calibration verification of these units. The same is true for balances in the quality control laboratory.

The frequency of verification performance checks depends on the frequency of use of the scale and the criticality and tolerance of the process or analytical step. Note that all batches of a product manufactured between two successive verifications would potentially be affected should the latter verification reveal a problem. Therefore, each firm's quality unit should be prepared to defend its chosen scale calibration verification frequency based upon a statistically sound scientific study conducted on multiple scales throughout the facility. The scale vendors' recommendations on an appropriate calibration verification frequency should be taken into account, but should not be the sole factor used in establishing it. The validity of infrequent calibration verifications, e.g., performed on only a monthly basis, may be questioned by the FDA or customer GMP auditors of a firm since the potential for calibration drift is higher for scales which are frequently used between verifications. In general, the allowed accuracy tolerance should be within 0.1% of the standard weight's reading on the scale being verified.[10]

It also must be noted that calibration verification cannot be accomplished by the use of a single standard reference weight. This is because a calibration curve or line cannot be defined by a single point. Thus, a minimum of two and preferably three standard weights should be used for every calibration verification. These weights should lie between 10% and 90% of the typical mass use range of the scale. All verification weights used by dietary supplement firms should be traceable to the National Institute of Standards and Technology (NIST) in the US or other recognized weights and measures standard setting organizations, such as the Federal Commission for the Protection against Sanitary Risk (COFEPRIS) in Mexico and the National Research Council Institute for National Measurement Standards (NRC-INMS) in Canada.

Laboratory Controls System

5. Signature/Countersignature of Laboratory Record

Since finished goods must be tested against specifications with respect to monograph and/or internally established quality parameters, it is clear that proper laboratory records are an essential element of the final, fully executed batch record for every batch released by a firm. Unfortunately, 21 CFR Part 111 does an inadequate job of describing all critical elements of a complete laboratory record. In this respect, the dietary supplement regulation does not compare well with the drug product regulations, 21 CFR Part 211. For example, there is no statement anywhere in Subpart J of 21 CFR Part 111 which specifically requires that completed laboratory records be

signed/initialed and dated by the analyst and countersigned/initialed and dated by a reviewer. Part 111.325(b)(2)(i) merely states "The person who conducts the testing and examination must document, at the time of performance, that laboratory methodology established in accordance with this subpart J is followed." This requirement does not pertain to assuring the accuracy and completeness of the tests conducted and the corresponding results recorded.

By comparison, USP <2750> does include the following statement in the section Laboratory Records: "The initials or signature of the person who performs each test and the date(s) the tests were performed." USP <2750> does not explicitly require documented review of laboratory records themselves by a second person. It does stipulate in the section Batch Production and Control Records that the "quality control unit: (a) Reviewed the batch production record, including: (ii) Review of the results of any tests and examinations, including tests and examinations conducted on components, in-process materials, finished batches of dietary supplements, and packaged and labeled dietary ingredients and dietary supplements..." While this is not the quite the same as specifically requiring that a second analyst vet the results the original analyst wishes to record in the laboratory record, it at least requires a quality control review of laboratory results during the process of reviewing the overall executed batch record as a condition of release of the batch.

In this case, dietary supplement product firms should consider following the requirements of the drug product regulations 21 CFR Part 211.194 with respect to laboratory records. Section 211.194(a)(7) requires "The initials or signature of the person who performs each test and the date(s) the tests were performed." Section 211.194(a)(8) further requires "The initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards." The lack of any requirement in Part 111 Subpart J for laboratory records to be signed and countersigned is completely inconsistent with the required elements of batch records as described in Part 111.260. As a result, dietary firms should go beyond the analyst's signature mandated by USP <2750> and also require the countersignature of a second, knowledgeable person acting as the reviewer of the analyst's laboratory record.

Conclusion

Ideally, the FDA's previously published positions on those regulatory compliance examples specifically covered in this article would corroborate the recommendations made by the author. Unfortunately, the FDA has been slow to publish dietary supplement firm Establishment Inspection Reports (EIRs) on its website. It is difficult to find anything the Agency has written after about 2008 or so. The dietary supplement firm Warning Letters published concern those firms with nonexistent quality systems as defined by 21 CFR Part 111 and are not directly applicable to the examples covered. Thus, in the absence of specific interpretation of regulations by the FDA's Enforcement Division, it is important for dietary supplement firms to rely upon a rigorous self-interpretation of the regulations to ensure that they form 483 observations are not received for laxity in compliance during future FDA inspections.

Although the language is similar in some instances, there are a number of examples of more rigorous language and the inclusion of clarifying elements in the USP General Chapter <2750> as compared to the 21 CFR Part 111 regulations. As a consequence, USP <2750> should be considered as an important supplemental regulatory template by all firms seeking to develop or improve their quality systems related to good manufacturing practices for dietary supplement manufacture. Additionally, given the similarity of operations within the dietary supplement product industry to the drug product industry, firms should seriously consider adopting some of the drug product regulations, 21 CFR Part 210/211, as the bases for their internal quality systems. It is clear that lack of adherence to proper cGMP practices can have an equally harmful effect on consumers of either drug or dietary supplement products due to ingredient mischarge or to contamination. It is further recommended that firms which produce both drug and dietary supplement products should operate with a single quality system based upon 21 CFR Part 210/211 regulations alone for internal consistency.

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About the Author

Edward G. Malawer, PhD received his BS in chemistry from the City College of the City University of New York. He subsequently received his MS and PhD in physical chemistry from New York University. Dr. Malawer spent the largest portion of his professional career (28 years) at GAF Chemicals, later called International Specialty Products (ISP), where he ultimately served as Vice President responsible for corporate analytical R&D, product stewardship, quality assurance, and the technical library until 2007. He subsequently established a consulting firm, Malawer and Associates Consulting, LLC specializing in cGMP auditing /quality systems improvements for the pharmaceutical and dietary supplement industries, analytical chemistry problem solving, and Process Analytical Technology (PAT). Dr. Malawer earned his Certified Quality Auditor (CQA) credential through the American Society for Quality (ASQ) and is a senior member of the ASQ. He has served on several USP expert committees including the Povidones Expert Panel and the <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients Advisory Panel. Dr. Malawer holds 10 granted US patents and has authored 36 peer-reviewed publications, including several textbook chapters. He can be contacted by email: emalawer@malawerconsulting.com.

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ISPE International Honor Awards 2013

The International Honor Awards for 2013 were announced at ISPE's Annual Meeting held 3- to 6 November in Washington, DC, US. Nancy S. Berg, President and CEO of ISPE, presented the awards representing the ISPE Board of Directors.

In appreciation of those Members and companies who contribute to our industry's best practices, quality management, and patient health, ISPE presented the following awards:

- **Dr. John Berridge** was honored with the **Joseph X. Phillips Professional Achievement Award**, a special honor for contributions not only to ISPE, but the industry as a whole. John Berridge, PhD spent more than 31 years at Pfizer, retiring as vice president of pharmaceutical science in 2006. Dr. Berridge's dedication to his research has resulted in more than 40 publications in high-performance liquid chromatography highlighting chemometrics to aid method development. He is heavily involved in ICP processes, contributing as the past industry rapporteur for the Common Technical Document and currently as the industry rapporteur for the pharmaceutical guideline (Q8). Dr. Berridge is a past winner of an IPS award and the Royal Pharmaceutical Society Chiroscience award. Today, he dedicates his time as an independent consultant supporting development and CMC strategy, as well as a being a trusted advisor to ISPE.

- **Jean-Francois Duliere** of Technip, France was awarded the **Max Seales Yonker Member of the Year Award**, which recognizes a Member who has made significant contributions to ISPE in the past 12 months. Jean Francois has more than 20 years of pharmaceutical experience working in quality control, oral solid dosage manufacturing, packaging, raw materials, industrial development, equipment qualification, and process validation.

  Duliere in his 10 years of experience in pharmaceutical engineering has contributed to the conceptual design phases for oral solid dosage forms facilities and in the conceptual design phases for sterile products facilities aseptic filling, freeze drying. With his expertise in containment issues, production equipment sizing, facility layout design, GMP design reviews, and Regulatory Affairs, Dulier has made significant contributions as acting Chair of ISPE's France Affiliate Board.

- **Stephen Tyler** and **Winnie Cappucci**, were both honored with the **Richard B. Purdy Distinguished Achievement Award**, given in recognition of multiple years of dedicated service to ISPE. Stephen Tyler, a past international board member for ISPE, is a Director of Quality Engineering in Operations Quality Systems at AbbVie, a research based biopharmaceutical company, Illinois, US. Winnie Cappucci has more than 43 years of pharmaceutical industry experience. Before retiring, she was responsible for Bayer's global computerized standards. Cappucci is a past member of ISPE International Board of Directors, Chair of the GAMP Council, member of the GAMP America Steering Committee and the GAMP Editorial Board.

- The **Drug Shortages Initiative Team** was named **Committee of the Year**, recognizing outstanding work of the Society's committees, councils, task teams, or community of practice steering committees. This committee is chaired by François Sallans, Vice President and Chief Quality Officer, Pharmaceutical, Johnson & Johnson. The ISPE Drug Shortages Initiative represents a renewed effort by ISPE to lead significant industry issues. ISPE engaged teams of executives, companies, and regulators to explore and motivate proactive changes in tech transfer, manufacturing, quality systems, and regulatory and governance practices to mitigate shortages. The Drug Shortage Initiative was published in the *Wall Street Journal* and more than 700 global media markets. The committee's initiative also provided current drivers for drug shortages workshops at every ISPE event in 2014. Team Member Steve Mahoney accepted the Award on behalf of the entire team.

Drug Shortages Initiative Team	
Chair: François Sallans	
Task Force Core Team	**Task Force Members**
Nancy Berg	Georges France
John Berridge	Brian Johnson
Joe Famulare	Zena Kaufman
Donna Gulbinski	Larry Kranking
Karleen Kos	Betsy Pileggi
Steve Mahoney, Sr.	Lou Schmukler
Sam Venugopal	Andy Skibo
Bryan Wright	Udo Vetter
	Thomas Zimmer
	Fran Zipp

...Honor Awards 2013

Continued.

- The **ISPE Pacific Northwest Chapter** and **ISPE China** were recognized with the **Affiliate and Chapter Excellence Award**. This award honors the outstanding work of one of ISPE's International Affiliates and Chapters, as reflected by membership development and services, management, industry and society support and innovation.

  The ISPE Pacific Northwest Chapter has nearly 200 local members, dedicating its efforts to recruiting, facilitating networking venues, and sharing information within the local life science industry. Emily Stump, Chapter Vice President accepted the award on behalf of the entire Pacific Northwest Chapter.

  ISPE China increased membership more than 50% to a record 1,076 Members. In 2013, ISPE China launched a comprehensive website in Chinese, developed two world class conferences, and organized a fourth Student Chapter. ISPE China has supported the Society's mission hosting important meetings which in turn provide ISPE with considerable brand exposure. ISPE China also develops local services and benefits for members, such as tailor-made training programs and conferences, translation of ISPE technical guidelines, and live COP events. Charles Tong, ISPE China Chair, accepted the honor on behalf of ISPE China.

- **Johnson & Johnson** was named **Company of the Year**, an award that honors outstanding support provided by a company as reflected in commitment to the mission of the organization as well as through company employees' significant active participation in the Society's committees, councils, task teams, COPs, programs and activities. Johnson & Johnson and their employees have shown extraordinary support of ISPE through volunteer roles. Johnson & Johnson members have served on ISPE Board of Directors, in local chapters, and as contributors in ISPE's Communities of Practice. Currently, there are 149 active ISPE members that are a part of Johnson & Johnson. Jim Breen, Vice President Worldwide Engineering and Technical Operations accepted the award on behalf of Johnson & Johnson.

- **Gordon Leichter, PhD** and **John Spohn, CPIP** were awarded the **Roger F. Sherwood Article of the Year Award** for their article, "Automating a Manual Cleaning Program in a Multi-Product Biopharmaceutical Manufacturing Operation," published in the January/February 2013 issue of *Pharmaceutical Engineering* Magazine.

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ISPE's Facility of the Year Program Celebrates its 10th Anniversary

A Decade of Recognition

Since its inception in 2004, ISPE's Facility of the Year Award (FOYA) has recognized a decade of pharmaceutical innovations and manufacturing visionaries. FOYA is an annual program established to recognize state-of-the-art pharmaceutical manufacturing projects using innovative technologies to advance the quality and capital investment of their product. This year, FOYA's 10th anniversary, award winners will experience an enhanced ISPE presence and additional global recognition for their contributions to the pharmaceutical industry.

History of FOYA

In its inaugural year, ISPE received submissions from 28 pharmaceutical manufacturing facilities across five continents. In 2005, the Danish healthcare company Novo Nordisk became the first winner based on their groundbreaking 18 month, fast-track modular design constructed to meet the urgent need for a life-saving hemophilia drug. Ten years later, modular design is considered best practice for efficient construction. Recognizing and promoting modern manufacturing practices reflects ISPE's continual commitment to educational advancement and technical efficiency within the pharmaceutical industry.

Novartis, Process Innovation category winner and FOYA's overall 2013 winner, leads the industry with cell-culture technology in a facility easily transformed to quickly produce vaccines in the event of a pandemic. In a partnership with the US Department of Health and Human Services, Novartis breaks the tradition of egg based vaccines, in order to secure an alternative process that will meet the potential need of a population in crisis. Recognizing the vaccine shortages during the H1N1 pandemic, Novartis set out to build a facility in Holly Springs, NC with flexible process innovations as well as advanced biological technologies. In a time of drug shortages, Novartis sets forth innovative solutions for the pharmaceutical manufacturing industry.

Throughout the past decade, ISPE has continued to set the standard and recognize innovations from cell-culture technology to modernizations in automated systems. Award winning facilities have demonstrated and sustained a safe, productive manufacturing environment, while incorporating innovative technological solutions.

Winning attributes of past award winning facilities:

- Product delivery through modular design
- Effective use of practical innovative technology
- Progressive planning, flexibility, and adaptability
- Inventive project delivery methods

Dedicated to Innovative Manufacturing: Past FOYA winners		
2005: NovoSeven	2008: Pfizer	2011: MedImmune
2006: Baxter BioPharma	2009: Roche MAB	2012: Merck
2007: Cook Pharmica	2010: Genentech	2013: Novartis

2014 FOYA Program Schedule

24 May to 3 February 2014
Submission packages accepted

3 January 2014
Deadline for Intent to Submit forms

3 February 2014
Submission deadline

14 March 2014
Judging panel meets to select Category Winners and Facility of the Year Awards Overall Winner

Week of 21 March 2014
Category Winners notified

Second Quarter 2014
Category Winners develop collateral materials for display at ISPE Pharmaceutical Quality Week

2 – 5 June 2014
Category Awards Winners are recognized at FOYA Celebratory Banquet during ISPE Pharmaceutical Quality Week

12 – 15 October 2014
Category Winners attend ISPE Annual Meeting where winning facilities are recognized and the 2014 Facility of the Year Awards Overall Winner is announced during the Plenary Session

ISPE's Facility of the Year Program...

Continued.

- Manufacturing solutions with attention to environmental impact
- Applied technologies in regards to equipment
- Modernization of industrial facility design
- Optimization of industry best practices

A New Decade to Remember

The prestigious FOYA program will continue to give companies the opportunity to showcase industry innovations and share discoveries that directly affect the manufacturing and safety of pharmaceutical products. ISPE, in its own quest for excellence and industry quality, will renew their commitment to share the achievements of industry leaders by expanding the global presence for Category Winners. As a premier award in the pharmaceutical industry, the FOYA program will recognize category achievements at the ISPE Annual Meeting and honor winners during the newly created Pharmaceutical Quality Week. A new gala at the ISPE-FDA CGMP Conference during Pharmaceutical Quality Week will celebrate the achievements of winning facilities and recognize distinguished companies that contribute to innovations in manufacturing.

State-of-the-art biotechnology or pharmaceutical facilities that have been recently designed, built, or renovated are encouraged to submit their entries. The FOYA program ventures to identify the best new or renovated pharmaceutical manufacturing facilities that combine all aspects of the building into a superior working environment.

ISPE will assemble a judges' panel of experts and industry leaders from manufacturers, equipment suppliers, regulators, design consultants, construction managers, validation consultants, and academia. The 2014 Facility of the Year Awards panel will convene after the submission deadline to evaluate all entries. Judges will be looking for concise, relevant informa-

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ISPE Launches New Expanded E-Learning Courses

In our continued dedication to share the latest best practices in manufacturing, quality, and compliance, ISPE announces four expanded E-learning courses.

- Basic Principles of Computerized Systems Compliance: Apply the GAMP® 5 Guide: a Risk-based Approach to Compliant GxP Computerized Systems
- Biotechnology Basics
- Containment Fundamentals
- GMP Auditing for the Pharmaceutical Industry

Our E-learning expanded courses are an opportunity for pharmaceutical manufacturing professionals to participate in ISPE signature courses from any home or office. The interactive courses are designed for a web-based platform and include downloadable presentations for convenient note-taking, explanatory graphics, reference materials, regulatory links, and assessments (pre- and post) to measure specific subject understanding.

Courses are narrated in English and available immediately after registration from the ISPE Dashboard. Length and volume of courses are dependent on each specific module. Shorter courses can be completed in a few hours, while longer more in-depth courses can range from one to two days. Presentations can be started or stopped at any point which adds a flexible perk for any demanding industry schedule.

As with all ISPE courses, the newly expanded additions are devised by ISPE instructors who are industry experts in their field. Industry professionals can expect to fill knowledge gaps and learn the latest science-based pharmaceutical solutions in our ever-evolving field. ISPE Continuing Education Units (CEUs) are available for each E-learning course upon module completion, as well as an 80% achievement based on a post-assessment, and a course evaluation.

Industry professionals interested in an E-learning course can log-in to their ISPE dashboard with their member information or create an ISPE profile if needed. Demo modules and ISPE's full catalog of E-learning courses are available on our website. Instructions for registration, course catalogs, and FAQs are available on the ISPE website: http://www.ispe.org/elearning.

ISPE also invites all pharmaceutical professionals to share their expertise with the industry by providing content that may be used in Online Learning modules. Information for proposals can also be found on the ISPE website: http://www.ispe.org/knowledge-and-learning/call-for-proposals.

Basic Principles of Computerized Systems Compliance: Applying the GAMP® 5 Guide: A Risk-based Approach to Compliant GxP Computerized Systems

Duration: 2 Days (self-paced) **ISPE CEUs:** 1.3

Description:
This course introduces regulatory requirements for computerized systems in the pharmaceutical industry and explores internationally recognized methods of meeting those requirements. GAMP guidance provides an effective framework for achieving computerized systems that are fit for intended use and meet current regulatory requirements.

There are eight modules within this course composed of at least three main objectives for each.

Brief sample of course objectives:
- Explain the concept of "GxP" Risk" and general principles of computerized system compliance and validation
- Define the key structures and concepts of GAMP® 5
- Describe how the categorization of software and hardware components of a system can help define a life cycle strategy
- Illustrate the five steps in the GAMP® 5 Quality Risk Management approach
- Describe the structure of the Operational Phase in GAMP® 5

Biotech Basics: Fundamental Principles of the Biotechnology Industry

Duration: 1 Day (self-paced) **ISPE CEUs:** 0.6

Description:
This course explores the history of the biotechnology industry and fundamental concepts of biotechnology science. Participants will learn basic terminology and its application within the industry. The course will identify basic process science and unit operations for the manufacture of products and the regulatory foundation that makes biological products different from traditional pharmaceutical products. There will be discussions to evaluate emerging technologies and their industry impact. The course will also classify validation issues surrounding compliance with GMP and define basic requirements for facilities that manufacture biological products.

There are 3 modules in this course with 2-4 main objectives in each.

ISPE buyers GUIDE 2014

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www.ISPE.org/BuyersGuide

API Manufacturing

NNE Pharmaplan AB
Hanningfield Process Systems Ltd
Aflex Hose USA
AMCOL International
Apache Stainless Equipment Corp.
Class Biologically Clean, Ltd.
Cockram Construction
Dalton Pharma Services
Dec Group
Fareva
Federal Equipment Company
Hermann WALDNER GmbH & Co. KG
Matcon China
Matcon Japan
Matcon Pacific PTY Ltd.
Matcon USA
New Wayz Consulting Ltd
PharmaCore, Inc.
ProSys Containment & Sampling Technology
Q Pharma consulting India
Savillex Corporation
Svanholm.com
USV Limited
Wayahead Systems

API Solubilization Technologies

Thermo Scientific – Material Characterization

Academia

DDK Scientific Corp.

Aerosol Filling

ASM Aerosol-Service AG
Dynamic Air Quality Solutions

Agglomeration

Freund-Vector Corporation
Glatt Air Techniques, Inc.
Magnasafe Int'l
The Fitzpatrick Company

Analytical Equipment

TSI Inc
ASCO Numatics
B&W Tek, Inc.
Endress+Hauser
enviroflo, inc.
Fluid Imaging Technologies, Inc.
FRITSCH GmbH - Milling and Sizing
GE Analytical Instruments
Higuchi Inc.
Mettler-Toledo Thornton Inc
Microbeam, S.A.
MKS Instruments, Inc.
PANalytical
Physical Sciences Inc.
Quantachrome Instruments
Rigaku Raman Technologies
Shimadzu Scientific Instruments
Svanholm.com
Swagelok
Thieme Corporation
TRI Air Testing, Inc.
Western Test Solutions

Analytical Laboratory Services

Azzur Labs, LLC
Genesis Engineers, Inc.
Actlabs
Biomanufacturing Training and Education Center (BTEC)
Bureau Veritas North America, Inc.
Catalent Pharma Solutions
Ceutical Laboratories, Inc.
Chemical Solutions Ltd.
ENV Services, Inc.
Fluid Imaging Technologies, Inc.
International Products Corporation
Microbiology & Quality Associates, Inc.
NSF Pharma Biotech
Q Laboratories, Inc.
Quantachrome Instruments
Swagelok
Trace Analytics, LLC
TRI Air Testing, Inc.
University of Iowa Pharmaceuticals
Western Test Solutions

Analytical Methods Development

Actlabs
Avid Bioservices, Inc.
Bureau Veritas North America, Inc.
Ceutical Laboratories, Inc.
Chemical Solutions Ltd.
Dalton Pharma Services
Frontage Laboratories, Inc.
HealthCore, Inc.
Q Laboratories, Inc.
Western Test Solutions

Analytical Validation Studies

Ceutical Laboratories, Inc.
Chemical Solutions Ltd.
CoreRx, Inc.
HealthCore, Inc.
Q Pharma consulting India

Anti-Counterfeiting Technology

Adigohar Engineers & Consultants (P) Ltd.
AlpVision SA
Complete Inspection Systems, Inc.
Compliance Control Ltd
Equipnet (India) Private Limited
InfraTrac
PANalytical
Ticona Engineering Polymers
Uhlmann VisioTec GmbH
Uhlmann VisioTec GmbH

Architecture/Engineering/Construction

NNE Pharmaplan A/S
NNE Pharmaplan Consultoria Ltda.
NNE Pharmaplan sas
NNE Pharmaplan (Tianjin) Co., Ltd. Shanghai Branch
Stantec
Telstar Life Sciences
AES Clean Technology, Inc.
Altera doo
Bouchard Consulting Services
Business Horizons
CE&IC
Century 3 (Shanghai) Inc.
Clean Rooms West, Inc.
Cleanroom Consulting, LLC
Cleanseal Door Systems - A Division of ASI Technologies
Cockram Construction
CRB
DDK Scientific Corp.
Flad Architects
Fluor Corporation
Hipp Engineering & Consulting, Inc.
IPS-Integrated Project Services
J D Pharma Consultants
Jacobs/Wyper Architects LLP
Key Resin Company
M+W Group
M+W Process Industries GmbH
M+W Saudi Arabia Ltd.
M+W Taiwan
M+W Thailand Ltd
Mangan Biopharm
McCarthy Building Companies, Inc.
mitchell architectural group, p.c.
ModularPartners
ModWave
MSS Clean Technology Ltd
Mussett Nicholas and Assoc., Inc.
NEST Consulting
O'Neal, Inc.
Pacific Environmental Technologies, Inc.
PM Group
PPS Engineers, Inc.
Precis Engineering, Inc.
PROGMP SAS
PS&S, LLC
SABArchitects, Inc.
Seismic Installations, Inc.
Sika Corporation
Skanska
Sweett Group
Talboom PharmaChem NV
WSP CEL
Zarpac Inc.

Aseptic Processing

Allegheny Bradford Corporation
AWS Bio-Pharma Technologies
Bausch + Stroebel
Bosch Packaging Technology
Burkert Fluid Control Systems
Marchesini Group USA
NNE Pharmaplan NV
TSI Inc
Acro Associates
adam fabriwerk pvt ltd
Aflex Hose USA
Agalloco & Associates, Inc.
Altera doo
Bausch Advanced Technology Group
BioPharma Systems
Bioquell, Inc.
ChargePoint Technology
Class Biologically Clean, Ltd.
DXC Consulting Ltd.
Fareva
Fedegari Group
GEA Westfalia Separator
Grand River Aseptic Manufacturing, Inc.
Hydro-Thermal Corp
IMA Life North America, Inc.
Integrated Compliance Solutions, LLC
Jung Gummitechnik GmbH
Lighthouse Worldwide Solutions
ModWave
Pentair Sudmo
PharmaSystems, Inc.
Powder Systems Ltd (PSL)
Proditec
PSL USA
REMCON Plastics
Rompharm Company
Sartorius Stedim Biotech
Shibuya Hoppmann Corporation
SKAN AG
STERIS Life Sciences
The Williamsburg Group, LLC
University of Iowa Pharmaceuticals
Vanrx Pharmasystems
Watson-Marlow Pumps Group
Weiler Engineering, Inc.
ZenPure

Auditing

Azzur Group, LLC
NNE Pharmaplan India Limited
NNE Pharmaplan Sdn. Bhd.
OOO NNE Pharmaplan
PSC Biotech
Catalyst Pharma Consulting
Cold Chain Consultants Pty Ltd
Compliance Control Ltd
Compliance Insight, Inc.
Consultoria Asfalia S.L.
David H. Artiss and Associates, Inc.
Document Center Inc.
EduQuest, Inc.
Empowerment Quality Engineering Ltd
GMP Engineering
GxP Associates
Halfmann Goetsch Partner AG
Integrated Compliance Solutions, LLC
M+W Process Industries GmbH
Malawer & Associates Consulting, LLC
MasterControl Inc.
NetDimensions (UK) Limited
Noblitt & Rueland
NSF Pharma Biotech
PharmaSys, Inc.
pi
PJC Pharma Consulting Ltd
PROGMP SAS
Q Pharma consulting India
QPharma, Inc.
SeerPharma (Singapore) Pte Ltd
Soluciones GXP (Infodynamics s.r.l.)
The Williamsburg Group, LLC
TRAQuE Pte Ltd
USDM
VPCI, Inc.

Automation

Burkert Fluid Control Systems
Hanningfield Process Systems Ltd
NNE Pharmaplan A/S
NNE Pharmaplan Consultoria Ltda.
NNE Pharmaplan Inc.
NNE Pharmaplan NV
NNE Pharmaplan (Tianjin) Co., Ltd.
NNE Pharmaplan (Tianjin) Co., Ltd. Guangzhou Branch
NNE Pharmaplan (Tianjin) Co., Ltd. Shanghai Branch
optek-Danulat, Inc.
Spraying Systems Co./Fluid Air
Top Line Process Equipment Company
ABB Control Technologies
Acquire Automation
AIV Solutions
Alpha Controls & Instrumentation
Applied Control Engineering, Inc.
ASCO Numatics
Astech Projects
Avanceon

Banner Engineering Corp
BatchControl Ltd.
Beamex, Inc.
Broadley-James Ltd
Burns & McDonnell
Burns Engineering
CrossPoint Engineering
DAI
DAKSWAN Automation, Inc.
Dart Controls, Inc.
E2i
Endress+Hauser
Energy Engineering Co.,Ltd.
Enhanced Information Solutions (EIS)
Exigo Manufacturing
Fike
FlexFit Hose LLC
Fluid Air
Freezerworks
GE Analytical Instruments
Getinge Life Science Americas
GSC Engineering, Inc.
Hardy Process Solutions
Harrington Pure
Huffman Engineering Inc
Hyde Engineering + Consulting Inc
Intempco Instrumentation
IPR, Inc.
Isthmus Engineering & Manufacturing
ITCM
K-Tron G.B. Ltd
K-Tron Pitman
K-Tron Salina
Kahle Automation
Kevin Technologies Pvt. Ltd.
M+W Automation
M+W Group
MagneMotion
Mangan Biopharm
Meriam Process Technologies
Metrohm NIRSystems
MKS Instruments, Inc.
New England Controls Inc.
Optimation
Parsec Automation
Pentair Sudmo
PPS Engineers, Inc.
Praxair, Inc.
Process Plus LLC
Provalidus
QSPEC Solutions Inc.
Rees Scientific
Rotronic Instrument Corp
Schenck Process
seepex Inc.
Sensor Technology Ltd
Siemens Industry, Inc
SNC-Lavalin
Spirax Sarco
SVF Flow Controls, Inc.
Swagelok
Swan Analytical USA
TATNUCK, INC.
Technical Engineering Ltd
TiPS Incorporated
Uhlmann VisioTec GmbH
Werum Software & Systems AG
Yokogawa
Zenith Technologies
Zeta Biopharma GmbH

Bar Coding

Banner Engineering Corp
Complete Inspection Systems, Inc.
Control Micro Systems, Inc.
Covan Systems
Equipnet (India) Private Limited
Freezerworks
GA International Inc.
Innovatum, Inc.
PRISYM ID
Wayahead Systems

Barrier Isolation

AWS Bio-Pharma Technologies
Bosch Packaging Technology
BioPharma Systems
Bioquell, Inc.
Chase-Logeman Corporation
Class Biologically Clean, Ltd.
DEC-USA
EnGuard Systems
enviroflo, inc.
Extract Technology Ltd.
F.P.S. Food and Pharma Systems
Getinge Life Science Americas
Getinge-La Calhene
Isolation Systems, Inc.
Lighthouse Worldwide Solutions
M+W Products GmbH
M. Braun
NuAire, Inc.
ONET Technologies UK Ltd
PharmaSystems, Inc.
Pharminox Isolation Ltd
Powder Systems Ltd (PSL)
ProSys Containment & Sampling Technology
RPA
Sartorius Stedim Biotech
SKAN US, Inc.
Solo Containment
Telstar North America, Inc.
Walker Barrier Systems

Bio-analytical Services

Actlabs
Biomanufacturing Training and Education Center (BTEC)
Frontage Laboratories, Inc.
Warsash Scientific
Western Test Solutions

Bio-diagnostic Manufacturing and Devices

NNE Pharmaplan NV

Bio-processing – Disposable

Stantec
ChargePoint Technology
Colder Products Company
Dow Corning Corporation
G&G Technologies, Inc.
Global Innovations
Jeff Smith & Associates, Inc.
Meissner Filtration Products Inc
Pall Life Sciences
Sartorius Stedim Biotech
Value Plastics, a Nordson Company
Williams Process Ltd
ZenPure

Biological Testing

Azzur Labs, LLC
Associates of Cape Cod, Inc.
Azbil BioVigilant
DNA Genotek Inc.
Feldmeier Equipment
Microbiology & Quality Associates, Inc.
Perritt Laboratories
Q Laboratories, Inc.
SKAN US, Inc.
Skytech Systems (I) Pvt. Ltd
Technical Safety Services
TRI Air Testing, Inc.

Biologics Manufacturing

Bioproduction Group (BIO-G)
Business Horizons
Dow Corning Corporation
Fisher BioServices
GEA Westfalia Separator
Patheon, Inc.
WaterSep Technology Corp.

Biologics Process Development

Biomanufacturing Training and Education Center (BTEC)
Bioproduction Group (BIO-G)
M+W Saudi Arabia Ltd.
WaterSep Technology Corp.
ZenPure

Biometrics

Amarex Clinical Research
Feldmeier Equipment

Biopharmaceuticals / Biotechnology

Burkert Fluid Control Systems
NNE Pharmaplan AG
NNE Pharmaplan GmbH
NNE Pharmplan Hong Kong Limited
NNE Pharmaplan Inc.
NNE Pharmaplan India Limited
NNE Pharmaplan Sdn. Bhd.
NNE Pharmaplan (Tianjin) Co., Ltd.
NNE Pharmaplan (Tianjin) Co., Ltd. Guangzhou Branch
NNE Pharmaplan (Tianjin) Co., Ltd. Shanghai Branch
Stantec
Aflex Hose USA
Amarex Clinical Research
AMCOL International
Aqua-Chem, Inc.
ASCO Numatics
Associates of Cape Cod, Inc.
Bioproduction Group (BIO-G)
Budzar Industries
DNA Genotek Inc.
Dyadic International, Inc.
DynPort Vaccine Company LLC, A CSC Company
Feldmeier Equipment
Fisher BioServices
Foster Wheeler
G-CON Manufacturing
GEA Diessel GmbH
Gemu Valves Limited
Global Innovations
ILC Dover
Kewaunee Scientific Corporation
Lives International
LJ Star Inc
M+W Group – Total Facility Solutions, Inc.
M+W Israel Ltd
M+W Process Industries GmbH
M+W Singapore Pte Ltd
Millrock Technology, Inc.
New England Sales, Inc.
New Wayz Consulting Ltd
Pall Life Sciences
Physical Sciences Inc.
REMCON Plastics
Savillex Corporation
Spirax Sarco
Svanholm.com
WaterSep Technology Corp.
Williams Process Ltd

Bioprocess Manufacturing

adam fabriwerk pvt ltd
Aflex Hose USA
Avid Bioservices, Inc.
Banner Engineering Corp
Bioproduction Group (BIO-G)
G-CON Manufacturing
Jeff Smith & Associates, Inc.
M+W Group – Total Facility Solutions, Inc.
Pall Life Sciences
Physical Sciences Inc.
Production Modelling
Sartorius Stedim Biotech
WaterSep Technology Corp.

Bioprocess Validation

M+W Taiwan
PS&S, LLC
TRAQuE Pte Ltd

Biostatistics

AICOS Technologies Ltd.
Amarex Clinical Research
Business & Decision Life Sciences

Blending

Fristam Pumps USA
Matcon Ltd.
A & M Process Equipment Ltd.
Absolute Handling Systems Ltd.
Benz Technology International, Inc.
CDM
Dart Controls, Inc.
Dec Group
DEC-USA
Entegris Inc
Gerteis Maschinen + Processengineering AG
GlobePharma, Inc
Hardy Process Solutions
K-Tron G.B. Ltd
Matcon China
Matcon Japan
Matcon Pacific PTY Ltd.
Matcon USA
REMCON Plastics
Romaco FrymaKoruma
SPX Flow Technology
Sterling, Inc.

Bulk/API

Matcon Ltd.
Stantec
Andreasen & Elmgaard A/S
ChargePoint Technology
Hecht Technologie GmbH
K-Tron (Shanghai) Co.,Ltd.
Matcon France & Germany
Pharmatech Process Equipments
ProSys Containment & Sampling Technology
REMCON Plastics

CGMP Synthesis

PharmaCore, Inc.

CRO – Clinical or Contract Research

AAIPharma
BSSN Software
Cardinal Systems
CoreRx, Inc.
Dyadic International, Inc.
Frontage Laboratories, Inc.
Global Research Services, LLC
Kinexus Bioinformatics Corporation
PharmaCore, Inc.
Vanta Bioscience LC

Calibration/Measurement

Ace Control Systems Ltd.
Alpha Controls & Instrumentation
Beamex, Inc.
Burns Engineering
CAS DataLoggers
CrossPoint Engineering
E+E Elektronik Corp.
Endress+Hauser
ENV Services, Inc.
ESS Ltd.
FRITSCH GmbH - Milling and Sizing
Gemini Data Loggers
GenesisSolutions
Johnson Controls
Masy Systems, Inc.
Meriam Process Technologies
Mettler-Toledo Thornton Inc
Microbiology & Quality Associates, Inc.
Optimation
Prime Technologies, Inc.
PS&S, LLC
QS Pharma
RPA
Sensor Technology Ltd
Siemens Industry, Inc
Skytech Systems (I) Pvt. Ltd
Technical Safety Services
TESTO Inc.
Unidec

Central Lab Services

ETC Service and Sterilizer Support
Johnson Controls
Siemens Industry, Inc

Chemical Analysis

Actlabs
Mettler-Toledo Thornton Inc
PANalytical
Polymer Solutions
Rigaku Raman Technologies
Warsash Scientific

Chemical Cleaning

Allegheny Surface Technology
Astro Pak
Ateco Services AG
McFlusion Corp
Veltek Associates, Inc.

Chemicals and Raw Materials

AMCOL International
Qorpak

Clean In Place / Sterilization In Place (CIP/SIP)

Burkert Fluid Control Systems
Fristam Pumps USA
GEA Process Engineering
Spraying Systems Co./Fluid Air
adam fabriwerk pvt ltd
AIRVAC, Inc.
Alfa Laval
American Plastic Technologies Inc
APV, An SPX Brand
Aquafine Corporation
ARS/Beverly Pacific Sterilizers
Astro Pak
Bioquell, Inc.
Budzar Industries
Colder Products Company
Dec Group
Electrol Specialties Co.
Endress+Hauser
Environmental Water Systems
Fike
FlexFit Hose LLC
G&G Technologies, Inc.
Gamajet, part of the Alfa Laval Group
GEA Lyophil GmbH
Getinge Life Science Americas
Hach - Particle Counting Division
Holloway America
Hyde Engineering + Consulting Inc
Hydro-Thermal Corp
IWT srl
M+W Group – Total Facility Solutions, Inc.
M+W Saudi Arabia Ltd.
McFlusion Corp
McFlusion Inc
MKS Instruments, Inc.
New England Sales, Inc.
Pick Heaters, Inc.
Process Plus LLC
PSC Asia
Stainless Solutions
Steriflow Valve, Div of Jordan Valve
Turn-Key Modular Systems, Inc.
Unidec
Veltek Associates, Inc.
WCB, An SPX Brand
Zenith Technologies

Clean Room Equipment and Supplies

Mar Cor Purification
Anguil Environmental Systems, Inc.
Christ Nishotech Water Systems Pvt. Ltd
DDK Scientific Corp.
gammaSUPPLIES
International Products Corporation
Isolation Systems, Inc.
M+W Products GmbH
Microzone Corporation
Nextteq LLC
Q Applied Systems, Corp.
Remco Products Corporation
RPA
Solo Containment
Spirax Sarco

Clean Room Services

Flanders Corporation
AES Clean Technology, Inc.
Astro Pak
Bioquell, Inc.
Camfil Farr
Clean Air Products
Clean Rooms West, Inc.
Cleanroom Consulting, LLC
Cleanroom Solutions Ltd
Controlled Contamination Services
DDK Scientific Corp.
Energy Engineering Co.,Ltd.
ENV Services, Inc.
ESS Ltd.
Farmatec Engineering Sdn Bhd
Filter Technologies, Inc.
M+W Israel Ltd
M+W Products GmbH
M+W Saudi Arabia Ltd.
M+W Taiwan
Microzone Corporation
MSS Clean Technology Ltd
NEST Consulting
Pacific Environmental Technologies, Inc.
Quality Tech Services

Cleaning/Cleaning Validation

Allegheny Surface Technology
PSC Biotech
Validation, Inc.
AIRVAC, Inc.
Alfa Laval Tank Equipment
Andreasen & Elmgaard A/S
Ateco Services AG
Belimed, Inc.
Bioquell, Inc.
Controlled Contamination Services
Gamajet, part of the Alfa Laval Group
GlobePharma, Inc
Hyde Engineering + Consulting Inc
International Products Corporation
IWT srl
McFlusion Inc
McGee Pharma International
Nilfisk-Advance, Inc.
Performance Validation
PharmEng Technology
ProPharma Group
Quality Tech Services
Rozembersky Group Inc.
STERIS Life Sciences
Veltek Associates, Inc.

Clinical Analysis

HealthCore, Inc.

Clinical Monitoring

Amarex Clinical Research
Cardinal Systems
Elpro Services, Inc.
Global Research Services, LLC

Clinical Trials Management

Amarex Clinical Research
BioClinica
Business & Decision Life Sciences
Cardinal Systems
CoSign by ARX
Fisher BioServices
Freezerworks
Frontage Laboratories, Inc.
Global Research Services, LLC
Innovatum, Inc.
Werum Software & Systems AG

Clinical/Investigational Products

Clinigen CTS
Creapharm
DNA Genotek Inc.
Emerson Resources, Inc

Coating and Lamination

Spraying Systems Co./Fluid Air

Cold Chain

Vaisala
Alpha Controls & Instrumentation
AndersonBrecon
BioConvergence LLC
Cold Chain Consultants Pty Ltd
Creapharm
Elpro Services, Inc.
Fisher BioServices
GA International Inc.
Gemini Data Loggers
Intelleflex
Praxair, Inc.
Sartorius Stedim Biotech
Sensitech Inc.
Thermal Compliance Ltd

Commercial Drug Sourcing

Clinigen CTS
Creapharm

Computer Services

Azzur Group, LLC
CQV (CimQuest Vantage)
andesys international corp.
BatchControl Ltd.
BSSN Software
Business & Decision Life Sciences
Compliance Control Ltd
Consultoria Asfalia S.L.
DAKSWAN Automation, Inc.
Enhanced Information Solutions (EIS)
Nivasoft, Inc
OctaveSoft GmbH
PleaseTech Ltd.

Construction Services/ Management

AllianzOne Private Limited
Burns & McDonnell
Century 3 (Shanghai) Inc.
Clean Rooms West, Inc.
Cockram Construction
CRB
DECCO, Inc.
Dome Construction
Energy Engineering Co.,Ltd.
Fraser Engineering, Inc.
GMP Piping, Inc.
Hipp Engineering & Consulting, Inc.
International Coatings
IPS-Integrated Project Services
Kinetic Systems, Inc.
M+W Group
M+W Group – Total Facility Solutions, Inc.
M+W Process Industries GmbH
M+W Taiwan
M+W Thailand Ltd
McCarthy Building Companies, Inc.
ModularPartners
MSS Clean Technology Ltd
O'Neal, Inc.
Pacific Environmental Technologies, Inc.
PS&S, LLC
SNC-Lavalin

Consulting – Health Safety and Environment (HSE)

PS&S, LLC
Williams Process Ltd

Consulting – Process Analytical Technology (PAT)

CAI (Shanghai) Engineering Consulting Co. Ltd.
Commissioning Agents, Inc.
Commissioning Agents International
Commissioning Agents International Singapore Pte. Ltd.
Commissioning Agents Ireland Ltd.
Commissioning Agents Puerto Rico LLC
Malawer & Associates Consulting, LLC
Tunnell Consulting, Inc.
Uhlmann VisioTec GmbH
Uhlmann VisioTec GmbH
Zarpac Inc.

Consulting – Quality Management Systems

CAI (Shanghai) Engineering Consulting Co. Ltd.
Commissioning Agents, Inc.
Commissioning Agents International
Commissioning Agents International Singapore Pte. Ltd.
Commissioning Agents Ireland Ltd.
Commissioning Agents Puerto Rico LLC
CQV (CimQuest Vantage)
NNE Pharmplan Hong Kong Limited
Vaisala
Acquire Automation
andesys international corp.
Bouchard Consulting Services
Changeover.com
Cold Chain Consultants (UK) Ltd.
Cold Chain Consultants Pty Ltd
comes compliance services
Compliance Control Ltd
Compliance Insight, Inc.
Complya Consulting Group, LLC
Deloitte
DynaGMP
DynPort Vaccine Company LLC, A CSC Company
Electrol Specialties Co.
Empowerment Quality Engineering Ltd
Enhanced Information Solutions (EIS)
GE Analytical Instruments
GenesisSolutions
Halfmann Goetsch Partner AG
Hyde Engineering + Consulting
Hyperion Pharma Consultancy
Kelly Engineering Resources
Malawer & Associates Consulting, LLC
MasterControl Inc.
Maxiom Group
McGee Pharma International
MIVADO GlobalPerformance Inc.
Nivasoft, Inc
Performance Validation
PharmaConsult Us, Inc
pi
PJC Pharma Consulting Ltd
ProPharma Group
Q Pharma consulting India
Rescop BV
SeerPharma (Singapore) Pte Ltd
STEXCON
TRAQuE Pte Ltd
Tunnell Consulting, Inc.
USDM
USDM
Zarpac Inc.

Consulting – Records Management

CQV (CimQuest Vantage)
comes compliance services
Document Center Inc.
DynaGMP
Noblitt & Rueland
Recordsforce Inc

Consulting – Regulatory

CAI (Shanghai) Engineering Consulting Co. Ltd.
Commissioning Agents, Inc.
Commissioning Agents International
Commissioning Agents International Singapore Pte. Ltd.
Commissioning Agents Ireland Ltd.
Commissioning Agents Puerto Rico LLC
NNE Pharmaplan Inc.
PSC Biotech
Business & Decision Life Sciences
Cardinal Systems
Catalyst Pharma Consulting
Ceutical Laboratories, Inc.
Christy Pavano Consulting
Cold Chain Consultants (UK) Ltd.
Cold Chain Consultants Pty Ltd
comes compliance services
Complya Consulting Group, LLC
Document Center Inc.
DXC Consulting Ltd.
DynPort Vaccine Company LLC, A CSC Company
EduQuest, Inc.
Foster Wheeler
Frontage Laboratories, Inc.
HealthCore, Inc.
Hyde Engineering + Consulting
Integrated Compliance Solutions, LLC
Kevin Technologies Pvt. Ltd.
Malawer & Associates Consulting, LLC
MasterControl Inc.
MIVADO GlobalPerformance Inc.
New Wayz Consulting Ltd
NSF Pharma Biotech
PharmaSys, Inc.
PharmEng Technology
pi
PSC Asia
SeerPharma (Singapore) Pte Ltd
Specialty Operations Solutions, Inc.
The Williamsburg Group, LLC
Tunnell Consulting, Inc.
USDM
VPCI, Inc.

Consulting Services

Burkert Fluid Control Systems
DME Alliance Engineering Consultants
NNE Pharmaplan AB
NNE Pharmaplan AG
NNE Pharmaplan A/S
NNE Pharmaplan Consultoria Ltda.
NNE Pharmaplan GmbH
NNE Pharmaplan Inc.
NNE Pharmaplan NV
NNE Pharmaplan sas
Telstar Life Sciences
Agalloco & Associates, Inc.
AICOS Technologies Ltd.
AllianzOne Private Limited
American Plastic Technologies Inc
Andreasen & Elmgaard A/S
ARNOULT.ORG
Benz Technology International, Inc.
Bouchard Consulting Services
BSSN Software
Business & Decision Life Sciences
Cleanroom Consulting, LLC
Cockram Construction
Compliance Insight, Inc.
Complya Consulting Group, LLC
Consultoria Asfalia S.L.
CYBERVAL
DAI
David H. Artiss and Associates, Inc.
DynaGMP
DynPort Vaccine Company LLC, A CSC Company
Enhanced Information Solutions (EIS)
Fluor Corporation
Hipp Engineering & Consulting, Inc.
Hyperion Pharma Consultancy
IPS-Integrated Project Services
J D Pharma Consultants
Job Consultoria
Kelly Engineering Resources
Kelly Services
M+W Automation
M+W Group
M+W Process Industries GmbH
M+W Singapore Pte Ltd
Malawer & Associates Consulting, LLC
MAM Pharma Engineering Consultants
Maxiom Group
McGee Pharma International
Michelle Marketing
ModularPartners
MSS Clean Technology Ltd
Multisorb Technologies
Natoli Engineering Company, Inc.
NEST Consulting
NSF Pharma Biotech
ONET Technologies UK Ltd
Pharmatech Associates, Inc.
PharmEng Technology
Pharminox Isolation Ltd
Polymer Solutions
PPS Engineers, Inc.
PROGMP SAS
QSPEC Solutions Inc.
Redline PdM a division of Caltrol
Robert C. Vincek Design Associates LLC
Rozembersky Group Inc.
Soluciones GXP (Infodynamics s.r.l.)
Strong Plastics Engineering Inc.
sys-tek
TalentWRx Life Sciences Staffing
Techceuticals
Techniserv, Inc.
The Williamsburg Group, LLC
TiPS Incorporated
Tunnell Consulting, Inc.
Validation Technologies, Inc.
ValSource, LLC

Container Testing

PTI Inspection Systems
ATC Inc. - Advanced Test Concepts Inc.
Nikka Densok USA, Inc.
ZebraSci, Inc.

Containment

Camfil Air Pollution Control
Flanders Corporation
Hanningfield Process Systems Ltd
Telstar Life Sciences
AFC Air Filtration & Containment GmbH
Affygility Solutions
AIRVAC, Inc.
BioPharma Systems
Bureau Veritas North America, Inc.
CDM
ChargePoint Technology
Class Biologically Clean, Ltd.
Contained Technologies LLC
Dec Group
DEC-USA
Donaldson Torit
Dycem LTD
enviroflo, inc.
Extract Technology Ltd.
F.P.S. Food and Pharma Systems
Federal Equipment Company
Flad Architects
Floura LLC
G-CON Manufacturing
GEA Lyophil GmbH
GEA Pharma Systems
GEA Pharma Systems - Collette
Gerteis Maschinen + Processengineering AG
Getinge-La Calhene
Glatt Air Techniques, Inc.
Harrington Pure
Hecht Technologie GmbH
Hermann WALDNER GmbH & Co. KG
ILC Dover
Integrated Containment Systems
Isolation Systems, Inc.
Jacobs/Wyper Architects LLP
Jung Gummitechnik GmbH
M+W Products GmbH
M. Braun
Matcon France & Germany
Matcon Japan
Matcon USA
Microzone Corporation
ModWave
ONET Technologies UK Ltd
ONFAB Limited
PharmaConsult Us, Inc
Pharminox Isolation Ltd
Powder Systems Ltd (PSL)
ProSys Containment & Sampling Technology
PSL USA
Russell Finex Inc
seepex Inc.
Sepratech International
Shickel Corporation
Sixlog
SKAN AG
SKAN US, Inc.
Solo Containment
Telstar North America, Inc.
Thomas Engineering Inc
University of Iowa Pharmaceuticals
Walker Barrier Systems

Contaminant Analysis
CHEMIR
Floura LLC
PANalytical
PharmaConsult Us, Inc
Sixlog
ZebraSci, Inc.

Contract Manufacturing
Vetter Pharma International GmbH
AAIPharma
Aqua-Chem, Inc.
ASM Aerosol-Service AG
Avid Bioservices, Inc.
BioConvergence LLC
Catalyst Pharma Consulting
Christy Pavano Consulting
CoreRx, Inc.
Fareva
New Life Resources, Inc
Patheon, Inc.
Plainfield Precision
Quality Tech Services
Rompharm Company
Tapemark
Watson-Marlow Pumps Group

Contract Packaging
Vetter Pharma International GmbH
A+ Secure Packaging
AAIPharma
AndersonBrecon
ASM Aerosol-Service AG
Astro Pak
Creapharm
Fareva
Quality Tech Services
Strong Plastics Engineering Inc.

Contracting Services
AAIPharma
ASM Aerosol-Service AG
Associates of Cape Cod, Inc.
ESS Ltd.
Higuchi Inc.
Kelly Engineering Resources
McCarthy Building Companies, Inc.
Millrock Technology, Inc.
pi

Custom Manufacturing
Allegheny Bradford Corporation
Spraying Systems Co./Fluid Air
VNE Corporation
AdvantaPure
Apache Stainless Equipment Corp.
Aqua-Chem, Inc.
Arc Machines, Inc.
ASM Aerosol-Service AG
Behringer Corporation
BioPharma Systems
Brevetti Angela S.R.L.
Burt Process Equipment, Inc.
Camfil Farr
Ceramaret SA
Control Micro Systems, Inc.
Custom Powder Systems
DCI, Inc.
Degage Corp
Electrol Specialties Co.
Enerquip, LLC
Fab-Tech, Inc.
Fike
Filamatic
Fluid Air
Fraser Engineering, Inc.
G&G Technologies, Inc.
Garvey Corporation
GMP Piping, Inc.
Holloway America
Integrated Containment Systems
Isolation Systems, Inc.
Nickel Systems
NJM Packaging
Paul Mueller Company
Plainfield Precision
Quality Service Products
Rompharm Company
Savillex Corporation
Shickel Corporation
Stainless Solutions
Strong Plastics Engineering Inc.
Symetix
Techniserv, Inc.
Thieme Corporation
Wintek Corporation
ZenPure

Custom Synthesis
Catalyst Pharma Consulting
PharmaCore, Inc.

Data Management
ARNOULT.ORG
BioClinica
Blue Mountain Quality Resources, Inc.
BSSN Software
CoSign by ARX
Global Research Services, LLC
Lives International
M+W Automation
New England Controls Inc.
OctaveSoft GmbH
PleaseTech Ltd.
Prime Technologies, Inc.
Recordsforce Inc
Rescop BV
tergene biotech
TiPS Incorporated
Werum Software & Systems AG

Database Systems
Blue Mountain Quality Resources, Inc.
Freezerworks
OctaveSoft GmbH

Disinfectants
Mar Cor Purification
Ateco Services AG
Bioquell, Inc.
By Dezign Products
Hanovia
Sixlog
STERIS Life Sciences
Veltek Associates, Inc.

Disposable Device Development and Manufacturing
Gemü Valves
AdvantaPure
AllPure Technologies, Inc.
Broadley-James Ltd
By Dezign Products
CDM
Colder Products Company
Contained Technologies LLC
DCI-Biolafitte
Dynarex Corporation
GA International Inc.
Global Innovations
Greiner Bio-One GmbH
Saint-Gobain Performance Plastics
Tapemark
Value Plastics, a Nordson Company

Distillation
APV, An SPX Brand
Buss-SMS-Canzler GmbH
GMP SYSTEMS LTDA.
LCI Corporation
Paul Mueller Company
Pope Scientific, Inc.
Praj Industries Limited

Distribution – Clinical Trials
AndersonBrecon
Clinigen CTS
Cold Chain Consultants (UK) Ltd.

Distribution – Commercial
Camber Pharmaceuticals
Cold Chain Consultants (UK) Ltd.
Nickel Systems

Documentation Support Services
Complya Consulting Group, LLC
CrossPoint Engineering
ETC Sterilization Systems
MasterControl Inc.
Pharmaceuticals and Medical Supply L.P.
PleaseTech Ltd.
Recordsforce Inc
Soluciones GXP (Infodynamics s.r.l.)
ValSource, LLC

Dosage Form Development
Corpaul Pharmaceutical Plant
Dalton Pharma Services
Emerson Resources, Inc
Huxley Bertram

Downstream Processing
Camfil Air Pollution Control
optek-Danulat, Inc.
Broadley-James Ltd
Entegris Inc
Jeff Smith & Associates, Inc.
Pall Life Sciences
WaterSep Technology Corp.

Drug Delivery Systems
Astech Projects
Catalent Pharma Solutions
Doctor Pack India
Strong Plastics Engineering Inc.
Ticona Engineering Polymers

Drug Development Services
Vetter Pharma International GmbH
Catalent Pharma Solutions
Emerson Resources, Inc
Kinexus Bioinformatics Corporation
Patheon, Inc.
Vanta Bioscience LC

Drug Discovery
Kinexus Bioinformatics Corporation

E-Pedigree
Acquire Automation
InfraTrac
Intelleflex
Maxiom Group

Efficacy Testing
Veltek Associates, Inc.

Electronic Data Management
ARNOULT.ORG
BioClinica
Blue Mountain Quality Resources, Inc.
CoSign by ARX
Lives International
OctaveSoft GmbH
PleaseTech Ltd.
Prime Technologies, Inc.
Recordsforce Inc
Rescop BV
Werum Software & Systems AG

Electropolishing
Allegheny Surface Technology
Astro Pak
Exigo Manufacturing

Engineering and Design Services
DME Alliance Engineering Consultants
Genesis Engineers, Inc.
NNE Pharmaplan AG
NNE Pharmaplan GmbH
NNE Pharmaplan Inc.
NNE Pharmaplan India Limited
NNE Pharmaplan sas
NNE Pharmaplan (Tianjin) Co., Ltd. Guangzhou Branch
OOO NNE Pharmaplan
Telstar Life Sciences
Alden
Burns & McDonnell
CE&IC
GenesisSolutions
Hart Companies
Hecht Technologie GmbH
Hofmeister Engineering, PC
International Coatings
IPS-Integrated Project Services
Key Resin Company
M+W Group
M+W Israel Ltd
M+W Process Industries GmbH
M+W Singapore Pte Ltd
Mangan Biopharm
Mussett Nicholas and Assoc., Inc.
NEST Consulting
North Shore Mechanical Contractors Inc
O'Neal, Inc.
PM Group
Precis Engineering, Inc.
QSPEC Solutions Inc.
Rogers Machinery Co., Inc.
Techniserv, Inc.
Unidec

Enterprise Resource Planning
Production Modelling

Environmental Analysis

Azzur Labs, LLC
TSI Inc
Anguil Environmental Systems, Inc.
Lighthouse Worldwide Solutions
Performance Validation
Q Laboratories, Inc.
Technical Safety Services
Warsash Scientific

Equipment/Components

Matcon Ltd.
Acro Associates
AGRU Kunststofftechnik GmbH
Alfa Laval
Alfa Laval Tank Equipment
Bematek Systems
Benz Technology International, Inc.
Buchi Pilot Plant & Reactors Systems
Buchiglas USA Corp
Buffalo Air Handling
Burns Engineering
Clean Air Products
Custom Powder Systems
DCI, Inc.
DENSO Robotics
Donaldson Torit
E+E Elektronik Corp.
Exigo Manufacturing
G&G Technologies, Inc.
Garvey Corporation
GMP SYSTEMS LTDA.
GMP Systems, Inc.
Hardy Process Solutions
Haskel International, LLC
Heleon BV
HEMCO Corporation
Hurst Corporation
IWT srl
Jung Gummitechnik GmbH
K-Tron G.B. Ltd
Kahle Automation
Kraemer US, LLC
LCI Corporation
LJ Star Inc
Michelle Marketing
Nextteq LLC
Nikka Densok USA, Inc.
Pfaudler Balfour / Edlon
PRIMUS Sterilizer Company, LLC
QEC Qualified Equipment and Components Limited
Qualicaps
Sepratech International
Spirax Sarco Ltd
Techceuticals
Technical Engineering Ltd
Thomas Engineering Inc
Turn-Key Modular Systems, Inc.
Unidec
Wintek Corporation
Zeta Biopharma GmbH

European QP

Clinigen CTS

Facilities Design

AWS Bio-Pharma Technologies
DME Alliance Engineering Consultants
Genesis Engineers, Inc.
NNE Pharmaplan AG
NNE Pharmaplan GmbH
NNE Pharmaplan Inc.
Stantec
AllianzOne Private Limited
Altera doo
Business Horizons
Catalyst Pharma Consulting
CE&IC
Century 3 (Shanghai) Inc.
Cleanroom Consulting, LLC
Cleanroom Solutions Ltd
Cleanseal Door Systems - A Division of ASI Technologies
Crane Composites
CRB
Dagard Clean Room
Farmatec Engineering Sdn Bhd
Flad Architects
G-CON Manufacturing
Hart Companies
HEMCO Corporation
Hipp Engineering & Consulting, Inc.
Hofmeister Engineering, PC
J D Pharma Consultants
Jacobs/Wyper Architects LLP
Key Resin Company
Kinetic Systems, Inc.
M+W Group
M+W High Tech Projects Philippines Inc.
M+W Process Industries GmbH
Manrochem Limited
McGee Pharma International
Microzone Corporation
mitchell architectural group, p.c.
ModularPartners
Mussett Nicholas and Assoc., Inc.
nora systems, Inc.
North Shore Mechanical Contractors Inc
Pharmatech Associates, Inc.
PM Greene Engineers
PM Group
PPS Engineers, Inc.
Process Plus LLC
SABArchitects, Inc.
Talboom PharmaChem NV
VPCI, Inc.
WSP CEL

Facility Construction

AES Clean Technology, Inc.
Crane Composites
CRB
Foster Wheeler
GMP Piping, Inc.
Hart Companies
International Coatings
Kinetic Systems, Inc.
M+W Singapore Pte Ltd
M+W Thailand Ltd
McCarthy Building Companies, Inc.
ModularPartners
nora systems, Inc.
North Shore Mechanical Contractors Inc
O'Neal, Inc.
Paul Mueller Company
Skanska
Stonhard
WSP CEL

Facility Engineering and Maintenance

Allegheny Surface Technology
Azzur Group, LLC
Ace Control Systems Ltd.
Altera doo
Avanceon
Dart Controls, Inc.
ETC Service and Sterilizer Support
Fluor Corporation
Fraser Engineering, Inc.
GenesisSolutions
GMP Templates
Hofmeister Engineering, PC
International Coatings
Kelly Engineering Resources
Key Resin Company
M+W Group – Total Facility Solutions, Inc.
Meriam Process Technologies
North Shore Mechanical Contractors Inc
PPS Engineers, Inc.
Precis Engineering, Inc.
Production Modelling
Redline PdM a division of Caltrol
Rogers Machinery Co., Inc.
Skanska
SPIE GmbH, Facility Solutions
Spirax Sarco
TATNUCK, INC.

Facility Management Services

Business Horizons
Johnson Controls
M+W Group
Skanska
SPIE GmbH, Facility Solutions
The Mundy Companies

Facility Planning

AllianzOne Private Limited
Crane Composites
Flad Architects
Hart Companies
Hofmeister Engineering, PC
J D Pharma Consultants
Lighthouse Worldwide Solutions
McCarthy Building Companies, Inc.
mitchell architectural group, p.c.

Feasibility Studies

NNE Pharmaplan AB
PTI Inspection Systems
Burns & McDonnell
Foster Wheeler
GMP Engineering
ITCM
J D Pharma Consultants
Manrochem Limited
McFlusion Inc
mitchell architectural group, p.c.
Mussett Nicholas and Assoc., Inc.
Sweett Group
sys-tek

Fermentation

Brooks Instrument
Biomanufacturing Training and Education Center (BTEC)
Broadley-James Ltd
DCI-Biolafitte
Dyadic International, Inc.
Hermann WALDNER GmbH & Co. KG
Luthra Industrial Engineering Corporation
Praj Industries Limited
Sartorius Stedim Biotech
Svanholm.com
Turn-Key Modular Systems, Inc.
Williams Process Ltd

Filling

Bausch + Stroebel
Bosch Packaging Technology
Gemü Valves
Marchesini Group USA
NJM Packaging
NNE Pharmplan Hong Kong Limited
NNE Pharmaplan Sdn. Bhd.
ASM Aerosol-Service AG
BellatRx Inc.
BioPharma Systems
Bioquell, Inc.
Brevetti Angela S.R.L.
Brinda Pharma Technologies
Capmatic Ltd.
Chase-Logeman Corporation
Cozzoli Machine Company
Dabrico, Inc.
Dynamic Air Quality Solutions
enviroflo, inc.
Filamatic
GMP SYSTEMS LTDA.
Grand River Aseptic Manufacturing, Inc.
groninger USA
Hecht Technologie GmbH
IMA Life North America, Inc.
ITCM
Jung Gummitechnik GmbH
Kirby Lester
Lyophilization Technology, Inc.
M&O Perry Industries, Inc.
OPTIMA pharma
OPTIMA pharma GmbH
PallayPack Inc
PharmaSystems, Inc.
Proditec
Rommelag USA Inc.
Shibuya Hoppmann Corporation
SKAN AG
Vanrx Pharmasystems

Filtration Equipment and Supplies

Camfil Air Pollution Control
Mar Cor Purification
Anguil Environmental Systems, Inc.
Benz Technology International, Inc.
Christ Nishotech Water Systems Pvt. Ltd
Donaldson Torit
International Products Corporation
Jeff Smith & Associates, Inc.
Meissner Filtration Products Inc
Mott Corporation
Pall Life Sciences
Q Applied Systems, Corp.
Qorpak
Schenck Process
Sepratech International
SPX Flow Technology

Filtration Services

Camfil Air Pollution Control
Flanders Corporation
AFC Air Filtration & Containment GmbH
Donaldson Torit
Filter Technologies, Inc.
Meissner Filtration Products Inc
Rozembersky Group Inc.

GAMP

AIV Solutions
andesys international corp.

BatchControl Ltd.
Consultoria Asfalia S.L.
DAI
Deloitte
Empowerment Quality Engineering Ltd
GE Measurement & Control
GMP Templates
Halfmann Goetsch Partner AG
Kevin Technologies Pvt. Ltd.
ONFAB Limited
Performance Validation
PharmEng Technology
PROGMP SAS
Provalidus
QS Pharma
SeerPharma (Singapore) Pte Ltd
TATNUCK, INC.

GLP Auditing

NetDimensions (UK) Limited

GMP Auditing

NNE Pharmaplan India Limited
NNE Pharmaplan Sdn. Bhd.
OOO NNE Pharmaplan
PSC Biotech
Compliance Insight, Inc.
Consultoria Asfalia S.L.
David H. Artiss and Associates, Inc.
EduQuest, Inc.
GMP Engineering
GxP Associates
Halfmann Goetsch Partner AG
Integrated Compliance Solutions, LLC
M+W Process Industries GmbH
Malawer & Associates Consulting, LLC
NetDimensions (UK) Limited
Noblitt & Rueland
PharmaSys, Inc.
PJC Pharma Consulting Ltd
PROGMP SAS
USDM
VPCI, Inc.

Genomic/Proteomic

Dyadic International, Inc.
Kinexus Bioinformatics Corporation

HVAC

Flanders Corporation
Genesis Engineers, Inc.
Ace Control Systems Ltd.
Alpha Controls & Instrumentation
Anguil Environmental Systems, Inc.
Buffalo Air Handling
Clean Rooms West, Inc.
Energy Engineering Co.,Ltd.
Farmatec Engineering Sdn Bhd
Johnson Controls
Kinetic Systems, Inc.
M+W Products GmbH
MSS Clean Technology Ltd
Munters Corporation
Q Applied Systems, Corp.
QS Pharma
RPA
Siemens Industry, Inc
Somar Engenharia Ltda
SPIE GmbH, Facility Solutions
sys-tek
tekWorx LLC
TESTO Inc.

Hazardous Waste Management

Nilfisk-Advance, Inc.

Health/Safety/ Environmental

Affygility Solutions
Anguil Environmental Systems, Inc.
BPE Design and Support Ltd
By Dezign Products
Contained Technologies LLC
Fike
Jung Gummitechnik GmbH
Kewaunee Scientific Corporation
ModWave
Nextteq LLC
Nilfisk-Advance, Inc.
ONFAB Limited
Solo Containment

IT – Clinical Trials Management

CoSign by ARX
Freezerworks
Innovatum, Inc.

IT – Data Collection

Bioproduction Group (BIO-G)
E2i
OctaveSoft GmbH

IT – LIMS

CQV (CimQuest Vantage)
CoSign by ARX
CYBERVAL
Freezerworks
Kevin Technologies Pvt. Ltd.

IT – Outsourcing Services

CQV (CimQuest Vantage)
Empowerment Quality Engineering Ltd
Nivasoft, Inc.

IT – Process Automation

ABB Control Technologies
Avanceon
Beamex, Inc.
DAI
Enhanced Information Solutions (EIS)
GE Analytical Instruments
Kevin Technologies Pvt. Ltd.
Optimation
Werum Software & Systems AG
Yokogawa
Zenith Technologies

Image Analysis and Microscopy

MNEMONICS, INC.
Okolab: Live Cell Microscopy

Imaging

BioClinica
MNEMONICS, INC.
ZebraSci, Inc.

Immunobiology Services

Kinexus Bioinformatics Corporation

Information Technology

AICOS Technologies Ltd.
ARNOULT.ORG
CoSign by ARX
DAI
Deloitte
Nivasoft, Inc
PleaseTech Ltd.
Production Modelling

Instruments and Controls

Brooks Instrument
Burkert Fluid Control Systems
Gemü Valves
optek-Danulat, Inc.
TSI Inc
Vaisala
ABB Control Technologies
Ace Control Systems Ltd.
Alfa Laval Tank Equipment
Alpha Controls & Instrumentation
ATC Inc. - Advanced Test Concepts Inc.
BatchControl Ltd.
Beamex, Inc.
Brookfield Engineering Laboratories, Inc.
Burns Engineering
E+E Elektronik Corp.
Endress+Hauser
Energy Engineering Co.,Ltd.
Gemini Data Loggers
Huffman Engineering Inc
Intempco Instrumentation
Meriam Process Technologies
MKS Instruments, Inc.
Okolab: Live Cell Microscopy
Proditec
Rotronic Instrument Corp
Steriflow Valve, Div of Jordan Valve
SVF Flow Controls, Inc.
Swan Analytical USA
Yokogawa

Investigational Products

Clinigen CTS
Creapharm
DNA Genotek Inc.
Emerson Resources, Inc
Integrated Compliance Solutions, LLC
University of Iowa Pharmaceuticals

Laboratory Equipment

Mar Cor Purification
PTI Inspection Systems
A & M Process Equipment Ltd.
ARS/Beverly Pacific Sterilizers
Bahnson Environmental Specialties, LLC.
Belimed, Inc.
Bematek Systems
Bioquell, Inc.
Buchi Pilot Plant & Reactors Systems
Burns Engineering
Buss-SMS-Canzler GmbH
Cincinnati Sub-Zero
Dagard Clean Room
DJS Enterprises
DNA Genotek Inc.
Enerquip, LLC
enviroflo, inc.
ETA Process Instrumentation
ETC Service and Sterilizer Support
Exergy, LLC
Fab-Tech, Inc.
Fedegari Group
Filamatic
Freund-Vector Corporation
FRITSCH GmbH - Milling and Sizing
Gemini Data Loggers
Getinge-La Calhene
Greiner Bio-One GmbH
Harrington Pure
HEMCO Corporation
Huxley Bertram
IMA Life North America, Inc.
John Guest USA, Inc.
Kewaunee Scientific Corporation
LAUDA DR. R. WOBSER GMBH & CO. KG
Magnasafe Int'l
Metrohm NIRSystems
Microzone Corporation
Natoli Engineering Company, Inc.
Nikka Densok USA, Inc.
NuAire, Inc.
Okolab: Live Cell Microscopy
Perfex Corporation
Pharmatron, Inc.
Q Applied Systems, Corp.
Q-Lab Corporation
Rotronic Instrument Corp
Russell Finex Inc
Safety Emporium
Shimadzu Scientific Instruments
Siemens Industry, Inc
Skytech Systems (I) Pvt. Ltd
SnowPure Water Technologies
Thieme Corporation
Watson-Marlow Pumps Group
Weiss Envirotronics

Laboratory Operations

CYBERVAL
Prime Technologies, Inc.
Specialty Operations Solutions, Inc.
Weiss Envirotronics

Laboratory Supplies

Berkshire
Brinda Pharma Technologies
gammaSUPPLIES
International Products Corporation
Kimberly-Clark Professional
Nextteq LLC
Q Applied Systems, Corp.
Qorpak
Safety Emporium
Savillex Corporation
Solo Containment

Logistics

AndersonBrecon
Intelleflex
Modality Solutions LLC
New Wayz Consulting Ltd
Sensitech Inc.

Lyophilization

BioConvergence LLC
Millrock Technology, Inc.
PharmaSystems, Inc.

Machinery Design and Construction

ITCM
Kahle Automation
Pharmaceuticals and Medical Supply L.P.
Techniserv, Inc.

Maintenance

Allegheny Surface Technology
Azzur Group, LLC

Ace Control Systems Ltd.
Altera doo
Ateco Services AG
Avanceon
Dart Controls, Inc.
ESS Ltd.
ETC Service and Sterilizer Support
Fluor Corporation
Fraser Engineering, Inc.
GenesisSolutions
GMP Templates
Hofmeister Engineering, PC
International Coatings
Kelly Engineering Resources
Key Resin Company
M+W Group – Total Facility Solutions, Inc.
Meriam Process Technologies
Nickel Systems
Nilfisk-Advance, Inc.
North Shore Mechanical Contractors Inc
PPS Engineers, Inc.
Precis Engineering, Inc.
Production Modelling
Redline PdM a division of Caltrol
Rogers Machinery Co., Inc.
Skanska
SPIE GmbH, Facility Solutions
Spirax Sarco
TATNUCK, INC.
The Mundy Companies

Manufacturing – Aseptic Fill/Finish

Genesis Engineers, Inc.
Vetter Pharma International GmbH
adam fabriwerk pvt ltd
American Plastic Technologies Inc
AMO (Hangzhou) Co., Ltd.
Bausch Advanced Technology Group
Dalton Pharma Services
DXC Consulting Ltd.
Federal Equipment Company
G-CON Manufacturing
gammaSUPPLIES
Grand River Aseptic Manufacturing, Inc.
MAM Pharma Engineering Consultants
OPTIMA pharma
PharmaSystems, Inc.
Rompharm Company
Shibuya Hoppmann Corporation
University of Iowa Pharmaceuticals
Vanrx Pharmasystems
Watson-Marlow Pumps Group

Manufacturing – Generics

Rompharm Company
Tapemark

Manufacturing – High Containment Operations

Camfil Air Pollution Control
Flanders Corporation
CDM
Class Biologically Clean, Ltd.
Dec Group
Extract Technology Ltd.
Federal Equipment Company
Isolation Systems, Inc.
Jacobs/Wyper Architects LLP
M. Braun
ModWave
PharmaConsult Us, Inc
PSL USA
Russell Finex Inc
seepex Inc.
University of Iowa Pharmaceuticals

Materials Management

Fisher BioServices
Nickel Systems
Parsec Automation
Quality Tech Services

Medical Devices

Ceramaret SA
DNA Genotek Inc.
Dynarex Corporation
ETC Service and Sterilizer Support
Greiner Bio-One GmbH
New Wayz Consulting Ltd
Plainfield Precision
PRISYM ID
Ticona Engineering Polymers

Methods Development

Actlabs
Associates of Cape Cod, Inc.
Avid Bioservices, Inc.
Bureau Veritas North America, Inc.
Ceutical Laboratories, Inc.
Chemical Solutions Ltd.
Dalton Pharma Services
Frontage Laboratories, Inc.
HealthCore, Inc.
Polymer Solutions
Q Laboratories, Inc.
STEXCON
Western Test Solutions

Methods Validation

Polymer Solutions
ValSource, LLC

Microbiological Testing

Azzur Labs, LLC
Associates of Cape Cod, Inc.
Azbil BioVigilant
Microbiology & Quality Associates, Inc.
Perritt Laboratories
Q Laboratories, Inc.
SKAN US, Inc.
Skytech Systems (I) Pvt. Ltd
Technical Safety Services
TRI Air Testing, Inc.

Mixing and Granulating Equipment

Fristam Pumps USA
GEA Process Engineering
A & M Process Equipment Ltd.
Bematek Systems
Fluid Air
Glatt Air Techniques, Inc.
LCI Corporation
Matcon France & Germany
Matcon Pacific PTY Ltd.
Pharmaceuticals and Medical Supply L.P.

Nonclinical Research

Vanta Bioscience LC

Packaging – Anti-Counterfeiting

Access Creative Group
AlpVision SA
Complete Inspection Systems, Inc.
Covan Systems
Equipnet (India) Private Limited
InfraTrac
MNEMONICS, INC.

Packaging – Blister

A+ Secure Packaging
Glenroy, Inc.
Marchesini Group S.p.A.
Omori Machinery Co., Ltd

Packaging – Capsules

CurTec International
IMA S.p.A.
NJM Packaging
OPTIMA pharma GmbH
Qualicaps

Packaging – Clinical Trials

A+ Secure Packaging
AndersonBrecon
GA International Inc.
Kirby Lester

Packaging – Consultants

Cold Chain Technologies Inc
Noblitt & Rueland
Robert C. Vincek Design Associates LLC

Packaging – Creams and Ointments

Cozzoli Machine Company
Marchesini Group S.p.A.
Tapemark

Packaging – Design and Testing

Perritt Laboratories
Robert C. Vincek Design Associates LLC

Packaging – Development

Cold Chain Technologies Inc
Omori Machinery Co., Ltd
Robert C. Vincek Design Associates LLC

Packaging – Electronic Pedigree

Intelleflex
NJM Packaging

Packaging – Equipment – Custom

Capmatic Ltd.
Isthmus Engineering & Manufacturing
ITCM
Kahle Automation
OPTIMA pharma
Technical Engineering Ltd

Packaging – Filling

Capmatic Ltd.
Chase-Logeman Corporation
Cozzoli Machine Company
Filamatic
groninger USA
Hecht Technologie GmbH
Kirby Lester
M&O Perry Industries, Inc.
NJM Packaging
OPTIMA pharma GmbH
PallayPack Inc
Rommelag USA Inc.
Shibuya Hoppmann Corporation

Packaging – Form/Fill/Seal

A+ Secure Packaging
BioConvergence LLC
Labels,Inc./Flexprint
Marchesini Group S.p.A.
Omori Machinery Co., Ltd
PolyCine GmbH
Rommelag USA Inc.
Weiler Engineering, Inc.

Packaging – Labels

Innovatum, Inc.
Labels,Inc./Flexprint
Nuceria Adesivi
PRISYM ID

Packaging – Liquids

Capmatic Ltd.
Cozzoli Machine Company
Filamatic
Glenroy, Inc.
M&O Perry Industries, Inc.
Marchesini Group S.p.A.
OPTIMA pharma GmbH
Quality Service Products
Rommelag USA Inc.
Savillex Corporation
Weiler Engineering, Inc.

Packaging – OTC

Glenroy, Inc.

Packaging – Parenterals

AWS Bio-Pharma Technologies
Air-Tite Products Co.
Dabrico, Inc.
Dividella Pharma Technology Solutions
Grand River Aseptic Manufacturing, Inc.
Modality Solutions LLC
NJM Packaging
OPTIMA pharma
OPTIMA pharma GmbH
PallayPack Inc
PolyCine GmbH
Rommelag USA Inc.
Vanrx Pharmasystems
Weiler Engineering, Inc.
ZebraSci, Inc.

Packaging – Powders

GEA Process Engineering
Matcon Ltd.
Cozzoli Machine Company
CurTec International
M&O Perry Industries, Inc.
Matcon France & Germany
Matcon USA
PolyCine GmbH

Packaging – Samples

Glenroy, Inc.

Packaging – Solid Dosage

Matcon Ltd.
A+ Secure Packaging
Capmatic Ltd.

CurTec International
Hecht Technologie GmbH
IMA S.p.A.
Matcon China
Matcon Japan
NJM Packaging
Omori Machinery Co., Ltd
PallayPack Inc
Proditec

Packaging Equipment

Bosch Packaging Technology
Marchesini Group USA
PTI Inspection Systems
Absolute Handling Systems Ltd.
ASCO Numatics
Bausch Advanced Technology Group
BellatRx Inc.
Brevetti Angela S.R.L.
Capmatic Ltd.
Changeover.com
Control Micro Systems, Inc.
Dividella Pharma Technology Solutions
DJS Enterprises
Getinge-La Calhene
Isthmus Engineering & Manufacturing
Kirby Lester
M&O Perry Industries, Inc.
MAM Pharma Engineering Consultants
Marchesini Group S.p.A.
MNEMONICS, INC.
Nikka Densok USA, Inc.
NJM Packaging
Omori Machinery Co., Ltd
Rotek, Plastics Division of HydroHoist Marine Group
Shibuya Hoppmann Corporation
Techceuticals
Unidec

Packaging Materials

Access Creative Group
CurTec International
Degage Corp
Labels,Inc./Flexprint
Multisorb Technologies
Nuceria Adesivi
PolyCine GmbH
Qorpak
Rotek, Plastics Division of HydroHoist Marine Group
Ticona Engineering Polymers

Photo-stability

Bahnson Environmental Specialties, LLC.

Pilot Plants

Buchi Pilot Plant & Reactors Systems
Buchiglas USA Corp
CE&IC
GEA Lyophil GmbH
GSC Engineering, Inc.
Magnasafe Int'l
Pope Scientific, Inc.
SABArchitects, Inc.
Sepratech International
Thermo Scientific – Material Characterization

Pilot-Scale Filling

Dabrico, Inc.
enviroflo, inc.
Grand River Aseptic Manufacturing, Inc.

Plant Engineering

BPE Design and Support Ltd

Pre-formulation

Patheon, Inc.

Process Analytical Technology (PAT)

CAI (Shanghai) Engineering Consulting Co. Ltd.
Commissioning Agents, Inc.
Commissioning Agents International
Commissioning Agents International Singapore Pte. Ltd.
Commissioning Agents Ireland Ltd.
Commissioning Agents Puerto Rico LLC
TSI Inc
Entegris Inc
Fluid Imaging Technologies, Inc.
GEA Lyophil GmbH
GEA Pharma Systems - Collette
Malawer & Associates Consulting, LLC
McFlusion Inc
Metrohm NIRSystems
Mettler-Toledo Thornton Inc
MKS Instruments, Inc.
Parsec Automation
Physical Sciences Inc.
Rigaku Raman Technologies
Svanholm.com
Swagelok
Swan Analytical USA
Tunnell Consulting, Inc.
Uhlmann VisioTec GmbH
Uhlmann VisioTec GmbH
Watson-Marlow Pumps Group
Werum Software & Systems AG
Yokogawa
Zarpac Inc.

Process Control/ Automation

Burkert Fluid Control Systems
NNE Pharmaplan Inc.
NNE Pharmaplan (Tianjin) Co., Ltd.
NNE Pharmaplan (Tianjin) Co., Ltd. Guangzhou Branch
NNE Pharmaplan (Tianjin) Co., Ltd. Shanghai Branch
optek-Danulat, Inc.
Spraying Systems Co./Fluid Air
Top Line Process Equipment Company
ABB Control Technologies
AIV Solutions
Alpha Controls & Instrumentation
Applied Control Engineering, Inc.
Avanceon
BatchControl Ltd.
Beamex, Inc.
Broadley-James Ltd
Burns & McDonnell
Burns Engineering
DAKSWAN Automation, Inc.
Dart Controls, Inc.
E2i
Exigo Manufacturing
Fike
Fluid Air
Hardy Process Solutions
Harrington Pure
Huffman Engineering Inc
Intempco Instrumentation
K-Tron G.B. Ltd
Kevin Technologies Pvt. Ltd.
MagneMotion
Meriam Process Technologies
Metrohm NIRSystems
MKS Instruments, Inc.
Parsec Automation
Pentair Sudmo
Praxair, Inc.
QSPEC Solutions Inc.
Rees Scientific
Rotronic Instrument Corp
Schenck Process
seepex Inc.
Sensor Technology Ltd
Spirax Sarco
SVF Flow Controls, Inc.
Swagelok
Swan Analytical USA
TiPS Incorporated
Yokogawa
Zenith Technologies

Process Design

DME Alliance Engineering Consultants
NNE Pharmaplan A/S
NNE Pharmaplan Consultoria Ltda.
NNE Pharmaplan Sdn. Bhd.
OOO NNE Pharmaplan
Stantec
Altera doo
BPE Design and Support Ltd
Burns & McDonnell
CE&IC
DEC-USA
Electrol Specialties Co.
GMP Engineering
Hyde Engineering + Consulting Inc
Manrochem Limited
Pfaudler Balfour / Edlon
PharmaConsult Us, Inc
PM Greene Engineers
Talboom PharmaChem NV

Process Development/ Scale-Up Services

Alden
Avid Bioservices, Inc.
Biomanufacturing Training and Education Center (BTEC)
BPE Design and Support Ltd
GSC Engineering, Inc.
Meissner Filtration Products Inc
PharmaCore, Inc.
Rozembersky Group Inc.

Process Gases

Brooks Instrument
GMP Piping, Inc.
Praxair, Inc.
Swagelok
Trace Analytics, LLC

Process Validation Studies

OOO NNE Pharmaplan
GE Measurement & Control
Modality Solutions LLC
Pharmatech Associates, Inc.
ProPharma Group
TRAQuE Pte Ltd

Processing Equipment

Allegheny Bradford Corporation
Bausch + Stroebel
Brooks Instrument
Hanningfield Process Systems Ltd.
Marchesini Group USA
Spraying Systems Co./Fluid Air
Telstar Life Sciences
Top Line Process Equipment Company
VNE Corporation
accumac Ltd.
Acro Associates
adam fabriwerk pvt ltd
Alfa Laval
APV, An SPX Brand
Ateco Services AG
Beamex, Inc.
Benz Technology International, Inc.
BMT USA, LLC
Buchi Pilot Plant & Reactors Systems
Budzar Industries
Buffalo Air Handling
Buss-SMS-Canzler GmbH
Dabrico, Inc.
DCI, Inc.
DCI-Biolafitte
DJS Enterprises
Donaldson Torit
Dow Corning Corporation
Enerquip, LLC
Equipnet (India) Private Limited
ETA Process Instrumentation
Exergy, LLC
Exigo Manufacturing
F.P.S. Food and Pharma Systems
Fab-Tech, Inc.
Federal Equipment Company
Fluid Air
Freund-Vector Corporation
gammaSUPPLIES
GEA Pharma Systems
GEA Pharma Systems - Collette
GEA Tuchenhagen GmbH
Gemu Valves Limited
Gerteis Maschinen + Processengineering AG
Glatt Air Techniques, Inc.
Global Innovations
GlobePharma, Inc
GMP Systems, Inc.
Hardy Process Solutions
Hydro-Thermal Corp
Intempco Instrumentation
Isthmus Engineering & Manufacturing
Jeff Smith & Associates, Inc.
K-Tron (Shanghai) Co.,Ltd.
K-Tron Pitman
K-Tron Salina
Kahle Automation
L.B. Bohle
LCI Corporation
Lee Industries, Inc.
Leistritz
LJ Star Inc
Loedige Maschinenbau GmbH
Luthra Industrial Engineering Corporation
Magnasafe Int'l
Matcon China
Matcon Pacific PTY Ltd.

Millrock Technology, Inc.
New England Sales, Inc.
Nickel Systems
Paul Mueller Company
Pentair Sudmo
Pfaudler Balfour / Edlon
Pharmaceuticals and Medical Supply L.P.
Pick Heaters, Inc.
Pope Scientific, Inc.
Quadro Engineering Corp.
Qualicaps
REMCON Plastics
Rogers Machinery Co., Inc.
Romaco FrymaKoruma
Russell Finex Inc
S3 Process Limited
Schenck Process
Silverson Machines
SnowPure Water Technologies
Spooner Industries
Sterling, Inc.
Symetix
Telstar North America, Inc.
Terracon Corporation
The Fitzpatrick Company
Turn-Key Modular Systems, Inc.
WCB, An SPX Brand

Processing and Manufacturing

Allegheny Bradford Corporation
AWS Bio-Pharma Technologies
Top Line Process Equipment Company
Vaisala
Aflex Hose USA
Aquafine Corporation
FlexFit Hose LLC
GEA Westfalia Separator
L.B. Bohle
LAUDA DR. R. WOBSER GMBH & CO. KG
Luthra Industrial Engineering Corporation
Matcon France & Germany
Matcon Pacific PTY Ltd.
MECO
ONFAB Limited
PSL USA
Rogers Machinery Co., Inc.
Russell Finex Inc
Sabin Metal Corporation
Schenck Process
Silverson Machines
Steriflow Valve, Div of Jordan Valve
Thermo Scientific – Material Characterization
USV Limited
Wayahead Systems

Product Development

Alden
PJC Pharma Consulting Ltd
Ticona Engineering Polymers
Weiss Envirotronics

Project Management

NNE Pharmaplan AB
NNE Pharmaplan AG
NNE Pharmplan Hong Kong Limited
NNE Pharmaplan India Limited
NNE Pharmaplan sas
NNE Pharmaplan (Tianjin) Co., Ltd.
NNE Pharmaplan (Tianjin) Co., Ltd. Guangzhou Branch
NNE Pharmaplan (Tianjin) Co., Ltd. Shanghai Branch
Telstar Life Sciences
AllianzOne Private Limited
Applied Control Engineering, Inc.
BPE Design and Support Ltd
Cockram Construction
Cold Chain Technologies Inc
Compliance Control Ltd
CYBERVAL
Global Research Services, LLC
GMP Templates
M+W Group
M+W Singapore Pte Ltd
MAM Pharma Engineering Consultants
MIVADO GlobalPerformance Inc.
PM Greene Engineers
PM Group
ProPharma Group
QPharma, Inc.
RJR Technical Services
SPIE GmbH, Facility Solutions
STEXCON
Sweett Group

Protein Extraction/ Purification

GEA Westfalia Separator

Pumps and Pump Systems

Fristam Pumps USA
Top Line Process Equipment Company
Alfa Laval
APV, An SPX Brand
Burt Process Equipment, Inc.
Ceramaret SA
Haskel International, LLC
McFlusion Corp
North Shore Mechanical Contractors Inc
Pureflow, Inc.
QEC Qualified Equipment and Components Limited
seepex Inc.
SPX Flow Technology
tekWorx LLC
WCB, An SPX Brand
Wintek Corporation

Purification

Burt Process Equipment, Inc.
Entegris Inc
GEA Westfalia Separator
MECO
Rees Scientific
Sartorius Stedim Biotech
SnowPure Water Technologies

Quality Assurance/Control

NNE Pharmaplan AB
optek-Danulat, Inc.
PTI Inspection Systems
Vaisala
AICOS Technologies Ltd.
Alcon
Complete Inspection Systems, Inc.
Document Center Inc.
GE Analytical Instruments
GE Measurement & Control
GMP Templates
Hyperion Pharma Consultancy
Integrated Compliance Solutions, LLC
Kirby Lester
Metrohm NIRSystems
MNEMONICS, INC.
Pharmatron, Inc.
Prime Technologies, Inc.
Provalidus
PSC Asia
Quality Service Products
Rees Scientific
Rescop BV
Rotronic Instrument Corp
Trace Analytics, LLC
Tunnell Consulting, Inc.

Raw Materials Analysis

B&W Tek, Inc.
CHEMIR
CoreRx, Inc.
Fluid Imaging Technologies, Inc.
Microbeam, S.A.
PANalytical
Q Laboratories, Inc.
Rigaku Raman Technologies

Research and Development

Alden
Entegris Inc
ENV Services, Inc.
Warsash Scientific

Screening – Classifying

FRITSCH GmbH - Milling and Sizing

Separation Science

GEA Westfalia Separator

Serialization

Access Creative Group
Innovatum, Inc.
SNC-Lavalin
Uhlmann VisioTec GmbH

Site Selection

Crane Composites
Laces Farma

Size Reduction

Hanningfield Process Systems Ltd
Bematek Systems
DEC-USA
F.P.S. Food and Pharma Systems
Fluid Air
FRITSCH GmbH - Milling and Sizing
Quadro Engineering Corp.
S3 Process Limited
Sterling, Inc.
The Fitzpatrick Company

Software/Hardware Products

PSC Biotech
AlpVision SA
Blue Mountain Quality Resources, Inc.
Complete Inspection Systems, Inc.
CoSign by ARX
DAKSWAN Automation, Inc.
NetDimensions (UK) Limited
Parsec Automation
PleaseTech Ltd.
Prime Technologies, Inc.
Rescop BV
Sensitech Inc.
tekWorx LLC
TiPS Incorporated

Spectroscopy

B&W Tek, Inc.
CHEMIR
Metrohm NIRSystems
Microbeam, S.A.
Rigaku Raman Technologies
Shimadzu Scientific Instruments
Warsash Scientific
ZebraSci, Inc.

Spray Drying

GEA Process Engineering
Emerson Resources, Inc
Praxair, Inc.
SPX Flow Technology

Stability Studies

Actlabs
CSZ Testing Services
Masy Systems, Inc.
Quality Service Products

Sterile Filling

Bausch + Stroebel
Marchesini Group USA
NNE Pharmplan Hong Kong Limited
NNE Pharmaplan Sdn. Bhd.
Bioquell, Inc.
Brevetti Angela S.R.L.
Chase-Logeman Corporation
Cozzoli Machine Company
Dabrico, Inc.
groninger USA
IMA Life North America, Inc.
Jung Gummitechnik GmbH
Lyophilization Technology, Inc.
OPTIMA pharma
PharmaSystems, Inc.
Vanrx Pharmasystems

Sterile Products Processing

Belimed, Inc.
Colder Products Company
Dabrico, Inc.
Dec Group
gammaSUPPLIES
Meissner Filtration Products Inc
SKAN AG
The Williamsburg Group, LLC
Weiler Engineering, Inc.

Sterility Testing

Bioquell, Inc.
GE Measurement & Control
Lives International
M. Braun
Noxilizer, Inc.
ProSys Containment & Sampling Technology
SKAN AG

Sterilization

Burkert Fluid Control Systems
Fristam Pumps USA
GEA Process Engineering
Spraying Systems Co./Fluid Air
Telstar Life Sciences
adam fabriwerk pvt ltd
Agalloco & Associates, Inc.
AIRVAC, Inc.

Alfa Laval
American Plastic Technologies Inc
APV, An SPX Brand
Aquafine Corporation
ARS/Beverly Pacific Sterilizers
Astro Pak
Basiks Sterilisation Concepts Pvt. Ltd
Belimed, Inc.
Bioquell, Inc.
Budzar Industries
Colder Products Company
Dec Group
Electrol Specialties Co.
Endress+Hauser
Environmental Water Systems
ETC Service and Sterilizer Support
ETC Sterilization Systems
Fedegari Group
Fike
FlexFit Hose LLC
G&G Technologies, Inc.
Gamajet, part of the Alfa Laval Group
GEA Lyophil GmbH
Getinge Life Science Americas
Hach - Particle Counting Division
Holloway America
Hyde Engineering + Consulting Inc
Hydro-Thermal Corp
IWT srl
M+W Group – Total Facility Solutions, Inc.
M+W Saudi Arabia Ltd.
McFlusion Corp
McFlusion Inc
MKS Instruments, Inc.
New England Sales, Inc.
Noxilizer, Inc.
Pick Heaters, Inc.
Process Plus LLC
PSC Asia
Sixlog
Skytech Systems (I) Pvt. Ltd
Stainless Solutions
Steriflow Valve, Div of Jordan Valve
STERIS Life Sciences
Telstar North America, Inc.
Thermal Compliance Ltd
Turn-Key Modular Systems, Inc.
Unidec
Veltek Associates, Inc.
WCB, An SPX Brand
Zenith Technologies

Storage

BioConvergence LLC
Cold Chain Consultants (UK) Ltd.
Kewaunee Scientific Corporation
Masy Systems, Inc.
Salsbury Industries - Lockers.com

Sustainability/Waste Management

PM Greene Engineers
Spirax Sarco Ltd

Sustained Release Delivery Systems

CoreRx, Inc.

System Integration

ABB Control Technologies
Applied Control Engineering, Inc.
Astech Projects
DAI
DAKSWAN Automation, Inc.
E2i
Global Innovations
GMP Engineering
GMP Systems, Inc.
Huffman Engineering Inc
K-Tron Pitman
K-Tron Salina
Meriam Process Technologies
New England Controls Inc.
NJM Packaging
Optimation
QSPEC Solutions Inc.
Sartorius Stedim Biotech
Schenck Process
seepex Inc.
SPX Flow Technology
Techniserv, Inc.
Zeta Biopharma GmbH

Tablet Press Control Systems

IPR, Inc.

Tablet Presses

GEA Process Engineering
accumac Ltd.
Fette Compacting
GEA Pharma Systems
GlobePharma, Inc
Huxley Bertram
IPR, Inc.
K-Tron (Shanghai) Co.,Ltd.
KORSCH America Inc.
Natoli Engineering Company, Inc.
Techceuticals

Technology Transfer

Christy Pavano Consulting
Laces Farma
Manrochem Limited
Modality Solutions LLC
Tapemark
Validation Technologies, Inc.
Williams Process Ltd

Testing Laboratory

ATC Inc. - Advanced Test Concepts Inc.
Chemical Solutions Ltd.
CHEMIR
Christy Pavano Consulting
Cold Chain Technologies Inc
CSZ Testing Services
ENV Services, Inc.
Fike
Noxilizer, Inc.
Perritt Laboratories
Polymer Solutions
Q-Lab Corporation
SKAN US, Inc.
Trace Analytics, LLC
TRI Air Testing, Inc.
Weiss Envirotronics

Thermoplastic Molding

AdvantaPure
AGRU Kunststofftechnik GmbH
Plainfield Precision
Saint-Gobain Performance Plastics
Value Plastics, a Nordson Company

Torque Testing

AMETEK Test & Calibration Instruments
Pharmatron, Inc.
Sensor Technology Ltd

Trace Metal Analysis – ICP

Chemical Solutions Ltd.
CHEMIR

Traditional Pharmaceuticals

Laces Farma

Training

Agalloco & Associates, Inc.
AICOS Technologies Ltd.
cGMP Validation LLC
Changeover.com
Cold Chain Consultants Pty Ltd
Consultoria Asfalia S.L.
Controlled Contamination Services
David H. Artiss and Associates, Inc.
DynaGMP
EduQuest, Inc.
ESS Ltd.
Hyde Engineering + Consulting
ISPE
Laces Farma
Lighthouse Worldwide Solutions
Natoli Engineering Company, Inc.
NetDimensions (UK) Limited
Noblitt & Rueland
NSF Pharma Biotech
Pharminox Isolation Ltd.
PSC Asia
QPharma, Inc.
Rozembersky Group Inc.
SeerPharma (Singapore) Pte. Ltd.
Soluciones GXP (Infodynamics s.r.l.)
Specialty Operations Solutions, Inc.
ValSource, LLC
Zenith Technologies

Validation – Clinical

ARNOULT.ORG

Validation – Equipment Cleaning

Validation, Inc.
cGMP Validation LLC
DynaGMP
Gamajet, part of the Alfa Laval Group
Intempco Instrumentation
IWT srl
McFlusion Inc
Microbiology & Quality Associates, Inc.
Pureflow, Inc.
Validation Technologies, Inc.

Validation – Filtration

Christ Nishotech Water Systems Pvt. Ltd.
Harrington Pure

Validation – Manufacturing

NNE Pharmaplan AB
Validation, Inc.
Agalloco & Associates, Inc.
cGMP Validation LLC
CYBERVAL
DXC Consulting Ltd.
Fluor Corporation
GE Measurement & Control
Kirby Lester
MIVADO GlobalPerformance Inc.
pi
Provalidus
QS Pharma
Terra Farma SA DE CV
USDM
Validation Technologies, Inc.
Wayahead Systems

Validation – Services (Qualification/ Commissioning)

Azzur Group, LLC
CAI (Shanghai) Engineering Consulting Co. Ltd.
Commissioning Agents, Inc.
Commissioning Agents International
Commissioning Agents International Singapore Pte. Ltd.
Commissioning Agents Ireland Ltd.
Commissioning Agents Puerto Rico LLC
NNE Pharmaplan A/S
NNE Pharmaplan Consultoria Ltda.
NNE Pharmaplan GmbH
NNE Pharmplan Hong Kong Limited
NNE Pharmaplan Inc.
NNE Pharmaplan India Limited
NNE Pharmaplan NV
NNE Pharmaplan sas
NNE Pharmaplan Sdn. Bhd.
NNE Pharmaplan (Tianjin) Co., Ltd.
NNE Pharmaplan (Tianjin) Co., Ltd. Guangzhou Branch
NNE Pharmaplan (Tianjin) Co., Ltd. Shanghai Branch
OOO NNE Pharmaplan
PSC Biotech
Stantec
Telstar Life Sciences
Validation, Inc.
AIV Solutions
Applied Control Engineering, Inc.
Bahnson Environmental Specialties, LLC.
Century 3 (Shanghai) Inc.
cGMP Validation LLC
Christ Nishotech Water Systems Pvt. Ltd.
DDK Scientific Corp.
Deloitte
E2i
EduQuest, Inc.
Empowerment Quality Engineering Ltd
ETC Sterilization Systems
G.M.Project
GE Analytical Instruments
Glatt Air Techniques, Inc.
Hyperion Pharma Consultancy
IWT srl
Mangan Biopharm
Masy Systems, Inc.
Microbiology & Quality Associates, Inc.
Nivasoft, Inc.
Optimation
Performance Validation
PharmaSys, Inc.
Pharmatech Associates, Inc.
PM Greene Engineers
Process Plus LLC
PROGMP SAS
ProPharma Group
PSC Asia
QPharma, Inc.
QS Pharma

Rees Scientific
Rescop BV
RJR Technical Services
Sartorius Stedim Biotech
SKAN US, Inc.
SNC-Lavalin
Soluciones GXP (Infodynamics s.r.l.)
Somar Engenharia Ltda
Specialty Operations Solutions, Inc.
STEXCON
Sweett Group
Talboom PharmaChem NV
TATNUCK, INC.
Thermal Compliance Ltd
USDM
Validation Technologies, Inc.
WSP CEL

Valves/Fittings/Hoses/Tubing

Gemü Valves
Top Line Process Equipment Company
VNE Corporation
Acro Associates
AdvantaPure
AGRU Kunststofftechnik GmbH
Alfa Laval
Asahi/America, Inc.
ASCO Numatics
Behringer Corporation
Exigo Manufacturing
GEA Tuchenhagen GmbH
Gemu Valves Limited
Global Innovations
GlobePharma, Inc
Harrington Pure
Heleon BV
Idenor Ingenieria
John Guest USA, Inc.
New England Controls Inc.
Pentair Sudmo
Safety Emporium
Saint-Gobain Performance Plastics
SED North America
Spirax Sarco Ltd
Steriflow Valve, Div of Jordan Valve
SVF Flow Controls, Inc.
Value Plastics, a Nordson Company
WCB, An SPX Brand

Water Testing: Microbiology

Azzur Labs, LLC
Associates of Cape Cod, Inc.
Perritt Laboratories

Water Treatment Consulting

Environmental Water Systems
Filters, Water & Instrumentation, Inc.
Idenor Ingenieria

Water/Steam Systems

Mar Cor Purification
Telstar Life Sciences
AGRU Kunststofftechnik GmbH
Aqua-Chem, Inc.
Aquafine Corporation
ARS/Beverly Pacific Sterilizers
Burt Process Equipment, Inc.
Christ Nishotech Water Systems Pvt. Ltd.
Deltatec Pharma
DXC Consulting Ltd.
Farmatec Engineering Sdn Bhd
Filters, Water & Instrumentation, Inc.
Gemu Valves Limited
GMP Piping, Inc.
GMP SYSTEMS LTDA.
GMP Systems, Inc.
Hanovia
Heleon BV
Hydro-Thermal Corp
Idenor Ingenieria
Intempco Instrumentation
John Guest USA, Inc.
MECO
Mettler-Toledo Thornton Inc
Paul Mueller Company
Pick Heaters, Inc.
Praj Industries Limited
Pureflow, Inc.
Saint-Gobain Performance Plastics
Skytech Systems (I) Pvt. Ltd
SnowPure Water Technologies
Spirax Sarco
Spirax Sarco Ltd
Steriflow Valve, Div of Jordan Valve
Swan Analytical USA
Telstar North America, Inc.

Wet Chemical Analysis

Mettler-Toledo Thornton Inc

A & M Process Equipment Ltd.

Contact: John Lang, President
1801 Dundas St. E.
P.O. Box 70569
Whitby, Ontario L1N 9G3
Canada
johnlang@amprocess.com
www.amprocess.com
Tel: +1-905-619-8001
Fax: +1-905-619-8816

Manufacturer of sanitary dry powder mixing equipment including V-shell, Conical, Ribbon and Paddle blenders.

A+ Secure Packaging

Contact: Ronnie Smith, President and CEO
339 Mason Rd.
LaVergne, TN 37128
USA
ronnie.smith@apluspak.com
www.apluspak.com
Tel: +1-615-213-8283

A+ Secure Packaging is an FDA registered/inspected custom contract packager for the pharmaceutical, nutraceutical, animal health, medical device industries.

AAIPharma

Contact: Timothy R. Compton, Senior Director, Business Development
2320 Scientific Park Dr.
Wilmington, NC 28405
USA
services@aaipharma.com
www.aaipharma.com
Tel: +1-800-575-4224
Fax: +1-800-575-4224

Development, Manufacturing, Packaging and Material Testing Services.

ABB Control Technologies

Contact: George M Smith, Regional Channel Manager
29801 Euclid Ave.
Wickliffe, OH 44092
USA
george.m.smith@us.abb.com
www.abb.com/controlsystems
Tel: +1-770-335-8372

#1 global provider of control technologies to process industries. Extended Automation System 800xA; Essential Automation System Freelance 2013; Recorders, Controllers and HMI.

Absolute Handling Systems Ltd.

Contact: Sean Porter, Managing Director
Unit B3 Centrepoint, Rosemount Business
Blanchardstown
Dublin 11 Ireland
info@ahs.ie
www.ahs.ie
Tel: +353 1 8293520
Fax: +353 1 8293528

AHS design, supply, install, test and service GMP lifting and handling equipment. We supply high quality pharma user friendly equipment, which reduces the risk of operator injury.

Access Creative Group

Contact: Tom Fitzgerald, Owner
81 Walnut St.
Reading, MA 01867
USA
tomfitzgerald@accesscreativegroup.com
www.accesscreativegroup.com
Tel: +1-781-944-3101
Fax: +1-781-944-3324

We assist a wide range of clients in their marketing communications needs. Sub-specialty in cGMP labeling/printing/packaging and brand protection solutions for Life Science companies.

accumac Ltd.

Contact: Rod Aspden, Director
Unit E3
Fieldhouse Business Park
Rochdale, Lancashire OL12 0AA
United Kingdom
rodneya@accumac.co.uk
www.accumac.co.uk
Tel: +44 1706 718162

We specialise in the supply of quality pre owned tablet presses, technical support and training services. Our engineering services range from repair to full rebuild and GMP upgrades.

Ace Control Systems Ltd.

Contact: Denis O'Connor, Managing Director
Ballincollig Enterprise Park
Link Road
Ballincollig Ireland
doc@acecontrol.ie
www.acecontrol.ie
Tel: +353 21 487 3005
Fax: +353 21 487 5125

Ace Control Systems was founded in 1993 and today is recognised as one of Ireland's leading supplier of Building Energy Management Systems and HVAC Controls Systems Solutions.

Acquire Automation

Contact: Carrie Boink, Office Manager
9100 Fall View Dr.
Fishers, IN 46037
USA
sales@acquire-automation.com
www.acquire-automation.com
Tel: +1-317-849-3350
Fax: +1-317-849-0033

Acquire Automation provides vision inspection and custom equipment solutions, and automation services for Life Sciences, Food and Beverage, Consumer Goods, and numerous other industries.

Acro Associates

Contact: Winston Wong, Vice President, Sales and Marketing
1990 Olivera Rd., Suite A
Concord, CA 94520
USA
wwong@acroassociates.com
www.acroassociates.com
Tel: +1-925-676-8828

Acro Associates is a leading innovator of high performance fluid control systems for the medical device and bioprocessing markets.

company listing

Actlabs
Contact: Dan Williams, Life Sciences BD Manager
1348 Sandhill Dr.
Ancaster, Ontario L9G4V5
Canada
danwilliams@actlabs.com
www.actlabs.com
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ISPE Launches New Expanded E-Learning Courses

Continued.

Brief sample of course objectives:

- Understand the basic elements of biology important to biotechnology
- Discuss the basic scientific principles of the bioprocess
- Review biotechnology GMPs
- Describe key manufacturing facility design attributes
- Define biotech facility attributes

Containment Fundamentals

Duration: 2 Days (self-paced) **ISPE CEUs:** 1.3

Description:

This course focuses on airborne contaminants and discusses the definition, history, and rationale for the containment of compounds and processes. An exploration of different containment philosophies, methods of source containment, and a hierarchy of containment approaches will also be covered. The course also focuses on the importance of understanding a manufacturing process in all its dimensions (physical hardware, remedial containment provisions, facility considerations, operator interface, cleaning and decontamination, and other aspects) before optimal containment solutions are developed and incorporated into the manufacturing processes. In addition, the course addresses plant operations ranging from pilot scale to commercial manufacturing.

There are 2 modules within this course with 2-7 objectives in each.

Brief sample of course objectives:

- Definition, background, and fundamental concepts and risk
- Applying the Containment Hierarchy of Responses
- Containment applications
- Ongoing operations and relevant resources

GMP Auditing for the Pharmaceutical Industry

Duration: 2 Days (self-paced) **ISPE CEUs:** 1.3

Description:

This course addresses the critical function of auditing within

Concludes on page 84.

ISPE 2014 Drug Shortage Initiative

The mitigation and prevention of drug shortages is critical to public health. ISPE, as a not-for-profit global organization with both industry and regulator Members, is in a distinctive position to expedite communication within the pharmaceutical industry.

ISPE has announced multiple forums to address alleviating global drug shortages, as well as preventing the issues that initially lead to these shortages. The Society is committed to offer a series of educational sessions, training, and roundtable events that will benefit both industry leaders and regulators. The events will focus on the results of ISPE's 2013 Drug Shortages Survey and new pathways to improve processes with the potential to avert such a critical problem.

During our 2013 Annual Meeting, ISPE reported the possible connection between drug shortages and the lengthy Chemistry, Manufacturing, and Control (CMC) process. During the interactive part of the session, Captain Valerie Jensen, RPh, Associate Director for FDA's Center for Drug Evaluation and Research's (CDER's) Drug Shortage Program joined a panel hosted by ISPE for a question and answer session with the audience. This ISPE discussion panel, held just four days after the FDA's release of its Strategic Plan for Preventing and Mitigating Drug Shortages, is just the beginning of ISPE's commitment to this initiative. During all ISPE 2014 events, drug shortage sessions will be offered in order to explore all perspectives on the issue.

2014 Events

Industry Roundtable: Keys to Addressing Quality System Issues in Aseptic Manufacturing which May Lead to Shortages
ISPE Aseptic Annual Conference
24 to 25 February • Washington, DC, USA

Industry-Regulatory Roundtable: The Roles of Quality Culture and Regulatory Relationships in Preventing Shortages
ISPE Europe Annual Conference
28 to 30 April • Frankfurt, Germany

Plenary Session: Report of the ISPE Drug Shortages Task Force on Emerging Strategies for Preventing and Mitigating Shortages
and
Industry-Regulatory Roundtable: Implications of the Findings of the Drug Shortages Task Force
Pharmaceutical Quality Week
2 to 5 June • Washington, DC, USA

Industry Roundtable: IMPs and Drug Shortages
ISPE Investigational Products Conference
Date pending • Europe; City pending

Executive Session: Second Annual Report on ISPE Research Related to Preventing and Mitigating Drug Shortages
ISPE Annual Meeting
12 to 15 October • Las Vegas, Nevada, USA

Industry Roundtable: Facilities and Equipment Issues, the CMC Process, and Drug Shortages
The Conference at Pharma EXPO
2 to 4 November • Chicago, Illinois, USA

See more at: http://www.ispe.org/drug-shortage-events#sthash.agoZsmiq.dpuf.

...E-Learning Courses

Continued from page 83.

a pharmaceutical company. The course also examines the challenges of GMP and presents basic competencies required to effectively perform the auditor's responsibilities and improve performance. The course includes a supplemental module that provides guidance in preparing for regulatory GMP inspections and provides broad fundamental industry knowledge through a customized learning experience for individuals that want to expand their cGMP knowledge.

There are 6 modules and one supplement module in this course with up to 4 objectives in each.

Brief sample of course objectives:

- Define audits and preparations for an audit
- Explore auditor traits and skills
- Provide audit guidelines and timetable
- Provide guidance for managing findings and Exit Meeting preparation
- Review follow-up activities and problem solving tools
- Review inspection points to consider in auditing
- Preparing to host a regulatory GMP inspection
- Preparing for activities before and after the inspection

ISPE's Facility of the Year Program...

Continued from page 81.

tion that distinguishes a company's innovative facility apart from all others. The judges' panel will adhere to the schedule included in the submissions packet and will consider the quality of the submission not the quantity of information submitted. The judging team at their discretion may choose a special recognition facility that is not included within the group of category winners.

Award Categories and Definitions

Process Innovation
Application of novel process manufacturing techniques on existing and new facilities, including fundamental scientific processing approaches and related applied science-based solutions to existing and new challenges.

Project Execution
Application of novel tools and approaches to delivering projects that improved efficiencies, overcame unusual challenges, promoted effectiveness, and organized stakeholders and project team participants in ways that led to successful outcomes.

Equipment Innovation
Novel application of commercially available and custom developed process manufacturing and facility management tools, which yielded superior results, advanced processing understanding, improved competitive position, and imaginative collaboration with vendors/suppliers/manufacturers.

Facility Integration
Application of good design practices and superior conceptual planning, which led to excellent integration of facility and process, yielding efficient, clean, pleasant environments promoting business advantages for staff and enterprise, encouraging excellent processing outcomes. Synergistic merging of process and building to create environment of form and functional excellence.

Concludes on page 94.

ISPE Contributes to FDA Strategic Plan

SPE's June 2013 report on the Society's Drug Shortages Survey was cited twice in the newly published Strategic Plan for Preventing and Mitigating Drug Shortages released in October by the FDA.

The initiative of ISPE's survey reported conclusions on the prevention and mitigation of drug shortages. As a key stakeholder in the global pharmaceutical industry, ISPE believes that efforts in addressing the complex problem of drug shortages that directly affect patient health requires technical collaboration and clear communication between the pharmaceutical industry and global authorities.[1]

> *"The initiative of ISPE's survey reported conclusions on the prevention and mitigation of drug shortages.*

ISPE formed a Drug Shortage Task Force (Task Force) to assist stakeholders in identifying root causes for global drug shortages and define mitigation strategies to prevent supply disruption. The Drug Shortage Task Force understood there were many factors that may impact drug shortages. Given ISPE's technical expertise, the Task Force decided ISPE would focus on manufacturing and quality issues, which according to the FDA was the most significant cause (47%) for drug shortages.[2]

The ISPE Task Force developed and launched an anonymous survey conducted between February and March 2013 to identify root causes of manufacturing and quality problems that historically led or potentially could lead to drug shortages. The survey collected data from 175 individual participants and 37 companies from around the world totaling 212 contributions taken from actual shortage experiences - Figures 1 and 2.[1] The Task Force also requested participants to contribute possible solutions manufacturers and regulators may wish to adopt to help prevent future shortages.

The survey questions focused on elements of pharmaceutical quality systems included in inspection programs and outlined in the International Conference on Harmonization (ICH) guidelines. ISPE's Task Force also attempted to investigate the limited data of sub-elements within quality systems that may be overlooked when searching for shortage solutions.

ISPE's survey found no single technical or manufacturing cause for drug products, but data analysis concluded:

- Breakdown in manufacturing quality systems can contribute to drug shortages.
- Companies with no history of shortages focus on strong quality systems and company leadership.
- Improvements within regulatory interaction can mitigate the potential shortages.[2]

In the first section of the FDA's *Strategic Plan for Preventing and Mitigating Drug Shortages*, ISPE is cited in section one which discusses the understanding and response to drug

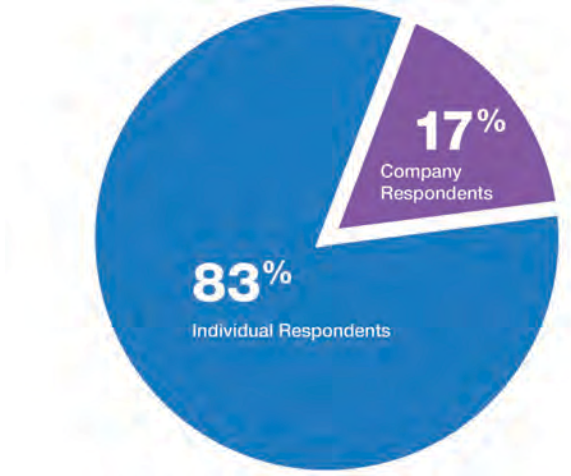

Figure 1. Respondents experiencing a shortage or near miss.[1]

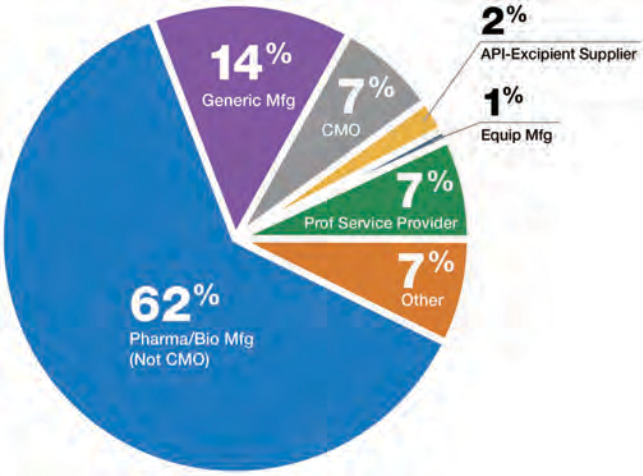

Figure 2. shortage/miss respondents by company type.[1]

ISPE Contributes to FDA Strategic Plan

Continued.

shortages. ISPE's conclusion that remediation efforts can lead to short-term risks, but are balanced by improvement expectations and a long-term, stable manufacturing capacity was used to support the FDA's identification of factors that trigger quality disruptions.[1-3]

The survey revealed potential opportunities to understand the causes of drug shortages and advance the industry's perspective.

The FDA also referred to ISPE in its second task that covers increasing knowledge and developing new strategies to address shortages. They outlined their intention to work with ISPE to analyze data in the *Report on the Drug Shortages Survey*. The FDA found significance in ISPE's information regarding technical, scientific, manufacturing, quality, and compliance issues found through the survey's participants who have actually experienced drug shortages.[1-3]

One of the main initiatives in the FDA's attempt to prevent drug shortages is clear communication from industry stakeholders.[3] ISPE is pleased to contribute to such a critical aspect of patient health and global well-being. The survey revealed potential opportunities to understand the causes of drug shortages and advance the industry's perspective. Since the initial publication of ISPE's findings, the Task Force has continued to investigate this important matter. ISPE will discuss its survey findings and present new findings at events scheduled throughout 2014.[1]

References

1. Berg N, Kos K, et al. *Report on the ISPE 2013 Drug Shortages Survey*. June 2013. Tampa, FL: International Society for Pharmaceutical Engineering. Available at http://www.ispe.org/drugshortages/2013JuneReport.
2. Susie Dill RN, B.S.N. 2012. "Overview of U.S. Drug Shortages." FDA: Webinar.
3. Food and Drug Administration. 2013. "Strategic Plan for Preventing and Mitigating."http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf.

FDA Strategic Plan Summary

The following is a brief summary of the US Food and Drug Administration Safety and Innovation Act signed into law for the purpose of relieving drug shortages and assuring the overall health of patients in need.[1]

Introduction

Following a Presidential Executive Order, government representatives enacted The Food and Drug Administration Safety and Innovation Act (FDASIA) on 9 July 2012.[2] Under this new law, Congress provided the FDA authority to contend with drug shortages in the US, as well as establishing new standards requiring manufacturers to notify the FDA of any potential issues resulting in shortages or disruptions in supply. Prior to FDASIA, manufactures aware of drug shortages for serious conditions were required to notify the FDA, but all other potential disruptions were reported on a voluntary basis only.[1]

Preventing disruptions in drug supplies is a top priority for the FDA. Drug shortages are prominent in treatments from life-saving antibiotics to intravenous treatments, such as chemotherapy. Practitioners have been faced with denying needed care or prescribing alternative therapies to patients that may be less effective. Drug shortages also have disrupted delayed research and development of new therapies. The FDA readily acknowledges their position to lower any public health threat due to manufacturing disruptions and assure ample drug supplies for those patients with a critical need.

Causes of Drug Shortages

A drug shortage is most likely the result of a manufacturing disruption. If no other manufacturer can alleviate the discontinuance or interruption with an increase in production, a shortage will occur.[3] A manufacturing disruption can be caused by several issues, such as a natural disaster, a discontinuation of an unprofitable product, product failures, or a compromise in facility quality. As shown in Figure 1, disruptions due to quality issues are almost two-thirds of the total source of shortages. A failure in area sterility, mold growth, or unsterilized containers are common issues that shut down production due to the high risk for patient safety. Shutdowns in manufacturing due to overall facility quality has not shown a great change; however, since 2011, there has been a decline in the number of shortages related to a specific product.

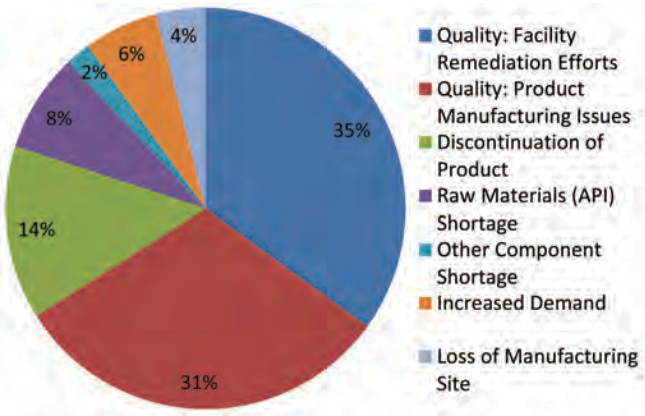

Figure 1. Drug shortages by primary reason for disruption in 2012 (Source: Data from FDA's internal drug and biologics databases).

Current FDA Efforts

Preventing or mitigating drug shortages begins with immediate notification to the FDA of any potential supply disruptions. The FDA will then evaluate the risk, impact, and strategies needed to prevent or alleviate the shortage. Manufacturers must alert the FDA as soon as possible, so any specific response can be coordinated between the manufacturer, professional organizations, interest groups, and health care professionals through FDA channels.

Assessing Risk Shortage

As part of assessing a drug's risk shortage, the FDA will prioritize any response by determining if the drug is considered medically necessary in order to treat or prevent a serious disease or condition. Alternate therapies and off label inventories are also taken into account. Once the risk of a shortage has been verified, the FDA may take the following steps:

- Collect information through a market research database to establish the stability of the product's current supply
- Collect all up-to-date inventory counts, demand rates, production schedules, and ordering patters
- Predict a shortage's development by evaluating inventory in the distribution chain

Alleviating Imminent Shortages

Once a drug has been identified as medically necessary and shortages are imminent, the FDA may seek to develop new options or use the following mitigating tools:

- Determine other manufactures with the capacity to increase production
- Expedite inspections and submission reviews
- Implement temporary discretions for new sources
- Participate in a manufacturer's exploration of shortage causes
- Assist with mitigating processes of a product not meeting standards

Concludes on page 92.

Pharmaceutical Engineering Expands Technical Focus, Seeks Contributors

Pharmaceutical Engineering is looking for subject matter experts in the global pharmaceutical industry with knowledge of the latest scientific and technical developments, regulatory initiatives, and innovative solutions to real life problems and challenges who can contribute application articles and case studies. Special features and guest editorials will be considered that focus on new technology, contemporary quality management practices, and production innovation.

New Departments include: facilities and equipment, information systems, product development, production systems, quality systems, research and development, supply chain management, and regulatory compliance. In addition to the Departments, each issue will feature a cover story or lead article on industry relevant hot topics, including biosimilars, breakthrough therapies, next generation manufacturing, quality metrics, quality risk management, supply chain integrity, and sustainability.

JULY/AUGUST 2014
Cover Story/Lead Article: Next Generation Manufacturing
Manuscripts Due: 6 March 2014
Publishes: 21 July 2014

SEPTEMBER/OCTOBER 2014
Cover Story/Lead Article: Quality Metrics in Pharmaceutical Manufacturing
Manuscripts Due: 8 May 2014
Publishes: 22 September 2014

NOVEMBER/DECEMBER 2014
Cover Story/Lead Article: Risk Management Strategies when Outsourcing Manufacturing
Manuscripts Due: 9 July 2014
Publishes: 24 November 2014

For more information, please visit **www.pharmaceuticalengineering.org** and click on **Submit Article.**

ISPE 2013 Annual Meeting Highlights

ISPE's 2013 Annual Meeting in Washington, DC was an overwhelming success bringing together more than 1,600 industry and regulatory attendees to discuss pharmaceutical industry challenges and potentials. Industry peers and pharmaceutical experts explored new ideas and shared significant information during in-depth educational sessions, training courses, and networking events.

The Plenary Session

FDA CDER Director Janet Woodcock and Baxter's Julie Kim had the annual meeting off to a lively start. Dr. Woodcock announced a reorganization of the FDA scheduled to take place next year. The restructuring includes the creation of the Office of Pharmaceutical Quality (OPQ) and Woodcock's vision of a pharmaceutical industry focused on quality and requiring minimal regulatory insight. ISPE is working with the FDA on metrics which will lead to increased manufacturing freedom while attaining consistent high quality products and processes.

Julie Kim underlined the importance of investing in manufacturing driving toward the goal of optimal patient health. Kim discussed Baxter's billion-dollar Covington, Georgia manufacturing facility and its potential to aid Alzheimer's patients and those with primary immunodeficiency disorders.

This year's Plenary Session also welcomed our new 2014 Incoming Chair, Damian Greene. He spoke about ISPE as a long-established leader in building knowledge, expertise, and industry dialogue in addition to his vision for ISPE's next year of growth.

Novartis was announced during the plenary session as ISPE's Facility of the Year Award winner. Their public-private partnership facility in Holly Springs, NC was honored for its innovative new cell-culture technology and facility flexibility with flu vaccine manufacturing.

Educational Sessions Aplenty

This year's ISPE Annual Meeting featured more than 50 sessions, the most educational opportunities at an ISPE annual conference to date. The Quality Metrics session were popular among industry professionals. Cindy Salamon from Bristol-Myers Squibb and Russ Wesdyk from the FDA discussed ideas for acceptable metrics related to batch failure rates and OOS/lab failure rates.

ISPE's Research Initiative session was also heavily attended as ISPE released its first ever patient survey results related to their experiences with clinical trials. ISPE also shared their Drug Shortage Initiative, which was recently cited in the FDA's *Strategic Plan for Preventing and Mitigating Drug Shortages*. A panel discussion outlined ISPE and FDA joint efforts and ISPE's plan to bring industry professionals together during its event in 2014.

Zimmer Named ISPE Vice President of European Operations

ISPE has named Dr. Thomas Zimmer to the newly-created position of Vice President of European Operations. This new opportunity will allow ISPE to develop strategic business models and advance operations in Europe. Dr. Zimmer as the new VP of European Operations, fills the role of Europe's regional head, working under the direction of Nancy S. Berg, President and CEO of ISPE.

Dr. Zimmer will be the new ambassador in Europe, representing ISPE in building a stronger presence and professional relationships with members of the life science industry. He will establish a new European office and work closely with an advisory team of industry representatives, regulatory organizations, and Member groups. This team will carry out ISPE's European business objectives while coordinating all operations with ISPE global Headquarters in Tampa, as well as other regional offices. With Dr. Zimmer's strong pharmaceutical foundations and industry relationships, ISPE is confident in Europe's potential for effective implementation of the Society's strategies, plans, and priorities.

Zimmer joins ISPE with a PhD in pharmaceutical technology and more than 30 years of pharmaceutical experience. He is a licensed pharmacist, a Qualified Person, and an ISPE member since 2005. Prior to becoming ISPE's VP of European Operations, Dr. Zimmer held a senior vice-president post at Boehringer Igelheim. He spent 32 years with the company gaining industry expertise in development, production, quality, and supply chain operations.

ISPE members may be familiar with Dr. Zimmer from his contributions to the ISPE Regulatory and Compliance Committee, ISPE's International Leadership Forum, and his other wide range of advisory posts within the pharmaceutical industry. ISPE welcomes Dr. Zimmer's knowledge and recognizes his experience as a great asset in continuing to offer influential solutions to the pharmaceutical and biopharmaceutical industries around the world.

...Annual Meeting Highlights

Continued.

The Breakthrough Therapies talk was an Annual Meeting stand-out. Prior to the meeting, the FDA announced its first breakthrough designation which was conferred on Genetech's Gazyva, a medication for chronic lymphocytic leukemia. A member of the Genentech team involved with the Gazyva Breakthough gave first hand observations of the Therapy sessions in addition to insights from the FDA.

An Industry Priority

Rob Wright, the editor for Life Science Leader, attended the ISPE Annual Meeting for the first time this year. Shortly after, he published a piece entitled, *Why Pharma Execs, Not Just Engineers, Should Attend ISPE*. This article is significant in promoting ISPE as a premier educational resource and facilitator in the pharmaceutical industry. The article reviews the industry-leading sessions he attended and his takeaway observations on why ISPE Annual Meetings should be an industry priority.

Not only did the ISPE Annual Meeting provide multiple topics for industry professionals on the pursuit of new pharmaceutical manufacturing knowledge, the Society also strategically planned networking opportunities. ISPE proudly credited the Society's achievements, future endeavors, and formally recognized specific Members who've made significant contributions in 2013. As billed, ISPE's Annual Meeting was definitely one of the industry's most significant events of the year bringing together top-level speakers, regulators, and pharmaceutical professionals all with the ultimate goal of manufacturing pharmaceuticals with the highest possible quality.

...Honor Awards 2013

Continued from page 79.

- The **International Student Poster Competition Awards** honor the top undergraduate and graduate student posters. The finalist won competitions earlier in the year and were selected by judges at the Annual Meeting.

  Kassi Stein accepted her award as ISPE's 2013 Undergraduate winner. Stein is from the Northeastern University, Boston Area Chapter.

  Vinu Krishnan from the University of Delaware, Delaware Valley Chapter was honored as ISPE's 2013 Graduate winner.

FDA Strategic Plan Summary

Continued from page 88.

The FDA is driven to meet patient demands by employing mitigating steps to increase supply, but standards for patient safety, efficacy, and quality will not depreciate based on inventory needs.

FDA's Strategic Plan

The FDASIA required FDA to develop and submit a strategic plan to Congress. This plan should outline the FDA's ability to address drug shortages. In response, the FDA established a Task Force concentrated on two core goals.

GOAL 1: Strengthen Mitigation Response

- Streamline Internal FDA Processes
- Improve Data and Response Tracking
- Clarify Roles and Responsibilities of Manufacturers
- Enhance Public Communications about Drug Shortages

GOAL 2: Develop Long-Term Prevention Strategies

- Develop Methods to Incentivize and Prioritize Manufacturing Quality
- Use Regulatory Science to Identify Early Warning Signals of Shortages
- Increase Knowledge to Develop New Strategies to Address Shortages

Contributions of Other Stakeholders

Successful strategies in preventing and alleviating drug shortages must be a collective effort of all stakeholders. The FDA has identified four key areas that should be considered for their potential to reduce drug shortages.

1. The FDA is limited with the economic means to promote innovation. Advances in discovery and development must have economic incentives. Manufacturing processes must move beyond outdated facilities and keep pace with advances in technology.
2. The FDA is committed to releasing quality information, but the buyer ultimately decides what product to purchase. Historical quality, recalls, and shortages are available and should be taken into account when purchasing. If purchasing decisions are made from a quality viewpoint, this may drive manufacturers to invest in maintaining quality rather than reducing costs which contributes to shortages.
3. The FDA cannot require a manufacturer to maintain a certain level of product or influence business decisions that cease manufacturing. Industry stakeholders may look to considered incentives to build redundancy, hold spare capacity, and increase inventory levels which could lower the risk of shortages.
4. The FDA has limited data on the downstream distribution of approved products, also called gray market. Manufacturers with extra product may collect it and sell at higher market price. This in turn, may open the opportunity for counterfeit products which highly increase safety risks and exacerbate the impact of existing shortages.4 Stakeholder actions to minimize gray market activities could play a role in mitigating the impact of shortages therefore, reducing patient risk.

Dialogue between the FDA and manufacturers is critical in preventing drug shortages. The FDA with the involvement of the President and Congress, has taken early shortage alerts and managed its resources to prevent at least 280 shortages in 2012 - *Figure 2*. Behind all of the industry statistics and findings, lie the patients depending on drug products for life-threatening diseases and infections. Preventing drug shortages continues to be a top-priority for the FDA and manufacturers who hold patient health in high regard.

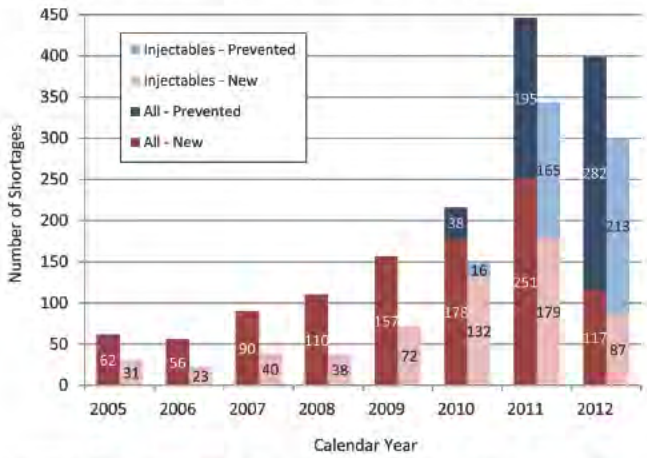

Figure 2. New drug shortages and prevented shortages by year (Source: Data from FDA's internal drug and biologics databases).

References

1. Food and Drug Administration. 2013. "Strategic Plan for Preventing and Mitigating." http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf.
2. Public Law 112-144: "Food and Drug Administration Safety and Innovation Act" (126 Stat. 993; Date: 7/9/12). http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf
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4. Susie Dill RN, B.S.N. 2012. "Overview of U.S. Drug Shortages." FDA: Webinar.

ISPE Europe Annual Conference

28-30 April, 2014 - Frankfurt, Germany

Driving Effectiveness in Pharmaceutical Operations within the New Quality Culture

As part of the global ISPE perspective, the first ISPE Europe Annual Conference will provide an overview of regulatory trends in Europe and in the rest of the world, and will connect the evolution of the pharmaceutical industry with regulatory market and technological developments.

This inaugural Annual Conference in Europe will bring together high-level top executives and pharmaceutical, regulatory and technology experts from around the world to contribute to the creation of a new pharmaceutical paradigm.

Chaired by

Dr Gabriele Wanninger, from the Bavarian Inspectorate

Jean-François Duliere, Pharmaceutical Process Technologist, Technip Life Sciences

Thomas Zimmer, PhD, VP Technical Operations, EuropeInternational Society for Pharmaceutical Engineering – ISPE (Executive Forum)

The Conference will feature:

- An **Executive Forum** to discuss the implementation of the Falsified Medicines Directive, especially with respect to the status of the Delegated Acts of the European Commission and to Mass Serialization. As a second topic, a representative from McKinsey will conduct an interactive session on current challenges for technical operations. Finally, there will be an update on Drug Shortages.
- **Three tracks** with panels of international, senior experts, industry executives and regulatory professionals:
  - Track 1: QbD – Reality Today? Implementation and Beyond
  - Track 2: Quality Risk Management (QRM)
  - Track 3: Pharmaceutical Facilities of the Future
- Educational sessions
- Interactive demonstration workshops
- Practical case studies
- Q&A sessions

Who should attend?

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ISPE Biopharmaceutical Manufacturing Facilities Guide

The first edition of the ISPE Biopharmaceutical Manufacturing Facilities Baseline Guide was issued in June 2004. The concepts developed at that time have been accepted and implemented in a phased approach over the years.

Since its issue, the Industry, processing technology and views to manufacturing have significantly matured. This second edition Guide defines the current Industry facility design benchmarks and discusses industry trends, including Future Facility and Flexible Facility concepts.

The Guide addresses the many factors that drive current facility designs, including smaller batch sizes with higher titers, single use systems, process closure technologies and the need for production flexibility. Perhaps the factor with the greatest impact on facility design is the application of closed processing technology on a majority of the process operations. Closed processing fully segregates the product from the room environment. As a result, aspects of the room environment are no longer Critical Process Parameters (CCPs) to the Croduct Quality Attributes (CQAs). Environmental particulates and viables do not impact the product and this can eliminate the need for classified environments for fully closed systems. This decoupling of the product from the facility allows for new and innovative facility design solutions, including multi-product production in the same processing room and production in controlled non-classified (CNC) environments.

Additional Key concepts discussed in the Guide:

- Regulatory support of production ballrooms from the January 2013 PIC/S CGMPs
- Process Closure definitions, closure discussions and sample Risk Assessment tools
- An overview of how traditionally designed production facilities with open processing, classified room environments and flows designed to reduce the "challenge" to that environment can adapt to the introduction of process closure.
- Discussion and examples of how these concepts readily apply to new construction and facility retrofits facilitating flexibility, increased production capacity and facility re-purposing.

This Guide defines the interconnectivity between product exposure and facility design and presents the CGMP facility design continuum from exposed product production facilities to Flexible and Future Facilities.

ISPE's Facility of the Year Program...

Continued from page 85.

Sustainability
Application of novel approaches, tools, and techniques intended to improve effective use of energy, minimize waste, reduce carbon footprint, incorporate green manufacturing techniques, reduce environmental impact, and result in more efficient processing, utilities support, and business advantage.

Operational Excellence
Application of modern management techniques aimed at improving operational efficiencies, promoting quality, ensuring consistency and yielding competitive cost of goods from existing and new facilities, processes, and manufacturing operations.

ISPE is looking forward to a new decade of pharmaceutical and biopharmaceutical innovations. Expanding FOYA's presence will distinguish industry merits and offer innovative facilities an opportunity to lead through award winning examples. Please visit the ISPE website to download the submissions packet and join your industry peers in advocating innovative manufacturing practices through the prestigious FOYA program.

Contact

For questions about the Facility of the Year Awards program, please contact Michael Phelan, at tel: +1-813-960-2105 or by email: mphelan@ispe.org.

If you are interested in advertising in the Facility of the Year Special Supplement of *Pharmaceutical Engineering* magazine, or to sponsor this web site, please contact John Phillips at tel: +1-813-739-2292 or by email: jphillips@ispe.org.

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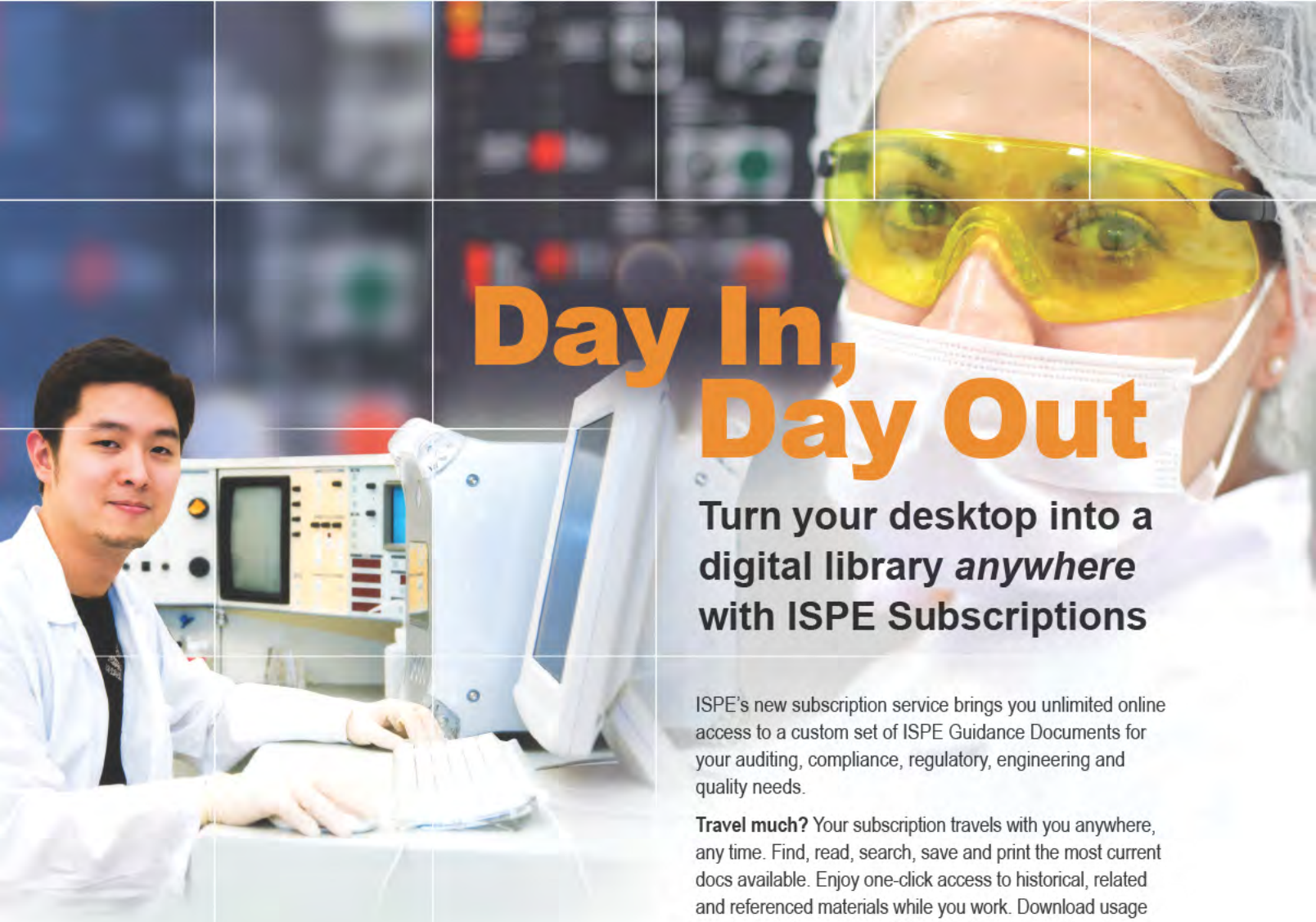

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