The Official Magazine of ISPE

Supplement to

PHARMACEUTICAL ENGINEERING®

May-June 2016

RECOGNIZING INNOVATION. BY DESIGN.

FOYA 2016

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2016

China ISPE Facility Award
for Process Innovation
Sanofi Minsheng Project
Hangzhou, China

2015

ISPE Facility of the Year Award
for Project Execution
AstraZeneca Supply Site Project
Taizhou, China

Applauding an Industry That Cares about Sustainability

As a healthcare company, Johnson & Johnson understands the connection between environmental health and human health. That is why we have been setting public environmental goals since the early 1990s, have made many investments to support our sustainability goals, and aspire to power our facilities with 100% renewable energy by 2050. Against this backdrop, we are very proud that ISPE has chosen to recognize our energy and water savings efforts at our San Lorenzo, Puerto Rico, facility with a 2016 Facility of the Year Sustainability award.

Kathy Wengel, Worldwide Vice President
Johnson & Johnson Supply Chain
Management Committee Member

Category Winners

A remarkable number of pharmaceutical and biotechnology companies made it onto *Newsweek's* annual ranking of the top green companies worldwide in 2015. Biogen captured the top spot on the list, which recognizes corporate sustainability and the environmental impact of the world's largest companies, while industry leaders Shire, Allergan, Roche, Novo Nordisk, Johnson & Johnson, and AstraZeneca were also named.[1] These are companies that have discovered the payoff that comes from embracing sustainable manufacturing and building practices that minimize energy and water use, greenhouse gas emissions, and waste generation.

That such a list of green leaders is filled with pharmaceutical and biotechnology firms should come as no surprise, given that many of them have recognized the importance of the triple bottom line: financial, social, and environmental.[2] Johnson & Johnson is but one company with a sustainability program that extends to its sourcing of raw materials, CO_2 emissions, water use, and its pursuit of alternative energy sources.

Corporate sustainability policies are being mandated by some governments, while market regulators and investors are encouraging or requiring public companies to measure and report sustainability metrics.

Here at ISPE, beyond what is expected or mandated, we know that sustainability makes sense for our industry: It makes economic and environmental sense, and it is socially responsible. In fact, we recently published our first Sustainability Handbook to serve as a global pharmaceutical sustainability baseline for the life sciences industry. We are proud to point out advances that are being made by our members in sustainability. This year's slate of FOYA winners demonstrates a commitment to develop innovative practices that underscore the importance of sustainability to our industry.

Companies are seeing benefits in their bottom lines by choosing to reduce greenhouse gas emissions, generate energy from renewable resources, use less water, and create less waste. One of these is this year's FOYA winner in the sustainability category, Ethicon, LLC, which won for its facility in San Lorenzo, Puerto Rico. With energy savings of 26%, water reduction of 9%, and an 11% increase in production compared to 2010, this project exemplifies that environmental care can be paired with economic benefits.

Industry groups are addressing these sustainable manufacturing processes. The Pharmaceutical Supply Chain Initiative released its "Pharmaceutical Industry Principles for Responsible Supply Chain Management" and PhRMA is one group that is investigating the troubling phenomenon of residual drugs in the environment.

Green chemistry is known to reduce costs, provide innovation, and help the environment. The American Chemical Society Green Chemistry Institute Pharmaceutical Roundtable has been encouraging innovation and the integration of green chemistry and engineering in pharmaceutical

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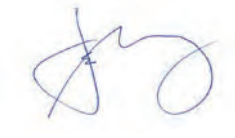
manufacturing for the past 11 years. Winners of a US Presidential Green Chemistry Challenge award, for such work as designing drugs that biodegrade more easily and thus do not persist in the environment, are Bristol-Myers Squibb, Eli Lilly, Merck, Roche, and Pfizer.[3] The European Chem21 Project was launched as a public-private partnership—and led by GlaxoSmithKline—to encourage the manufacture of sustainable drugs, specifically seeking alternatives to precious metal catalysts.[4]

There are also exciting developments in sustainable building practices in the design, construction, and running of facilities, with companies advertising their green stripes through the use of LEED certification. Genzyme has 10 LEED-certified buildings, GSK's US headquarters was awarded Double LEED Platinum, Shire has a LEED-certified single-use system manufacturing facility, Alexion Pharmaceuticals received LEED Gold certification for its headquarters in Connecticut, and Johnson & Johnson has 29 LEED-certified buildings, including the corporate headquarters of Janssen Pharmaceuticals.

Firms are taking the initiative to reduce their environmental footprints by embracing green energy sources such as wind and solar. Renewable energy pioneers Biogen, Novo Nordisk, and J&J are part of RE100, companies that are leading the way by setting a date by which they commit to meet all of their electricity needs from renewable resources.

GSK, Janssen, and DePuy Synthes have partnered to erect wind turbines to provide much of the electricity needs of their facilities in Cork, Ireland, while substantially reducing CO_2 emissions. Sanofi has built a large windmill at its facility in Ankleshwar, India, that provides 30% of the facility's electricity and will pay for itself within six years. Janssen's facility in Titusville, New Jersey, gets almost 85% of its electricity from an enormous array of solar panels. An innovative application is using solar instead of diesel fuel to generate power for steam, drying, and fermentation by Ram Pharma in Jordan.

While there is only one FOYA awarded for a project that epitomizes sustainability, this dedication to develop and implement innovative solutions that enhance the sustainability of pharmaceutical manufacturing shows that ISPE's members care. While keeping an eye on their need to be successful, they never lose sight of the well-being of their customers and of the environment we all share.



John E. Bournas
ISPE president and CEO

[1] Newsweek. "Top Green Companies in the World 2015." *Newsweek Online*. http://www.newsweek.com/green-2015/top-green-companies-world-2015
[2] Hutchens, C. "History and Relevance of Sustainability to the Pharmaceutical Industry." *Pharmaceutical Engineering*. Jan.-Feb. 2016. pp. 40-43.
[3] EPA – Presidential Green Chemistry Challenge Winners. http://www.epa.gov/greenchemistry/presidential-green-chemistry-challenge-winners
[4] Chem21. http://www.chem21.eu

FOYA 2017

Facility of the Year Awards

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The Challenges for FOYA Judges

The ISPE Facility of the Year Award (FOYA) sponsored by the International Society of Pharmaceutical Engineers (ISPE) has been in existence for 12 years. Each year a group of 10 to 15 leaders in the pharmaceutical industry meets to judge the submissions for these awards. These judges hail from leadership positions across many owner organizations from all regions of the world, and represent both small and large companies within the pharmaceutical or medical device global industries. All have extensive experience in their fields—engineering, manufacturing, and quality; most have global responsibilities. Several members of the judging team have lived or worked outside their native countries.

The FOYA award was initiated to recognize the outstanding efforts of project teams committed to delivering lifesaving medicines to patients and customers around the world. The annual FOYA forum celebrates the great teams that execute these projects and exposes the industry and ISPE Members to new technologies or methodologies.

As the judges review the submissions, they are always looking for new and innovative equipment, processes, or project methodologies to advance the pharmaceutical and medical device industries' ability to provide customers with high-quality, cost-effective products and timely delivery.

Over the years FOYA has developed awards in the following categories:

1. Process Innovation
2. Equipment Innovation
3. Facility Integration
4. Project Execution
5. Sustainability
6. Operational Excellence

James Breen
FOYA Judging Committee Chairman

Photo: Yossi May, Washington Talent

The categories have and will continue to evolve as ISPE responds to the needs and focus of the industry. In March 2016 the FOYA committee announced a new award category focused on the "Facility of the Future" to highlight emerging trends in manufacturing and data technologies.

The judging season starts in January with a one-day meeting to review the FOYA candidates, which are submitted directly to ISPE in the fourth quarter of the preceding year. The submissions come from around the world and represent projects in the pharmaceutical, medical, or biologic fields. The judges have the opportunity to select a project for each of the awards, if they believe a project demonstrates excellence in each of the categories. If the judges do not identify a project that demonstrates excellence in any one category, they will not award the category that year.

The judging committee has the opportunity to review each submission prior to the preliminary meeting in January to review and consider all FOYA submissions. Each judge arrives with an individual shortlist of projects by category, and will use his or her way of rating the projects in terms of cost, schedule, safety, and capability based on their experience and industry knowledge. The judges' team has a set template to help guide them to catalogue their thoughts, but each judge has the freedom to use his or her expert judgment

in the initial review of each project. This "pre-review" will leverage the judges' experience in engineering, manufacturing, quality, and supply chain competencies. They use their technical expertise to assess the submitted brief to determine if the project is leading-edge from a technology point of view, benchmarking from a cost and schedule point of view, and whether it leverages the strengths of the project team.

At the initial committee meeting, the judges review each submission and discuss the merits of each project within their submitted category, as well as whether those projects could qualify for other categories within the FOYA award portfolio. This process allows for much dialogue on the overall project, each judge's thoughts regarding the overall project, and if the project, in his or her opinion, was novel. The judges have the opportunity to exchange trends and ideas on the direction of the industry. The process leverages the entire judging team's knowledge of the industry as each company is typically at a different stage of a technology development, focused on different technologies or products, or on specific geographical areas of the world.

At this stage the judges use their collaborative experience to assess whether the proposed project meets the requirements as outlined in the overall FOYA award, and if it qualifies for one of the subcategories. After screening for compliance with the program requirements, the judges use their broad experience to understand the overall project: Do the proposed costs and schedule seem reasonable and did the project team clearly articulate the accomplishment and the business value for the overall outcome outlined in the project paper? The judges will also use their collective internal and external networks to benchmark the project information to ensure outcomes as stated were actually achieved.

One of the judges' major focus areas is to ensure that safety is top of mind for the project teams during execution, so they carefully review the safety portion of the submissions in terms of "days away, restricted or transferred," total recordable injury rate, and the overall tone of the safety culture of the project team. This leverages the judges' experience in recognizing that projects with strong safety performance will have better overall performance.

The overall FOYA award is determined by the judges from one of the subcategory winners for that year. This selection involves several rounds of discussions, followed by a few secret ballots to determine the overall winner. Once the winners are selected the judges are sworn to secrecy until the category winners are announced by ISPE, and the overall winner is announced at the ISPE Annual Meeting in the fall.

Judges also have the option to award special recognition to projects that do not win a specific category, but were clearly successful projects that overcame significant challenges to planning, execution, and delivery. Special recognition is typically given to projects in new technology or in challenging regions of the world.

One myth that I know all the judges would like to dispel is that only large complex projects win these awards. Nothing could be farther from the truth—the judges discuss this topic as they review the submissions. All would agree that the majority of projects are small projects to improve quality, are part of cost-improvement projects, transfer in new products, or implement new information technology solutions. The judges all understand that these types of projects are critical to the success of the business at each facility, so we do focus and award smaller projects that have a good return.

I have led the FOYA Judging Committee for the past three years and I have found it to be a wonderful experience for me, from both a personal and professional point of view. Having a group of leaders at these sessions allows us to share the recent trends in the industry, discuss the lessons learned from these projects, and discuss how we can communicate these best practices across the entire ISPE membership to advance the industry. I have learned a great deal judging these projects from a technology and project management point of view, which allows me to perform my duties for my employer better and more efficiently, while leveraging the latest trends in industry. I believe each ISPE FOYA judge would claim this same benefit.

Finally, we all enjoy working within an industry that improves the lives of our patients each day. To continue this mission as an industry, we need to strive to improve our performance each and every day; FOYA allows us to recognize the effort of those that do.

James Breen
FOYA Judging Committee Chair
VP Worldwide Engineering-Technical Operations
Johnson & Johnson

Facility of the Year Awards

2016

Baxter BioPharma Solutions
Operational Excellence
Solutions Oncology Manufacturing Expansion
Halle (Westfalen), Germany

Ethicon, LLC
Sustainability
San Lorenzo Conservation Strategy
San Lorenzo, Puerto Rico, US

Genentech, a Member of the Roche Group
Process Innovation
CCP2 Return to Service
Vacaville, California, US

Janssen Vaccines AG
Project Execution
ZEBOV in B81J
Bern, Germany

Pfizer Inc.
Equipment Innovation
PCMM: Portable, Continuous, Modular, and Miniature
Groton, Connecticut, US

Takara Bio Inc.
Facility Integration
Center for Gene and Cell Processing Construction Project
Kusatsu, Shiga, Japan

Greater Pharma Manufacturing Co. Ltd
Honorable Mention
New Facility
Bangkok, Thailand

University of Strathclyde, CMAC
Honorable Mention
Technology & Innovation Centre
Glasgow, Scotland

West Pharmaceutical Services, Inc.
Honorable Mention
Ready-to-Sterilize (RS) Expansion
Kinston, North Carolina, US

2015

Astellas Pharma, Inc.
Equipment Innovation
Tube Packaging and Labeling Equipment Project
Kerry, Ireland

AstraZeneca China
Project Execution (Overall Winner)
Market Supply Solid Dose Facility
Taizhou, China

IDT Biologika GMbH
Facility Integration
Biologics and Vaccines Production Facility
Dessau, Germany

Pharmalucence Pharmaceuticals
Honorable Mention: Execution and Entrepreneurial Spirit
Construction of New Aseptic Filling Facility
Billerica, Massachusetts, US

2014

Boehringer Ingelheim Pharma GmbH & Co. KG
Equipment Innovation
Aseptic Area 5 and Combi Line Facility
Biberach, Germany

F. Hoffmann – La Roche Ltd.
Sustainability
B250-Q2K Facility
Kaiseraugst, Switzerland

Grifols Therapeutics Inc.
Project Execution
Grifols North Fractionation Facility
Clayton, North Carolina, US

Patheon Pharma Services (formerly DSM Biologics)
Process Innovation
Biologics Plant of the Future
Brisbane, Australia

Penn Pharmaceutical Services Ltd.
Facility Integration
Project PennDragon- Contained Manufacturing Facility
Tredegar, South Wales, UK

Pfizer Ireland Pharmaceuticals
Operational Excellence (Overall Winner)
NSI Capacity Expansion
Grange Castle, Dublin, Ireland

WuXi Apptec Pharmaceutical of China
Honorable Mention: Process Innovation
Fully Single Use mAB Production Facility
Wuxi City, China

2013

Biogen Idec
Facility Integration
Flexible Volume Manufacturing Project RTP
North Carolina, US

F. Hoffmann – La Roche Ltd.
Project Execution
TR&D – Building
Basel, Switzerland

MedImmune
Equipment Innovation
UK Automation Upgrade Project Speke,
Liverpool, UK

Merck & Co., Ltd.
Operational Excellence
Vaccine and Biologics Sterile (VBSF) Project
County Carlow, Ireland

Morphotek, Inc.
Sustainability
Pilot Plant
Ambler, PA, US

Novartis Vaccines and Diagnostics
(Overall Winner)
Process Innovation
Flu Cell Culture Facility
Holly Springs, North Carolina, US

2012

Chiesi Farmaceutici S.p.A.
Sustainability
Chiesi Farmaceutici Research and Development Centre Facility
Parma, Italy

Eisai Pharmatechnology & Manufacturing Pvt. Ltd.
Project Execution
Eisai Knowledge Centre Facility
Andhra Pradesh, India

Merck & Co., Inc.
(Overall Winner)
Facility Integration
Merck Vaccine Bulk Manufacturing Facility (VBF) Program of Projects
Durham, North Carolina, US

Rentschler Biotechnologie GmbH
Equipment Innovation
REX III Manufacturing Facility
Laupheim, Germany

Roche Diagnostics GmbH
Operational Excellence
TP Expand Project
Penzberg, Germany

National Institute for Bioprocessing Research and Training (NIBRT)
Special Recognition:
Novel Collaboration for its New Greenfield Facility
Dublin, Ireland

12 Years of Innovation

2011

F. Hoffmann – La Roche Ltd.
Process Innovation
"MyDose" Clinical Supply Facility
Kaiseraugst, Switzerland

MedImmune, LLC
(Overall Winner)
Project Execution
Frederick Manufacturing Center (FMC)
Expansion Facility
Frederick, Maryland, US

Merck and Co., Inc.
Facility Integration
Global Clinica Supplies
Manufacturing, Packaging and
Warehouse Expansion Project
Summit, New Jersey, US

Novartis Vaccines and Diagnostics GmbH
Equipment Innovation
"MARS Project"
(Marburg Site) Facility
Marburg, Germany

Pfizer Health AB
Operational Excellence
Project Pegasus – Bio 7
Manufacturing Facility
Strängnäs, Sweden

Pfizer Manufacturing Deutschland GmbH
Sustainability
SPRING and E-MAP
(Strategic Plant Restructuring and
Energy Master Plan) Project
Freiburg, Germany

Shire HGT
Honorable Mention
Project Atlas, Building 400 Facility
Lexington, Massachusetts, US

2010

Biogen Idec
Operational Excellence
North Carolina, US

Genentech
(Overall Winner)
Project Execution
Tuas, Singapore

MannKind Corporation
Equipment Innovation and
Process Innovation
Connecticut, US

Pfizer Biotechnology Ireland
Sustainability
County Cork, Ireland

Pfizer Ireland Pharmaceuticals
Facility Integration
Dublin, Ireland

2009

Aseptic Technologies
Equipment Innovation
Gembloux, Belgium

Centocor Biologics Ireland
Sustainability
Ringaskiddy, Cork, Ireland

Centocor R&D Schaffhausen
Facility Integration
Schaffhausen, Switzerland

hameln pharma
Operational Excellence
Hameln, Germany

Orchid Chemicals & Pharmaceuticals
Regional Excellence
Aurangabad, India

Roche Pharma Biotech Production Basel
(Overall Winner)
Project Execution
Basel, Switzerland

2008

Boehringer Ingelheim Pharma GmbH & Co. KG
Facility Integration
Biberach, Germany

Bristol-Myers Squibb
Equipment Innovation
New Brunswick, New Jersey, US

IDT Biologika GmbH
Operational Excellence
Dessau-Rosslau, Germany

Pfizer Manufacturing Deutschland GmbH
(Overall Winner)
Process Innovation
Illertissen, Germany

F. Hoffmann La Roche AG
Project Execution
Basel, Switzerland

2007

Cook Pharmica, LLC
Facility Integration
Bloomington, Indiana, US

Genentech
(Overall Winner)
Project Execution
Oceanside, California, US

Shanghai Roche Pharmaceuticals, Limited
Project Execution
Regional Excellence
Shanghai, China

Taiyo Pharmaceutical Industry Co., Ltd.
Equipment Innovation
Takayama City, Japan

Vetter Pharma-Fertigung GmbH & Co. KG
Process Innovation
Ravensburg, Germany

2006

AstraZeneca
Large Scale Laboratory (LSL) Project
Macclesfield, UK

Baxter BioPharma Solutions
(Overall Winner)
Phase IV Vial and Syringe
Filling Project
Bloomington, Indiana, US

Daiichi Asubio Pharma Co., Ltd.
NBP (New Bio Plant) Project
Tokyo, Japan

Janssen Pharmaceutica
Small Volume Area Facility
Geel, Belgium

Wyeth Pharmaceuticals
The Wyeth BioPharma Campus
at Grange Castle Project
Dublin, Ireland

Biolex Therapeutics
Special Merit Recognition:
Pittsboro Phase II Facility
Expansion Project
Pittsboro, North Carolina, US

2005

Alkermes, Inc.
Brickyard Square
Manufacturing Site
Cambridge, Massachusetts, US

Apotex, Inc.
Expansion to its Etobicoke,
Ontario Manufacturing Facility
Winnipeg, Manitoba, Canada

KOWA Company Ltd.
New addition to its
Manufacturing Plant for
Oral Solid Dosage Products
Nagoya, Japan

Lundbeck Pharmaceuticals Ltd.
New Manufacturing Facility at
Seal Sands, Middlesborough, UK
Copenhagen, Denmark

Novo Nordisk A/S
(Overall Winner)
New Manufacturing Plant
Hillerød, Denmark

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  NDIR-Detection
- One system for
  hot and cold samples
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Congratulations

FOYA 2016 Category Winners

Operational Excellence

Baxter BioPharma Solutions

Sustainability

Ethicon, LLC

Process Innovation

Genentech, a Member of the Roche Group

Project Execution

Janssen Vaccines AG

Equipment Innovation

Pfizer Inc.

Facility Integration

Takara Bio Inc.

Honorable Mention

Greater Pharma Manufacturing Co., Ltd.

University of Strathclyde, CMAC

West Pharmaceutical Services, Inc.

FOYA 2016
Facility of the Year Awards
CATEGORY WINNER
Operational Excellence

Baxter BioPharma Solutions

"Baxter consistently applied operational excellence and lean manufacturing principles end to end for process, personnel, material, and waste flows, from the design phase of the project through to the operation of the facility."

Halle facility exterior after project completion


Large-scale filling line


Filling equipment and isolators

Project:
Solutions Oncology Manufacturing Expansion

Location:
Halle (Westfalen), Germany

Project mission:
A facility expansion built to meet patient needs worldwide

Total facility floor area:
18,815 sq ft (1,748 m^2)

Increasing Manufacturing Capacity for Future Growth

With market demand for contract manufacturing in the pharmaceutical industry on the upswing over the past few years, contract manufacturing organizations (CMOs) like Baxter BioPharma Solutions (BPS) are positioning themselves for future growth by increasing capacities today. Such was the case with BPS's facility in Halle (Westfalen), located in the northwestern part of Germany, which completed a challenging project in 2015 to add capacity to service the CMO market of parenteral oncology products while avoiding impact on current operations and customers.

A subsidiary of Baxter International Inc., BPS is a leading CMO that specializes in parenteral pharmaceuticals. It supports pharmaceutical companies in meeting their commercialization objectives by providing scientific expertise, sterile manufacturing solutions, parenteral delivery systems, and customized support services needed to meet the unique challenges that parenteral products face.

"The demand for contract manufacturing space has increased dramatically over the past 5 years," says Frank Generotzky, Plant Manager at BPS's facility in Halle. "Customers are shifting from small-molecule drugs to high-value complex-molecules such as biologics, immuno-oncology products, and antibody-drug conjugates. This increasing complexity requires dedicated facilities with experienced operators and sophisticated equipment, which is very costly to build. As a result, many companies are turning to outsourcing for this type of manufacturing."

To meet the growing demand, the decision was taken to expand the Halle facility. With over 60 years of experience, the facility has considerable expertise in handling complex sterile manufacturing challenges and has delivered product to more than 120 countries. A budget of $61.5 million was approved for an 18,800-square-foot (1,750-square-meter) expansion of the facility with an aggressive timeline of 39 months from the design phase to receiving the operating licenses to starting market supply.

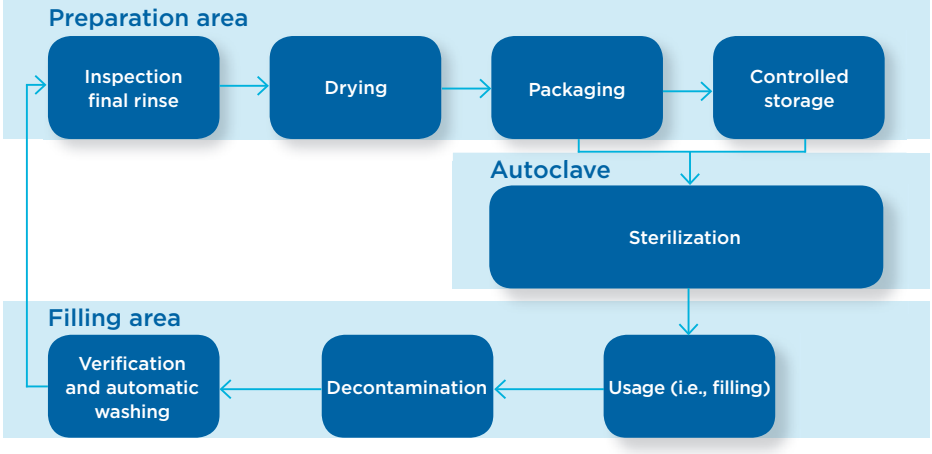
"The expansion of our fill-finish contract manufacturing facility in Halle offers capacity and flexibility as well as innovative processes and technologies that will allow Baxter to stay at the forefront of providing world-class parenteral manufacturing for oncology therapies to meet the needs of our pharmaceutical clients, all under one roof," says Generotzky. "These specialized services include the flexibility to offer both large-scale and small-scale liquid and lyophilized vial filling, aseptic formulation, terminal sterilization, and flexible formulation capacity for a variety of challenging oncologic and other sophisticated parenteral products. The ability to provide these services within a single facility is rare and enables us to accommodate short start-up times and minimize transfer costs."

In-house expertise

Also unique to BPS was its ability to execute an expansion of this magnitude with minimal reliance on external consultants. Its in-house experience provided a thorough understanding of each project phase/qualification, resulting in a manufacturing expansion that is an evolution of the high quality already existing at the facility. Project teams transitioned to routine manufacturing, retaining knowledge and experience throughout the project phases.

"We conceived, designed, and implemented the Halle-facility expansion with lean manufacturing philosophy at the core to ensure that the end result delivers maximum value for customers," says Generotzky. "We applied these lean principles through innovative manufacturing concepts, like state-of-the-art isolator technology combined with high flexibility for rapid changeover and broad flexibility to manufacture a wide variety of liquid formulations—a combination that helps ensure economical manufacturing and quality product. We also combined new equipment with innovative disinfection systems and an optimized layout to improve efficiency, prevent contamination, and keep potential losses on the filling line to a minimum."

When designing the new facility, Generotzky and his team used process flow diagrams to maximize efficiency and align diverse teams from engineering, production, and quality. They conducted simulations, visualizations, and risk analyses when selecting new equipment to ensure that they could seamlessly incorporate it into current manufacturing processes. Finally,



they adopted a modular design and were able to complete this expansion and deliver high-quality product with minimal impact on customers.

Filling line sensor

Modular-design concepts were used to allow for future line expansions and the doubling of lyophilization capacity without shutdown of manufacturing, helping to ensure a continuous supply of drug products to customers. Filling equipment was uniquely designed and tailored to meet the special requirements for filling oncologic products in a multipurpose facility. "While it may sound simple to offer these specialized capabilities under one roof, doing so posed many challenges we needed to overcome during planning and construction," says Generotzky. "We wanted to ensure that the new facility enhanced our efficiency and allowed us to abide by current processes and best practices. We also needed the facility to be 'future-proof' to not only meet the needs of current customers but also allow us to manufacture any appropriate product in the future and meet new requirements as they arise. Most importantly, we needed to successfully complete the expansion without disrupting current operations."

Innovative use of technology

To maintain BPS's leadership position as one of the world's largest CMOs for lyophilized parenterals, Generotzky and his team made use of both newer and older technologies in new applications.

Two innovative vial-filling lines were designed primarily by BPS's engineering team in Halle in collaboration and consultation with leading equipment suppliers. When combined, the two lines can fill up to 150 vials per minute—far outpacing the five fillers previously in use at the Halle facility. The small-scale filling line was implemented to offer the manufacturing of small-scale programs focused on high flexibility, whereas the commercial filling line was installed to assist current and future clients in the scale-up of their oncology programs focused on high throughput.

The facility also incorporates a large compounding capacity for the formulation of final products, which meets an existing oncology-market need. An additional focus of the facility's design was to provide adaptable equipment with capabilities for the most current formulation developments, such as nanosuspensions, biologics, organic solvents, batch sizes as low as 1 liter, and temperature-sensitive active pharmaceutical ingredients (APIs).

With the expansion, the facility also incorporates the latest innovations in manufacturing tracking and control, as well as advancements in product tracking and quality control.

The design of the filling equipment is tailored to meet the special requirements for filling oncologic products in a multipurpose facility (cleaning Grade A, decontamination). This manufacturing concept applies state-of-the-art isolator technology combined with high flexibility for rapid changeover and broad flexibility to manufacture a wide variety of liquid formulations (organic solvents, biologics, suspensions)—a combination that helps ensure economical manufacturing and quality product. Computer-controlled process flows enable process standardization for mixing, aseptic filling, cleaning, and decontamination.

Filling line—large scale

The filling process is equipped with 100-percent weighing control, which enables full control at the end of the batch filling. This helps to ensure full usage of the filling batch to the last vial. The facility will utilize IQ mobile sensors in all lyophilizers for process development and detailed process analysis of the lyophilization cycle. All vials can be printed online with batch number and time stamp after leaving the manufacturing line to ensure optimal traceability.

The crimping process will be performed in an isolator with Grade A air supply to be in alignment with current guidelines. This process will be 100-percent controlled by pressure, and by camera, to ensure tightness of the container closure system and therefore quality of the final drug product. In addition, the new facility is equipped with a semi-automated inspection system, utilized for 100-percent vial inspection.

Designed with the end patient in mind

Onsite construction and operations were conducted in accordance with Baxter's Environmental, Health and Safety (EHS) guidelines and policies, which were designed to comply with regulatory rules but also as part of an overall corporate EHS management system.

Several measures of hazard control were employed during the validation. All on-site contractors were trained according to Baxter's EHS program, which provides hazard control through proper training on safety practices with technical equipment and processes. As required by Baxter, all suppliers underwent a Baxter audit prior to contract close, and received certification. EHS checked all equipment in conformance with German law during factor acceptance testing.

"This expansion would not have been a success without the tireless support of workers throughout the organization who accommodated the planning and construction of the new facility while continuing to deliver the high quality our customers demand," says Generotzky. "Our employees are proud of the new facility and understand that the expansion enables us to better serve our customers, which, in turn, enables our customers to better serve patients." ■

Baxter

FOYA 2016
Facility of the Year Awards
CATEGORY WINNER
Operational Excellence

Your Premier CMO
for Specialized Sterile Injectables

Whether you face formulation challenges, clinical supply hurdles, surges in demand due to market fluctuations, risk mitigation concerns, or patent expiry challenges, we offer tailored, versatile solutions–and over 80 years of parenteral experience–to help you achieve your commercialization objectives.

Ultimately, our goal is to make you feel confident and secure in choosing BioPharma Solutions as your CMO–assisting you to avoid the unexpected and guiding you through marketplace complexities to help you achieve the full potential for your molecule.

Learn more about us at:
baxterbiopharmasolutions.com

Your Premier CMO

BioPharma Solutions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Ingenuity for life
Congratulations to Baxter BioPharma Solutions (Germany)
Winner 2016 Facility of the Year category "Operational Excellence"
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What the FOYA Judges Had to Say

Baxter International's parenteral manufacturing plant undertook a challenging project to add capacity to service the CMO market of parenteral oncology and other complex liquid and lyophilized products. Expansion was designed to accommodate the need for life-saving unit dose products, with flexibility and efficiency to offer both large-scale and small-scale liquid and lyophilizer vial filling, aseptic formulation, terminal sterilization, and flexible formulation capacity for a variety of challenging oncologic and other sophisticated parenteral products, small molecules, biologics, antibody-drug conjugates, emulations, liposomes, and suspensions. The intent was to provide full services "under one roof" that facilitate short start-up time and minimize transfer costs.

Baxter applied operational excellence principles to innovative manufacturing concepts with state-of-the-art isolator technology combined with high flexibility for rapid changeover and broad flexibility to manufacture a wide variety of liquid formulations (organic solvents, biologics, suspensions) in a combination that helps ensure product quality and economical manufacturing. This enabled Baxter to double output without impacting current operations. The overall project cost was $61.6 million, and the facility addition was 18,900 sq. ft. and produces ±15 million vials per year.

Baxter consistently applied operational excellence and lean manufacturing principles end to end for process, personnel, material, and waste flows, from the design phase of the project through to the operation of the facility. Key principles applied included:

- Lean manufacturing principles utilizing 3D design resulted in a facility made largely out of glass (>60%) where infrastructure design is optimized for processes in a "form follows function" concept.
- Designed primarily by in-house engineering staff who were then retained to operate the plant. All production processes were value-stream mapped and failure modes and effect analysis applied, including the intensive application of process simulations and computational fluid dynamics.
- Utilization of standard work in defining modular process design. Computer-controlled process flows enabling process standardization for mixing, aseptic filling, and cleaning and decontamination processes.
- Flexible design included a high-throughput commercial line that outpaces the five fillers previously in use at the facility and a small-scale filling line to offer the manufacturing of small-scale programs focusing on efficiency and high flexibility.
- Flexible design also provided adaptable equipment with capabilities for most current formulation developments such as nanosuspensions, biologics, organic solvents, batch sizes as low as 1 liter, and temperature-sensitive APIs.
- Filling-process quality improvements including 100-percent weighing control, enabling full control at the end of batch filling, and helping ensure batch-filling optimization to the last vial, and both semiautomated inspection and 100-percent vial inspection and tracking, minimizing any potential defects.
- Capabilities built into all lyophilizers for continued and improved process development and detailed process analysis of lyophilization cycles.

All of this contributed to the Baxter team's successful completion of their project, which resulted in a facility with planned operational excellence. For this accomplishment, Baxter BioPharma Solutions has been chosen as the winner in the Operational Excellence category.

In Their Own Words

1. Efficient project management proven by staying within budget and completion ahead of schedule.
2. Managing the project using Baxter's internal resources deepened knowledge and brought up innovations in process and equipment design.
3. Baxter's use of new technologies in decontamination has increased quality and efficiency in the area of manufacturing oncologic drugs.
4. Fast ramp-up of a new complex facility and exceptional knowledge transfer by the project team's transitioning from the project phase to routine operations for the manufacturing facility.
5. Integrating quality assurance and EHS into the process design right from the start has resulted in a holistic approach for qualification and validation of equipment, personnel, cleaning validation, and industrial-hygiene concepts.

Loading lyophilizer—large scale filling line

Compounding area—large scale filling line

Key project participants

Manufacturer/Owner	Baxter International, Inc. BioPharma Solutions One Baxter Parkway, DF4-3W 60015 Deerfield, Illinois, USA Dr. Burkhard Wichert Vice President, Manufacturing, BPS Plant Management
Process Facility Design/Build and Validation	Baxter Oncology GmbH Kantstraße 2 33790 Halle/Westfalen, Germany Frank Generotzky, Director, Technology & Engineering
Architect (non-process)	Baxter Oncology GmbH Kantstraße 2 33790 Halle/Westfalen, Germany Derik Feldhoff, Architect/Maintenance Coordinator
Construction Manager (non-process)	IP – Innovatives Planen GmbH Robert-Bosch-Straße 15 72654 Neckartenzlingen, Germany Christian Hage
WFI-Loop and Systems	DEWA Engineering und Anlagenbau GmbH Glückauf-Straße 6 38690 Goslar, Germany
Process Automation	Siemens AG Siemens Deutschland Industry Sector Neue Kasseler Str. 62 35039 Marburg, Germany
Clean Steam System	DEWA Engineering und Anlagenbau GmbH Glückauf-Straße 6 38690 Goslar, Germany
Autoclaves	Fedegari GmbH Lehrer-Götz-Weg, 11 81825 München, Germany
HVAC Subcontractor	Daldrop + Dr.Ing.Huber GmbH + Co. KG Daldropstraße 1 72666 Neckartailfingen, Germany
Particle Monitoring	On/Off Engineering GmbH Niels-Bohr-Str. 6 31515 Wunstorf, Germany
Freeze Dryers	HOF Sonderanlagenbau GmbH Ludwig-Rinn-Str.1-3 35102 Lohra, Germany
Filling Lines	Bausch + Ströbel Maschinenfabrik Ilshofen GmbH+Co. KG Parkstraße 1 74530 Ilshofen, Germany
Isolator Technology	SKAN AG Binningerstraße 16 4123 Allschwil, Switzerland
Compounding Systems	Hermann WALDNER GmbH & Co. KG Anton-Waldner-Str. 10-16 88239 Wangen, Germany

SHELMEQ® Core Competence

Rooms that are used for manufacturing products and processes requiring extreme protection from contamination are planned by architects, whereas the relevant technologies and building services are designed by engineering consultants. If the ensuing execution follows this segmentation, the interfaces generated by this lead to ambiguous regulations regarding responsibilities for the required guaranteed values. For production facilities needing a cleanroom environment, **SHELMEQ®** is a service that is viewed as a "key trade".

SHELMEQ® Cleanroom Technology is the definition of a scope of services that is designed to take on responsibility for complying with the guaranteed values for particle concentration, room pressure, room humidity and room temperature. To keep this responsibility in the hands of one company and to ensure the quality, interfaces to other trades and/or services must be defined so that it is clear where responsibilities start and end. The principle of **SHELMEQ®** Cleanroom Technology has its core competence in the design and construction of ventilation and air-conditioning facilities; it incorporates information about the users' process technology and has at its disposal its own knowhow in design and execution. What is more, we have our own production of important components and parts of the cleanroom shell. We are able to respond and react quickly, competently and flexibly to customers' demands. At Daldrop + Dr.Ing.Huber we have taken this principle to heart and pursue its consistent application to the benefit of our clients.

The ceiling system: The design and construction of each cleanroom ceiling fulfill the technical requirements of the project in question. If a suitable system is not already available, its development is an integrated project-related service. Air inlets or outlets, light fixtures and sprinklers are integral componentsof the cleanroom ceiling. If the cleanroom ceiling is walkable, then the light fixtures and outlets must also be walkable. The question of the right system arises, a question answered by the **SHELMEQ®** principle. The support structures for suspending the ceiling also belong to the ceiling system as does the coordination for anchorage, taking into account the structural requirements and the space needed for other trades.

The cleanroom wall: The walls are supplied with floor and ceiling tracks, the wall design and thickness meet the technical requirements in question. The individual wall elements, such as window elements, utility columns, material pass-thrus, rotating, sliding and vertical rise doors, can be assembled individually. Solutions for material pass-thrus, utility penetrations, either singly or integrated in complete utility panels, also belong to the cleanroom wall system. Air grilles for extracting air at floor level with pre-filters and/or HEPA filters, with devices for a contamination-free filter change, are also an integral part of the cleanroom wall.

The cleanroom floor: Supply of the finished floor in the cleanrooms is also part of the **SHELMEQ®** principle, either as a raised floor (microelectronic projects) or as epoxy, terrazzo or PVC floor. For pharmaceutical projects, the transition from floor to wall is created either by special coved floor tracks or by creating a coved transition with the material selected for the flooring.

Air-conditioning and ventilation: Cleanroom technology is a specialized area of air conditioning; therefore the ventilation supply of the cleanrooms is an integral part. This includes the air handling units with ventilation ducts and all necessary fixtures. Connections for the utility supply of the ventilation components such as cold/warm water and steam from a defined interface also belong to the scope of services.

Measuring and controls: **SHELMEQ®** also covers the complete measuring and control system. This includes temperature, humidity, velocity and pressure sensors, thermostats, damper actuators, control valves, limit switches and displays, PLC units with integrated user interface, a user-friendly software as well as the complete data link to an independent or higher-level network.

Daldrop + Dr.Ing.Huber congratulates Baxter Oncology GmbH on their ISPE Facility of the Year Award 2016

Electrical works: Control cabinets complete with all necessary components for control as well as sub-distribution for airlock controls, door actuators, light fixtures and sockets, including the electrical cabling. Complete electrical cabling between control cabinets or sub-distributors and the individual consumer units.

Qualification: **SHELMEQ®** assumes all qualification tasks (IQ/OQ) including documentation. Decision-making regarding qualification lies with the user and is included in the process validation. This includes the DQ and the risk analysis defined at the start of the project.

Daldrop + Dr.Ing.Huber
SHELMEQ®
Cleanroom Technologies

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FOYA 2016
Facility of the Year Awards
CATEGORY WINNER
Sustainability

Ethicon, LLC

"The site's sustainability efforts resulted in an energy reduction of 26% (4.4 million kWh) and a water reduction of 9% (1.25 million gallons), while increasing production volume by 11%."

View of Ethicon San Lorenzo facility in Puerto Rico.


Aerial view of 600 kW solar photovoltaic carport, far left

Project:
San Lorenzo Conservation Strategy

Location:
San Lorenzo, Puerto Rico

Project mission:
Reduce site CO_2 emissions to comply with J&J Healthy Future 2020 goals while achieving savings in energy costs.

Total facility floor area:
147,325 sq. ft. in five buildings

Setting Worldwide Example for Sustainability Initiatives

It was a tale of three projects and an event at the Ethicon, LLC, facility in San Lorenzo, Puerto Rico, that set out to reduce the plant's environmental footprint. The results have been truly impressive for Ethicon, a subsidiary of Johnson & Johnson (J&J), with annual benefits such as carbon dioxide (CO_2) reductions of 3,500 metric tons and water savings of 1.2 million gallons, generating cost savings of nearly $1.2 million.

The innovative initiatives and projects at Ethicon San Lorenzo represent the "triple bottom line": projects that give consideration to a company's social, economic, and environmental impacts.

The San Lorenzo facility develops and manufactures products that are primarily used in cardiovascular, neurosurgical, orthopedic, ophthalmic, and vascular procedures, as well as plastic surgery. Product lines manufactured in this plant are distributed worldwide, and include nonabsorbable surgical sutures, topical skin adhesives, meshes, and hemostats.

The three projects—Project COLD, Solar Photovoltaic, and Project Relight—and the Energy Treasure Hunt event were led by Joel Delgado Hernández, Facilities Management Site Manager, and Ramon Gomez, Energy Manager, Puerto Rico Campus. All of the projects were part of, and benefited from, J&J's Healthy Future 2020, an enterprise-wide initiative aimed at greatly reducing energy and water consumption using 2010 levels as a baseline.

"J&J has a CO_2 fund where each site can request funding to do a project," says Delgado. "It has to comply with certain requirements—cost savings, 15% internal rate of return [IRR], and CO_2 reductions. Our projects met that criteria, and we were approved to move forward with our implementation. The Healthy Future 2020 initiative is really good for the sites because we don't have to use up site capital and it provides an opportunity for us to pursue and achieve energy initiatives."

Project COLD

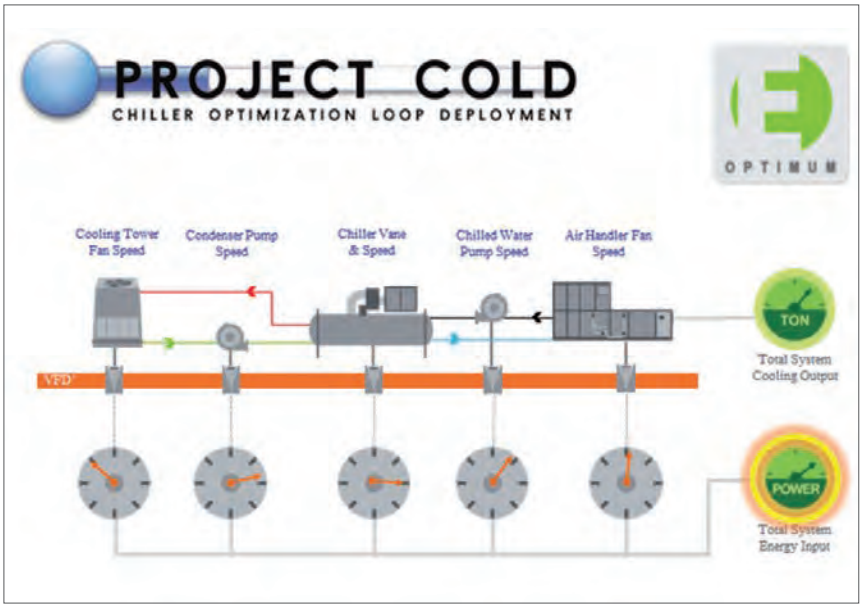
In early 2013, the team at Ethicon San Lorenzo began construction on a chiller optimization project that was developed by J&J's Worldwide Engineering and Technical Operations group. This initiative, dubbed "Project COLD," had already been successfully deployed at three of J&J's US sites. Ethicon San Lorenzo became the first site to deploy the program outside the United States and the first in the medical devices and diagnostics sector.

The objective of Project COLD was to "optimize the chiller system on the manufacturing site," says Delgado. "The main power consumption at a manufacturing site comes from this type of system because we used huge motors to run the chillers in order to maintain the environment for the manufacturing area."

The Project COLD team set out to achieve these improvements by installing highly efficient chillers, variable frequency drives (VFDs), heat pumps, and staging equipment, optimizing pumping strategy, management of standby equipment, and remote-monitoring strategies. The program includes a controls optimization strategy that balances the speed of the VFD equipment to ensure best coefficient of performance (COP) (kilowatt/ton) for a given load and outdoor conditions. The software provides continuous, system-level optimization of each component and real-time monitoring capability to maintain the efficiency improvements.

"The software uses algorithms to optimize the performance of the chiller pumps and cooling towers, and we can benefit depending on the

Solar photovoltaic carport



Total system schematic

View of chillers in mechanical room, part of Project COLD implementation.

environment," says Delgado. "If it's cold or hot outside, the system adjusts automatically. And although we run 24/7, if we have shifts where there are no people running manufacturing machines, the system will automatically adjust depending the consumption."

The annual benefits of this project include:

- Energy consumption savings of 1,402,368 kilowatt-hours (kWh)
  - Cost savings of $364,615
  - CO_2 savings of 1,050 metric tons
- Water savings of 227,481 gallons
  - Water cost savings of $2,275
- Total combined savings of $366,890

Solar photovoltaic system

In addition to work on Project COLD in 2013, Ethicon San Lorenzo began construction activities on a 600-kilowatt solar photovoltaic system in its employee parking lot. The project objective was to provide turnkey services to construct, operate, and maintain a carport solar photovoltaic system at the facility.

"We didn't have enough space to install the panels, so we installed the photovoltaic cells in a canopy in a parking lot," says Delgado. "That strategy was more complex because that's the only parking lot we have, so we divided the implementation into three phases to continue our manufacturing processes."

In addition to receiving funds from J&J, this project also secured $440,000 from the Puerto Rico Energy Affair Administration Green Energy Fund and a $500,000 rebate from Puerto Rico Industrial Development Company.

The scope of the work had an approximate value of $2.6 million, with an IRR of 17 percent.

The annual benefits of the project include:

- Energy consumption savings of 961,500 kWh
- Cost savings of $250,000
- CO_2 savings of 781 metric tons

Project relight

While construction continued on the solar photovoltaic system into 2014, the site simultaneously began the design and implementation of a large-scale relamping project, as part of a larger project across the Puerto Rico campus. Lighting is a significant energy user for Ethicon San Lorenzo, with approximately 3.6 million kWh consumed annually illuminating the facility.

"Project Relight came as a result of an initiative at the J&J worldwide engineering level," says Gomez. "The project was to upgrade all the lamps and fixtures on the site using LED [light-emitting diode] technology, and we did that at the campus level in this case. We replaced the lighting without any interruption to manufacturing operations, so it took a very coordinated effort between the different groups and engineering teams."

Following an illumination assessment, it was determined there was a need to replace a combined total of approximately 2,350 lamps, primarily made up of T8 lamp tubes for interior lighting. The project team replaced the T8 lamps with LED technology, which provides superior illumination while consuming less electricity.

Additional savings were realized in terms of heating, ventilation, and air conditioning (HVAC) operation since LED lamps generate less heat. Maintenance and disposal costs were also reduced as the lifetime of the

LED lamp tubes is 50,000 hours. The tubes also don't contain mercury and can be disposed of or recycled easily.

The project was funded using J&J's CO_2 Fund, and the scope of work had an approximate value of $540,000, with an IRR of 24%.

The annual benefits of the project include:

- Energy consumption savings of 439,400 kWh
- Cost savings of $101,068
- CO_2 savings of 357 metric tons
- Maintenance cost savings of $46,190
- Total project cost savings of $147,258

Energy treasure hunt

In October 2014, Ethicon San Lorenzo held an energy treasure hunt, a 2-day event in which managers, engineers, technicians, and others searched out energy-savings opportunities at the plant. A total of 27 employees and contractors from San Lorenzo and other facilities on the Puerto Rico campus participated, evaluating energy use from the plant floor to the parking lot.

"The event involves teams of six or seven members, with each team focusing on an area. So, we have a team for water, for HVAC, for compressed air, to look at manufacturing, and so on," says Gomez. "In the 2 days, the teams look for opportunities, and we use a software called Gensuite to account for all these prospects. In the end, we do a presentation for the site and make up a list by department for projects. We expense the project to identify the capital required and identify the ones we call 'Do it now.'

"After the 2 days, our teams were able to identify $1.2 million in opportunities. We prioritized the opportunities and put them in place, and as of January 2016 the sites had already implemented over $200,000, which is close to our $360,000 annual goal."

Triple bottom line

Individually and combined, these projects implemented at Ethicon San Lorenzo meet all aspects of the triple bottom line standard, with clear benefits for the company's profits and people, and, of course, the planet.

All told, these initiatives will reduce CO_2 emissions equivalent to:

- Removing 740 cars from the road in 1 year
- The energy consumed by 320 homes in 1 year
- The carbon sequestered by 2,880 acres of US forest in 1 year

In addition, the community benefits in Puerto Rico are significant. "We use general contractors to implement the projects," says Delgado. "So with this type of project, we certainly moved the economy of Puerto Rico." ■

What the FOYA Judges Had to Say

The Ethicon facility in San Lorenzo stands out in the Sustainability category. It was established in 1988 as a high-tech manufacturing facility for an array of medical devices. The site's sustainability efforts resulted in an energy reduction of 26% (4.4 million kWh) and a water reduction of 9% (1.25 million gallons), while increasing production volume by 11%, compared to 2010 consumption levels. The achievements in Ethicon San Lorenzo were accomplished in support of J&J's Healthy Future 2020 sustainability initiative.

Some of the sustainability elements include a chiller system optimization, solar photovoltaic installation, LED relamping, Energy Treasure Hunt, HVAC controls optimization, and Power Factor Improvement.

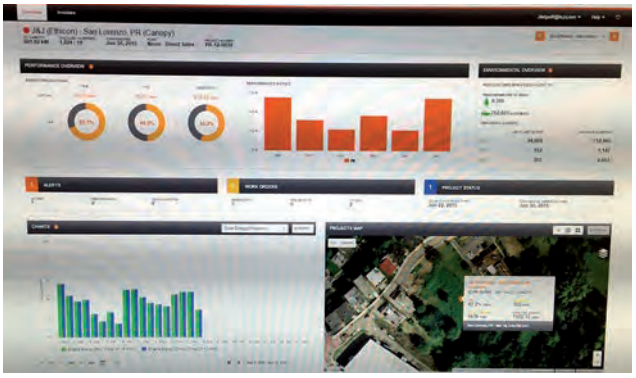
Ethicon San Lorenzo became the first JNJ site outside the US to implement a chiller optimization program called "Project COLD". This was funded by JNJ's CO_2 Fund, which provides $40 million per year in capital relief to business units who implement CO_2 reduction initiatives. This project had an IRR of 30%.

The facility installed a 600kW solar photovoltaic system that was funded in part by JNJ's CO_2 Fund, $440,000 from the Puerto Rico Energy Affair Administration Development Company (PREAA) and a $500,000 rebate from Puerto Rico Industrial Development Company (PRIDCO).

Additionally, they conducted an Energy Treasure Hunt, which identified another (36) projects that could reduce 2800 metric tons of CO_2 and 390,000 gallons of water annually, if implemented. And they have begun work on another JNJ initiative known as "Project n-AIR-g", which is focused on upgrading HVAC controls to reduce energy consumption.

The Ethicon facility team truly embraced J&J's Healthy Future 2020 initiative; it was actively supported by J&J's Worldwide Engineering & Technical Operations group and received financial support from J&J's CO_2 Fund and Puerto Rico.

Optimum software



Photovoltaic system software

In Their Own Words

The innovative initiatives and projects at Ethicon San Lorenzo truly represent the triple bottom line of sustainability. The initiatives decrease J&J's environmental impact by reducing greenhouse gas emissions and water consumption in a water-stressed area. They decrease operating costs as a business, and they benefit the community on both fronts—by mitigating negative impacts on the environment and ensuring employment opportunities and economic stability at the local and regional levels. The novel innovations at Ethicon San Lorenzo can be applied at many other J&J sites around the world to further reduce the environmental impacts of our business in support of the Healthy Future 2020 goals and beyond.

Ethicon San Lorenzo implemented the following five programs, which will cumulatively reduce CO_2 emissions by 27%, water consumption by 9%, and utility spending by 40%, all while increasing production volume by 11%:

1. **Project COLD:** A J&J energy program that includes premium efficient equipment selection (such as chillers and variable frequency drives, or VFDs), heat pumps, equipment staging, pumping optimization, standby equipment management and remote-monitoring strategies. The program also includes a controls optimization strategy that balances the speed of the VFD equipment to ensure optimal COP (kilowatt/ton) for a given load and outdoor conditions.

2. **Solar photovoltaic:** The installation of a 600-kilowatt carport solar photovoltaic system in the employee parking lot. The project objective was to provide turnkey services to construct, operate, and maintain a carport solar photovoltaic system at the facility. This solar array is invaluable to the facility in that it provides clean, on-site generation of electricity to a site where electricity from the utility can be expensive and unreliable.

3. **Project relight:** A J&J energy program that included analyzing the facility lighting systems and determining if a better technology, preferably LED with lighting controls, exists that could replace them. T8 lamps were replaced by LED lamps across the campus, realizing reductions in energy, maintenance, and disposal costs.

4. **Energy treasure hunt:** Employees and contractors from Ethicon San Lorenzo and other facilities on the Puerto Rico campus participated in this two-day event, in which energy use from the plant floor to the parking lot was evaluated. A total of 36 projects were identified that will save energy and water and reduce CO_2 emissions by 2,800 metric tons and utility spend by $1.1 million.

5. **Project n-AIR-g and power factor improvement:** Project n-AIR-g is a J&J energy program that includes optimal space set-point selection, AHU supply air reset control, heat recovery, air change rate minimization, low-pressure drop filters, and remote-monitoring strategies. In the Power Factor Improvement project, a capacitor banks were installed in order to improve the facility power factor. Both projects go beyond the scope of this award and should be considered supplementary, as they will be completed in 2016.

Key project participants

Manufacturer/Owner	Ethicon, LLC Road 183, KM. 8.3 Hato Industrial Area San Lorenzo, Puerto Rico 00754
Designer/Architect	AZ Engineering PMB #53, P.O. Box 6022, Carolina, Puerto Rico 00964-6022 Optimum Energy, LLC 6050 Santo Road, Suite 140 San Diego, California 92124
Engineer/Construction Manager/General Contractor/Automation and Control	SunEdison 12500 Baltimore Ave. Beltsville, Maryland 20705 Optimum Energy, LLC 6050 Santo Road, Suite 140 San Diego, California 92124
HVAC Subcontractor	Optimum Energy, LLC 6050 Santo Road, Suite 140 San Diego, California 92124

FOYA 2016
Facility of the Year Awards
CATEGORY WINNER
Process Innovation

Genentech, a Member of the Roche Group

"Revamping the existing CCP2 facility to support new process technology in lieu of building new resulted in significant savings in capital, while ensuring patient product supply."

Project:
CCP2 Return to Service

Location:
Vacaville, California

Project mission:
"One Team, One Goal"

Total facility floor area:
426,600 sq. ft.

Production support area:
166,600 sq. ft.

Delivery type:
Cost plus fee

Main entrance of the Vacaville, California, campus

Exterior of Building 9, which houses all of the main components of the CCP2 project.

The west yard, which was expanded to supply chemicals to CCP1 and CCP2 and handle all the wastestreams from both cell culture facilities.

Premium goes Prime

Introducing the self-priming pump developed for the pharmaceutical industry: the Alfa Laval LKH Prime UltraPure

The premium Alfa Laval UltraPure range of centrifugal pumps just gained a new family member, the Alfa Laval LKH Prime UltraPure. This energy-efficient, self-priming pump supplied with Q-doc documentation package is designed to meet the most stringent demands of the pharmaceuticals industry.
Designed primarily for Cleaning-in-Place duties and with the ability to pump product, this versatile, reliable, prime-performing pump delivers safe and hygienic production and increased uptime.

It's time to go Prime. Learn how at alfalaval.com/lkhprimeup

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LKHPF

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LKH Multistage

Alfa Laval
LKH Evap

Alfa Laval
LKH Ex

"One Team, One Goal": A Rapid Return to Service

When news came that the Genentech Cell Culture Plant 2 (CCP2) manufacturing facility in Vacaville, California, was to be returned to service (RTS) as quickly as possible to meet critical worldwide product demand, Chris Schreil and his project team knew that they were in for a challenge.

The plant had been in shutdown since 2010, and now, new good manufacturing practice (GMP) requirements needed to be met, changes in the compliance landscape had to be accounted for, new sustainability directives were in place, the plant's Environmental Microbial Control (EMC) had to be improved, and new manufacturing control system automation changes had to be incorporated.

In less than two years, however, the plant was once again ready to produce oncology products for patients—two months ahead of schedule and within the planned RTS budget.

Meet product demand quickly

Founded nearly 40 years ago, Genentech, Inc. is a leading biotechnology company that discovers, develops, manufactures, and commercializes medicines to treat patients with serious or life-threatening medical conditions.

In 2004, the original Genentech CCP2 project was driven by the need to add manufacturing capacity for two of Genentech's major oncology products to meet increased market demand. Demand for these products was expected to triple over a 5 -year period.

In 2009, Genentech was acquired by Roche, whose network includes plants around the world. The decision was made that the capacity of the CCP2 facility would not be needed, so CCP2 was shut down in 2010. There were many options for plant shutdown, but the forethought to leave the facility in a returnable state and keep the major infrastructure intact would prove to be significant.

In 2013, the demand for Roche biologic products had changed, with inventory forecasted to reach critically low levels. In September of that year, the decision was made to fast-track the restart of the CCP2 plant, with an RTS required by late 2015 to meet supply demand worldwide.

A team of engineers, contractors, and operational personnel was formed to execute the CCP2 RTS project with a mandate to meet the most recent standards while at the same time hiring and training new personnel and keeping the adjacent licensed CCP1 running.

That team was led by Chris Schreil, Senior Principal Engineer/Project Advisor at Genentech. At the start of the RTS project, Schreil and his team settled on a theme: "One Team, One Goal."

"As we started pulling the key team members together, we knew we had a pretty challenging mission in front of us," says Schreil. "We knew that the only way we could do it would be to partner and bring in several contract firms and people from other Genentech sites. Our theme throughout was that, regardless of the company you are from, we are all one team working for the same goal of getting the facility back up."

Schreil even brought in patients to speak to the group. "We had patients come in and talk about what the particular Genentech product meant to them and their families—how it helped them recover from their cancers,"

Four of the six chromatography columns in the recovery area. The LED lighting panels contribute to the over 50% reduction in lighting consumption.

When You Need To

Meet a Higher Standard

Congratulations Genentech

on being awarded a Facility of the Year Award (FOYA) for Process Innovation for your CCP2 Manufacturing Facility and Return to Service (RTS) project. We are proud to be a part of your team.

TECHNICAL AND CONSULTING SERVICES

- **C&Q Planning and Execution**
- **Cleaning and Process Validation**
- **Program Management and Tech Transfer Consultation**
- **Paperless Execution Solutions**

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he says. "These motivational things kept everyone focused on the real mission, which is to supply products to patients."

Achieving new standards

With the CCP2 facility dormant since 2010, almost everything other than a greenfield construction had to be done. The project's first activities were derived from a maintenance standpoint: "We needed to restart the HVAC systems and start performing all of the preventive maintenance that had not been done for several years," says Schreil.

During that period, mid- to late 2013, the team began their evaluation of the CCP2 facility. Since the facility was now part of Roche's global network, the evaluation revealed some operational, design, and engineering improvements to increase efficiency and capacity, as well as changes related to new regulatory requirements.

"We had equipment that needed modifications, rooms that needed to be reclassified, redesigned, or reconstructed as well as the procurement and installation of new equipment related to upgrades from what we had to do when we originally designed," says Schreil. "There was also a larger effort to bring the overall facility up to new standards of appearance, cleanliness, and environmental controls. We also took the opportunity, which is rare in the industry, to implement several sustainability initiatives, such as optimizing our HVAC systems, lighting, and water consumption during our CIP [clean-in-place] operations. It's rare to get that opportunity, because all of these systems had previously been validated. We took advantage of the Roche organization's specific initiatives on sustainability and were able to implement several things that met those initiatives' requirements."

The facility itself is large scale, including 450,000 square feet of manufacturing and support space. The manufacturing process utilizes some of the largest-scale cell culture drug substance production equipment in the industry, including eight 25,000-liter bioreactors, 1.8-meter-diameter chromatography columns, and CIP skids serving upstream and downstream areas. With this capacity, CCP2 is the largest and most advanced multiproduct cell culture production facility in the world.

"The 25,000-liter bioreactor fermenters are unique in their size and capability, and then in the chromatography areas, 1.8-meter-diameter columns, which have the ability to flow through those at the proper flow rates for recovery, are unique as well," says Schreil. "One thing that we did in the original design, that was a first for Genentech at the time, was the amount of in-line dilution. In the buffer downstream areas, there are corrosive salt solutions that are used, so we implemented disposable buffer-bag technologies and then in-line dilution to be able to concentrate in the bags and then dilute with either water or other solutions at our point of use in our chromatography operation. Expanding on that, in the RTS project we brought in technologies for pasteurization for all of our media."

Innovative approaches were used throughout the manufacturing process and key process support areas to convert the original design basis and installation to Genentech's newest process technology, global standards of best-in-class compliance standards, and sustainability goals while maintaining the shortest fast-track schedule possible.

A view of the media prep area, which includes: two 250-liter, one 1,600-liter, three 5,500-liter, and one 20,000-liter vessel.

This view shows the top-down flow of media prep area. The raw materials are added to the media prep tanks from above.

This buffer hold area was converted from unclassified to Biozone 3.1 as part of the RTS project. The recessed area in the ceiling is an example of forethought in design, addressing the complexity in converting the area to a Biozone 3.1. This lighting system allowed for visibility and operability while working on the filter housings.

Overcoming challenges

While both the original CCP2 greenfield construction and the CCP2 RTS project were run on time and on budget, they were not without their challenges.

"On the original project, one of the challenges was to get the facility up as quickly as possible," says Schreil. "So we used modular building technologies, where large portions of the building were built and tested at various locations around the United States. These modules were then shipped on trucks and fit into this facility shell to allow us to construct much quicker than what is typical. The challenges on the restart were about the timelines that were given by management and then quickly developing the designs for the areas that we had to modify as part of the restart, completing that construction and getting us back into GMP service for producing our first products."

In addition, Schreil and his team had to ensure that their project did not interfere with the adjacent CCP1 or any of the company's other activities on the Vacaville campus. "We are still producing product at CCP1, and on the Vacaville campus we have a QC [quality control] lab and materials management, among other things, within the Genentech/Roche network," says Schreil. "So one of our big missions was to do no harm to the existing operations."

In addition, the short year-and-a-half restart time frame envisioned for CCP2 served up a challenge for Genetech's human resources (HR) and training teams. "The average time from hiring a manufacturing technician to when she or he is proficient on the manufacturing floor is approximately 18 months," explains Schreil. "That is the same amount of time we had to restart the facility. While the project team was working, the HR team was hiring and all of Manufacturing and Quality Management was training; by the time we were ready to start up production, those folks were proficient and ready to be out on the floor." In all, several hundred manufacturing, quality control, lab, and support personnel were added to the site, which now employs approximately 1,000 people.

Looking back on the project, Schreil sees the benefits of the "One Team, One Goal" approach. CCP2 RTS capitalized on lessons learned for CCP2 and collocated all personnel (design, CM, automation, validation, and operations) in one location working under a common theme. This execution strategy paid off with big dividends.

With the restart of CCP2 in January 2015, two engineering runs of an oncology product began with recovery of final bulk, leading into nine qualification lots—beginning in June 2015 with completion in September 2015. All comparability data was good, and the licensure team is currently preparing the licensure submission application. ■

What the FOYA Judges Had to Say

Genentech, Inc., won the Process Innovation category for their large-scale Cell Culture Biologics Drug Substance Plant 2 (CCP2) located in Vacaville, California. This project focused on an upgrade to the original CCP2 facility, put into an "idle but keep warm" status in 2010, combined with a fast-track return to service (RTS) project. The RTS project, and its fast-track timing, was driven by a need to support product supply to patients of two significant oncology products whose market demand has tripled in recent years.

The facility itself is large scale including 450,000 square feet of manufacturing and support space. The manufacturing process utilizes some of the largest scale cell culture drug substance production equipment in the industry, including 8 x 25,000 l bioreactors, 1.8 meter diameter chromatography columns, and 7 CIP skids serving upstream and downstream areas.

Innovative approaches were used throughout the manufacturing process and key process support areas, to convert the original design basis and installation to Genentech's newest process technology, global standards of best in class compliance standards, and sustainability goals while maintaining the shortest fast track schedule possible.

Process innovations include high titre yields at the largest bioreactor scale used in the industry, and the complete conversion of downstream processing and all fluid handling systems to support the recovery of this higher titre output compared to the original installation's lower titre design criteria. Equipment redundancies and labor sharing were balanced between CCP2 and CCP1, and the facility and process automation was significantly expanded in scope to reduce product production cost.

Revamping the existing CCP2 facility to support new process technology in lieu of building anew resulted in significant savings in capital ($50 million). The project was completed two months ahead of schedule, ensuring patient product supply.

In Their Own Words

Impact to patients

As one of the largest cell culture manufacturing facilities in the world, CCP2 is an integral part of the Genentech/Roche supply chain, providing medicines to patients with serious and life-threatening conditions. At peak production, this facility can provide oncology products to over 500,000 patients annually.

Newer technology

The technology incorporated when CCP2 was constructed was state of the art. From the automation that was incorporated into the facility to shared labor costs between CCP1 and CCP2 to the equipment redundancy that will nearly eliminate downtime, CCP2 will achieve its goal of reducing the cost of lifesaving drugs to patients. This goal was paramount to the initial CCP2 project and also to the RTS project, making both projects award-winning applications of newer technology being used to benefit the patients.

Perseverance and overcoming challenges

From breaking the ground to the final validations and completion of qualification lots, the teams who worked on the CCP2 projects have shown a tremendous amount of drive, ingenuity, creativity, and perseverance to overcome challenges to return the facility to service. From the initial aggressive 5-year schedule to the disheartening task of shutting the facility down to the ambitious restart schedule, the teams have used all tools at their disposal to complete the tasks.

The CCP2 teams have already received recognition from outside agencies for their work on this facility. DPR Construction was awarded the Fiatech CETI (Celebration of Engineering & Technology Innovation) Award for outstanding technical contributions to the industry, and their electrical subcontractor, Long Electric, was awarded the Project Excellence Award by the National Electrical Contractors Association (NECA) of Northern California.

Facility uniqueness

The Vacaville CCP2 facility is a unique facility. With its 244,000-square-foot base isolated building, eight 25,000-liter fermentation bioreactors, reverse osmosis water system with ozone sanitization, totally automated systems from manufacturing control to batch record closeout, inline buffer dilution system and 1.8-meter-diameter chromatography columns, this facility, at full production, will produce medicine for nearly 500,000 patients. CCP2's size and complexity puts this facility in a class of its own.

Sustainability

In addition to building a world-class facility, implementing measures to protect endangered species, executing and encouraging recycling programs, and putting into action measures to reduce energy and water consumption, being good stewards of the environment and sustainability were priorities for the project teams. Whether it was taking mitigation steps to protect the burrowing owl or implementing studies and projects to further reduce energy and water consumption in an already state-of-the-art facility, the teams challenged themselves to make CCP2 an exceptional example of sustainability.

Key project participants

Manufacturer/Owner	Genentech, Inc. 1000 New Horizons Way Vacaville, California 95688
Designer/Architect/ Engineer	Fluor Enterprises, Inc. 4120 Dublin Boulevard, Suite 200 Dublin, California 94568
Construction Manager/ General Contractor	DPR Construction 1450 Veterans Blvd. Redwood City, California 94063
Piping Subcontractor	Kinetics Systems, Inc. 48400 Fremont Blvd. Fremont, California 94538 Acco Engineered Systems 630 Eubanks Ct # E Vacaville, California 95688
HVAC Subcontractor	Marelich Mechanical 24041 Amador St. Hayward, California 94544 Acco Engineered Systems 630 Eubanks Ct # E Vacaville, California 95688
Automation and Control Supplier	Honeywell Process Solutions 1250 West Sam Houston Pkwy. S Houston, Texas 77042
Major Equipment Suppliers Media Hold Tank	Holloway America 720 N Cedarbrook Ave. Springfield, Massachusetts 65802
Chromatography Columns	Eastern Rivers Inc. 6111 Heritage Park Dr. Chattanooga, Tennessee 37416
Large Bioreactor Vessels	Northland Stainless 1119 Bridge St. Tomahawk, Wisconsin 54487
Superskids	Paul Mueller Company 1600 W. Phelps Springfield, Missouri 65802
UFDF Skids	Millipore Corporation 80 Ashby Rd. Bedford, Massachusetts 01730
CIP Skids	Electrol Specialties Company 441 Clark St. South Beloit, Illinois 61080
Chromatography Control Skids	Therma1601 Las Plumas Ave. San Jose, California 95133-1613
Centrifuge	Alfa Laval Inc. 955 Meams Rd. Warminster, Pennsylvania 18974
WRO Tank and Distribution Piping	DCI 600 54th Ave. North St. Cloud, Minnesota 56302

FOYA 2016
Facility of the Year Awards
CATEGORY WINNER
Project Execution

Janssen Vaccines AG

"Their goal of designing a facility, in a race against the clock, that would be flexible enough to accommodate the likely changes in the production process was achieved through massively parallel activities in process development and facility design and construction."

Project:
ZEBOV in B81J

Location:
Bern, Switzerland

Project mission:
Provide a production facility for an Ebola vaccine

Total facility floor area:
700 m^2

Production support area:
975 m^2

Delivery type:
Design bid build

Fast-Tracked Ebola Vaccine Project Ignites New Spirit

The largest outbreak of the Ebola virus the world has ever seen is believed to have begun with a young Guinean child in December 2013. By mid-2014, the virus had spread to several other West African countries, and the World Health Organization had declared the outbreak to be a "public health emergency of international concern." As the world's attention focused on the growing epidemic, companies like Janssen Vaccines AG were looking for a way to help.

For Peter-Jost Spies, Interim Lead Platform Engineering and Maintenance, Vaccines and Advanced Therapies, at Janssen Vaccines AG, the quest began in August 2014 to find a suitable facility where mass quantities of fast-tracked Ebola vaccine could be produced in a short period of time.

The initial search yielded a number of possibilities for Spies and his team. Janssen Vaccines (then known as Crucell Switzerland AG) had a number of facilities that could qualify—facilities that might only require placement of equipment or a simple reassignment of people—yet it was a fortunate circumstance that led to the selection of the 81J facility in Bern. Already in the decommissioning stage from the manufacturing of another product, 81J became the stage for what Spies describes a "once-in-a-lifetime project" that featured a sharp company-wide focus, timely decisions, solid partnerships, a little bit of luck, and a strong sense of purpose.

Responding to a crisis

IIn mid-2014, Janssen, the pharmaceutical division of Johnson & Johnson, responded to the Ebola outbreak in West Africa and committed to accelerating the development of its candidate Ebola vaccine. From the beginning, the program was given the highest priority within Johnson & Johnson and had the full support of top management. The quest then began for the selection of a facility that could produce the first trial materials and have a manufacturing capacity that was large enough to supply up to five million doses.

"Initially we had a number of facilities to look at," says Spies. "Naturally, we looked at existing facilities where we would have space available for small-, mid- or large-size capacity. The facility in Bern was my suggestion because I knew what it was capable of. It was a bit of a lucky circumstance that it was already in the decommissioning stage."

With production activities scheduled to phase out in December 2014, the 81J facility would be available for renovation and adaptation in 2015. Dating from 1995, the building was in good condition and featured approximately 700 square meters of production area, 430 of which were Class D and C cleanrooms. Technical areas above and below the production level held the building's infrastructure.

Scientists and project specialists were brought in to evaluate the facility, which was previously used to produce a vaccine with a completely different process than that envisioned for the Ebola vaccine. "Janssen [then Crucell] had developed a PER.C6 cell line that can express a number of proteins of any kind," says Spies. "The virus vector that we used for the Ebola vaccine is called an adeno vector virus, and it is genetically modified to mimic the Ebola infection. This adeno-type vector virus grows in the PER.C6 cell, and it does that in disposable technology, in disposable bioreactors, in disposable mixing devices; we can even have disposable centrifuges. These are the technological platforms that build very small and can basically fit into laboratory-type installations.

"It really is a clever thing," continues Spies. "We could quickly refurbish an existing facility, change a few walls, install an air lock and then roll all of this mobile disposable equipment and basically run that process. That is the strategic advantage of this type of platform definition."

The scientists and project specialists agreed that the 81J facility had ample space for the Ebola vaccine, provided that Spies and his team could make certain changes to it. In this respect, utility hookups and process gases had to be adapted in the building alongside changes of air locks and sterilization equipment.

Risk-assessed compromises

As is common for fast-track projects, most of the projects in the program were executed in parallel. The success of such an approach is the seamless integration and efficient communication coupled with project execution within a reasonably wide design space to quickly respond to possible process changes.

For this to work, it's essential that the project management is experienced and that all subprojects are aware of the possible implications of changes within the overall program.

Spies selected Chemgineering Technology AG as the designer, engineering, and construction management partner. "I selected them because I know their project manager," he says. "They knew what they were doing and knew exactly where they had to provide enough design space for potential changes for that type of process."

Faced with a tight schedule, Spies and his team understood that the ideal scenario would be to make minimal changes to the facility. One prerequisite for the project was to preserve as much of the existing facility, such as cleanrooms and infrastructure, as they could to keep the schedule as short as possible. Nevertheless, no compromises were made on the future good manufacturing practices (GMP) operation or safety standards of the facility. "Our focus at the time was to do what was minimally needed without compromising safety or GMP," says Spies.

A decision was made early on that they would only make modifications to the existing heating, ventilation, and air-conditioning (HVAC) system in lieu of a complete HVAC replacement, as was initially proposed. "I negated that and decided to use the old system because it is balanced right and we were not changing any rooms," says Spies. "The other requirement was to improve fire protection at the facility, but we waived that and decided not to install any structures that would impact the schedule. These were the few risk-based deviations from Johnson & Johnson expectations or requirements that were consciously made in order to make the schedule."

The start phase of the refurbishment project in October 2014 was dominated by intense design workshops on the layout and definitions of personnel, material, product, and waste flows. Also, biological containment requirements of Biosafety Level 2 (BSL2) had to be engineered because the facility had not been designed to handle biologically active material.

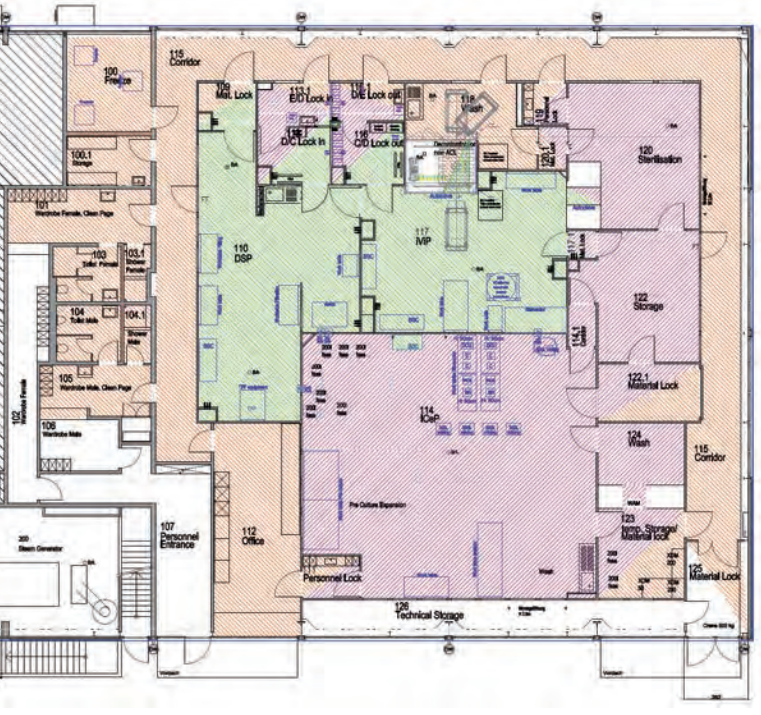
In addition, as the project advanced, it became evident that the manufacturing process for the Ebola vaccine would require two autoclaves: one for sterilizing equipment coming into the facility and the other to decontaminate potentially infectious material on the way out. Fortunately for Spies, Janssen had recently ordered an autoclave for a project that had since been cancelled. "We were lucky in that respect," he says. "Otherwise we would have added a minimum of 6 months to the schedule." This little bit of "luck" also saved the project some $200,000.

Challenges

No project is without its challenges, and this one was no different. To begin with, the 81J facility is a shared facility: Half is owned by Janssen, and the other half is leased to a tenant. As a result, Spies and his project team had to be careful that their project did not affect the tenant's production schedule.

Additionally, there was a potential conflict with a building demolition next door, which included the adaptation of electrical and gas infrastructure. As luck would have it, Spies was personally in charge of the demolition project, so the impact on the Ebola project was limited to the need for strong communication between project managers.

The Ebola project was completed on time and under budget, with the facility ready for production runs in September 2015, a mere 13 months after Spies and his team got involved. As Spies explains, the project was possible only with the strong commitment of the site's engineering team and active support of Johnson & Johnson's worldwide engineering organization. "It all went well because we sat together," says Spies. "There was a weekly meeting with the designer, the construction company, project experts, process experts, and our development department."



What the FOYA Judges Had to Say

In 2014 Janssen, the pharmaceutical division of Johnson & Johnson, responded to the Ebola outbreak in West Africa and committed to accelerate the development of its candidate Ebola vaccine. While the first volumes were produced in pilot scale, an idle facility was being refurbished for the scaled-up process providing a launch capacity of up to 5 million doses annually.

One of the major challenges in this project was the parallel ongoing process development and design of the facility. It was of utmost relevance that the design space was able to accommodate possible process changes without impacting the schedule for completion of the facility.

The main objective of the project was to have the facility ready for engineering runs in Q3 of 2015. This goal was achieved by September 2015 through massively parallel activities in process development and facility design and construction. The challenge was to design a facility that would be flexible enough to accommodate the likely changes in the production process. The ZEBOV project is now completed, and production activities have commenced.

The successful execution of the project was achieved by:

- Teaming up the process developers, the tech transfer team, and the facility designers to define the facility requirements in close collaboration
- Having all stakeholders in the project fully committed to reaching the goal and meeting the schedule
- Early and continuing involvement of local authorities to include their expectations in scope and design

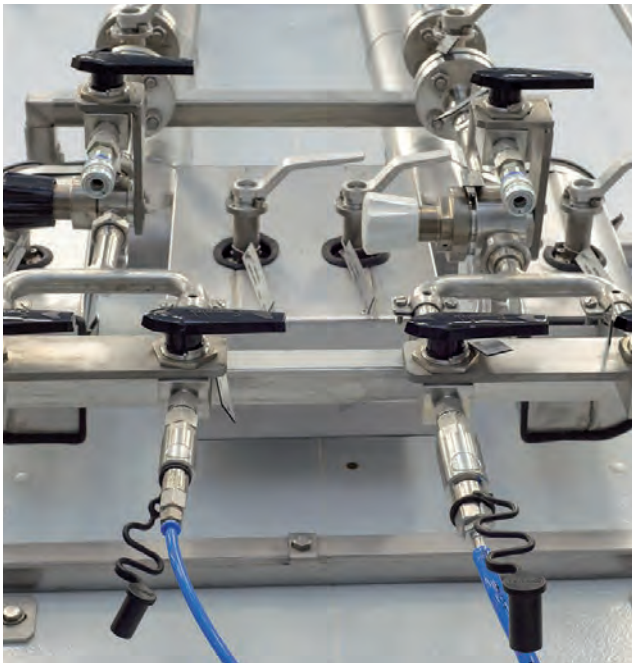
Once in a lifetime

Spies describes the opportunity to work on the Ebola project as "once in a lifetime." Usually, projects are focused on fulfilling a business need, but the Ebola project in Bern was quite different. "Here, we didn't have a business need; we had a world need to answer for what was then perceived as the one and only threat to human kind," he says. "Behind the scenes, top management at Johnson & Johnson were actively involved. The investment proposal, which on a scale like this normally takes a minimum of 3 months, was granted within 10 days."

He cites other examples of extraordinary efforts and procedural exceptions taken during the project, and not only at the Bern facility, including the offer to use a corporate jet to ship lab samples for weekend delivery. "This rather small refurbishment project is unique in that it took all of the friction away," says Spies. "Our project team was fully aligned, and everyone else was helping us; that's why it was such a success."

Today, thankfully, the Ebola outbreak has been contained and the team in Bern has now moved on to new projects. "We will probably, and maybe hopefully, never see the need for such an activity again," says Spies. "But we now know how to work together and focus on business needs. Our site in Bern has gone through that; we know how to motivate ourselves and find ways to work together.

"We believe that this small fast-track project is exemplary for good team building, cost control, and stakeholder communication," says Spies. "The project closed with a lessons-learned exercise that revealed once more how motivated and dedicated the team members were and still are. Coming at a time of phase-out onsite, this project created a new spirit in Bern. Its successful completion fills us with pride having delivered on the challenge to fight one of the deadliest diseases in the world." ■



In Their Own Words

- We delivered the project on time within a very short schedule and within budget by driving risk-based, concurrent tasks in process development, facility design, and construction.
- The project was successfully completed with 1,800 man-days without reportable incident due to careful planning and the application of Johnson & Johnson safety standards.
- In spite of the limited resources onsite and the weakened morale of employees following the phaseout of production, we were able to create a mission-focused team with great dedication and the spirit to succeed.
- The project's purpose of fighting the Ebola disease created a lot of commitment and attention among stakeholders, team members, and contractors. It also created a high visibility throughout Johnson & Johnson and the public. Schedule adherence was a given ultimate goal.
- The project made collaboration of all onsite entities necessary and forged a team spirit that has prepared us for the next challenges.

Key project participants

Manufacturer/Owner	Janssen Vaccines AG, Rehhagstrasse 79 CH-3018 Berne, Switzerland
Project Management	Johnson & Johnson Worldwide Engineering EMEA, Beerse, Belgium
Designer **Engineering (General Planner)** **Construction Management**	Chemgineering Technology AG, Binningerstrasse 2 CH-4142 Münchenstein, Switzerland
Project Control	Turner & Townsend, Austrasse 2, Reinach CH-4153 Basle, Switzerland
Procurement Process Equipment	Jacobs Italia S.p.A., Via Volta N 16 20093 Cologno Monzese, Milan, Italy
Piping Subcontractor	Bilfinger Industrial Services Schweiz AG, Niederlassung Rohrbau Hohenrainstrasse 10, CH-4133 Pratteln, Switzerland
HVAC	Honeywell Building Solutions, Honeywell AG, Javastrasse 2 CH-8604 Volketswil, Switzerland E. Kalt AG Klima- und Energietechnik Turbenweg 12 CH-8604 Volketswil, Switzerland
Cleanrooms	Lindner Reinraumtechnik GmbH, Bahnhofstraße 23 D-94424 Arnstorf, Germany
Floors and Buildings	Weiss+Appetito Holding AG, Statthalterstrasse 46 CH-3018 Bern, Switzerland
Electrical Design	SSE Engineering AG, Turbenweg 10 CH-3073 Gümligen, Switzerland
Electrical Installation	ETAVIS Arnold AG, Waldeggstr. 47 CH-3097 Liebefeld, Switzerland
Monitoring System/Automation	Retel Neuhausen AG, Rundbuckstrasse 6 CH-8212 Neuhausen, Switzerland
Main Equipment Supplier (Sterilizer)	Belimed Sauter AG, Zelgstrasse 8 CH-8583 Sulgen, Switzerland

FOYA 2016
Facility of the Year Awards
CATEGORY WINNER
Equipment Innovation

Pfizer Inc.

"Throughout the design process, innovative approaches were incorporated to increase speed, enhance quality, and reduce overall project cost—all ultimately aimed at benefiting patients globally, and making significant contributions to the pharmaceutical industry."

Project:
The Portable, Continuous, Miniature, and Modular Collaboration

Location:
Groton, Connecticut, USA

Project mission:
Enable portable, continuous, miniature, and modular, manufacturing for OSD dosage forms

Site information:
Building 90, Pfizer campus, Groton, CT; a warehouse structure that had never been used for therapeutic manufacturing

POD section being delivered to Pfizer's Groton, CT site


POD section being craned into Pfizer facility


Exterior image—Fully installed PCMM POD in Pfizer facility

Portable, Continuous, Miniature, and Modular Facility

Revolutionary changes are happening in the pharmaceutical industry. In the biological sciences, especially those where breakthrough therapies are rapidly progressing through the clinical trial process, timelines associated with creating clinical and commercial dosage forms are under increasing pressure. At the same time, a wave of technology advances external to the pharmaceutical industry is producing new sensors, data analytics, and information technologies.

Today, the pharmaceutical industry generally uses batch processing to develop and manufacture new therapies. Very small batches of capsules and tablets are made for the initial clinical trials, medium-size batches are made for later stage trials, and high volume batches are made for commercial manufacturing. Normally, each batch size may require different equipment and processes; in addition, batch processes are complex and often require dedicated facilities.

It is in this context that Pfizer, Inc., formed a consortium with GEA and G-CON Manufacturing to design and build a portable, autonomous manufacturing environment for continuous oral solid dosage (OSD) production. Together, they designed a platform using G-CON Manufacturing's POD system coupled with GEA's ConsiGma-25 process equipment. The result is what Pfizer calls "PCMM" (portable, continuous, miniature, and modular), an innovative platform technology that can take new products through their entire life cycles, from development to commercial manufacturing.

"We see an integrated approach to development and manufacturing where a platform technology like PCMM can be used to make clinical supplies, and then either the same equipment or a clone/replica of that equipment can be used to make commercial supplies," says Daniel O. Blackwood, Director, Advanced Technologies Prototyping & Implementation, Pfizer. "We are moving our organization from batch paradigms that require technology transfers and process scale-ups, to a knowledge-accrual paradigm where with each subsequent batch that we make on this platform we gain new and greater insights. As we step through the clinical and ultimately commercial stages of the program, we have a robust knowledge of how to make these dosage forms; we think that this positions us well for the future.

Key partnerships

In September 2012, Pfizer announced its collaboration with GEA and G-CON Manufacturing for the PCMM concept. "We had two teams of Pfizer colleagues from a number of our R&D and Manufacturing sites collaboratively working to pull this design together: one team working with the G-CON Manufacturing group to design the PODs, and another team working with GEA, to design the process equipment" says Blackwood. "We spent the better part of a year designing this equipment and then integrating that design with the PODs."

The continuous processing equipment, designed and fabricated at GEA's facility in Wommelgem, Belgium, incorporates both wet granulation and direct compression process capabilities. Both systems convert powder to tablets within minutes using the standardized platform technology.

G-CON Manufacturing designed and fabricated the POD system at its manufacturing facility in College Station, Texas. Each system was fully assembled and functionally tested prior to shipment to the final assembly site at Pfizer's Worldwide Research and Development campus in Groton, Connecticut. "We entered factory acceptance testing in December 2014 and completed that activity in January 2015," says Blackwood. "We received the equipment at Groton in March 2015, and it took us about eight weeks to get it installed, powered up, lights on, and operational. We drove the qualification efforts through the summer of 2015. During the fourth quarter of 2015, we made practice batches with placebos and a few active batches. These practice batches have served to direct our organization along the learning curve associated with this technology. We are seeking to be cGMP-ready (current good manufacturing practice) in the second quarter of 2016."

The facility of the future?

The benefits of the PCMM concept are many, including a possible direct benefit for patients wherever they are around the globe. The ability to place a portable facility in a POD with the equipment that is housed in it could allow a company like Pfizer to locate its manufacturing facilities closer to patient population centers.

GEA's ConsiGma-25

Blackwood believes that the PCMM platform places Pfizer at the leading edge of the industry's transition from batch to continuous processing. "We think this is an adoptable and adaptable means of incorporating new technology into our facilities, gaining advantage in using these technologies quickly but also maintaining a sustainability framework so that we can continue to evolve and take advantage of new technologies as they emerge," he says.

Indeed, in this initial project, Blackwood and his team introduced new technology that changed the manufacturing processes. "We created an efficient means of taking powder streams and blending them together, which is at the heart of our drug product operations," he says. "The new mixer we created takes these powder streams and blends them together and continuously feeds them to the tablet press."

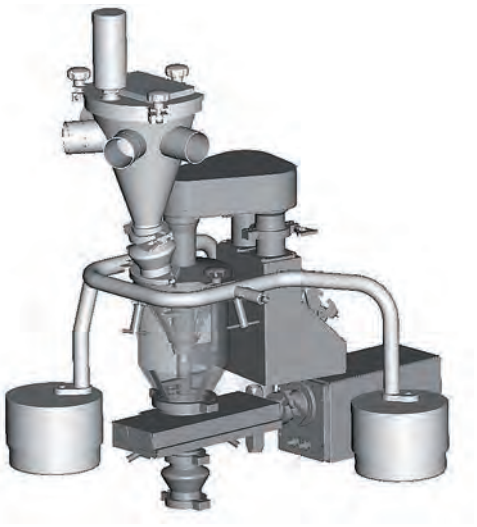
In addition, the team introduced five process analytical technology (PAT) sensors before and after key material transformation steps. "These sophisticated sensors allow us to extract data-rich information as materials are being passed across the detecting devices," explains Blackwood. "The integration of that data from these advanced sensors along with the process data that's being recorded with our integrated controller really gives us a great opportunity to transform that information into insight and knowledge of our processes. We are recording ±2,000 data points every

Exterior image—PCMM POD at G-CON Manufacturing facility prior to shipment

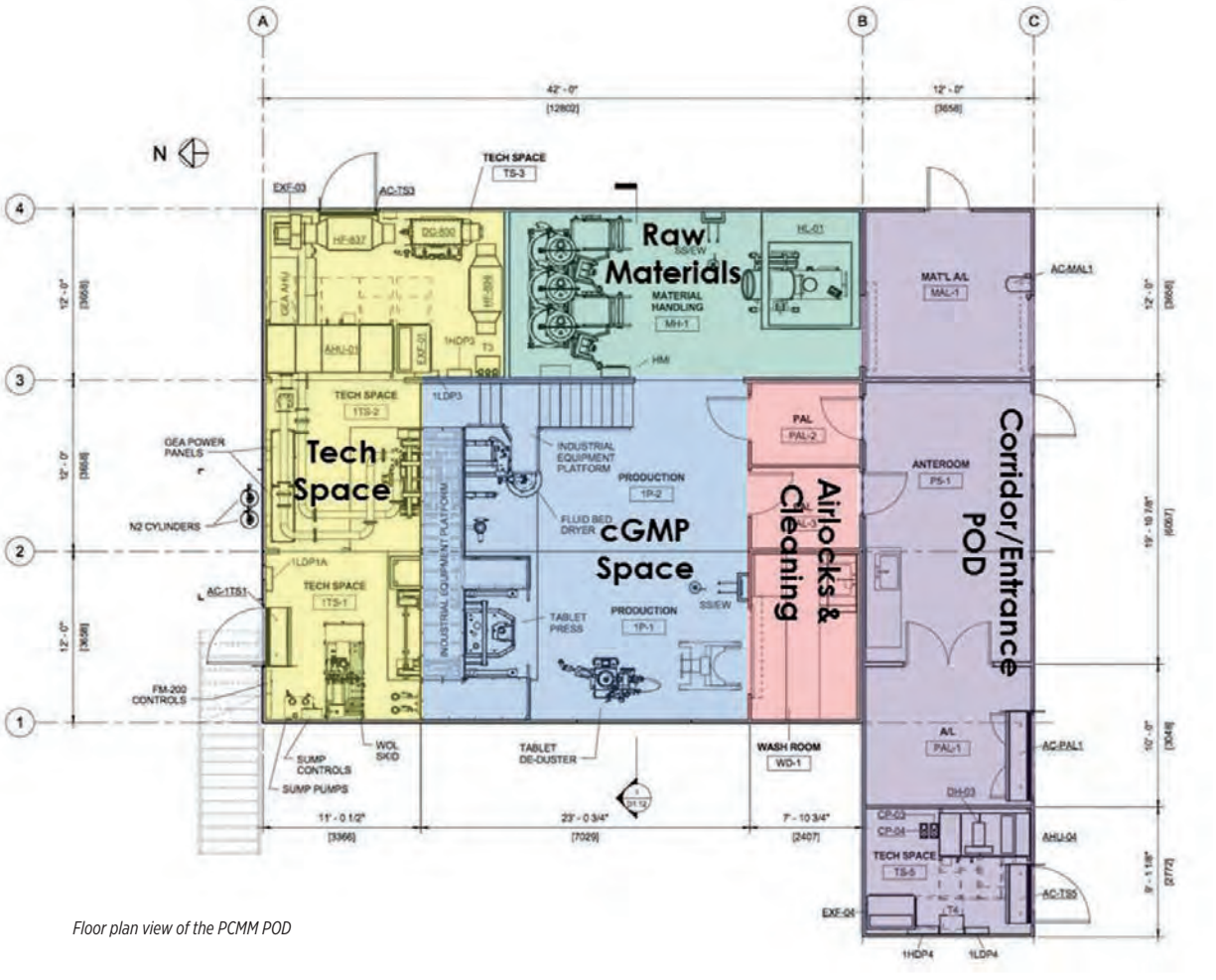
couple of seconds out of this process, and that provides us with the ability to extract knowledge from the material transformation steps we're doing."

PCMM's modular design also allows Pfizer to embrace new technology as it is introduced. "We recognize that technology is going to continue to evolve, and we needed to create a sustainable model where we can readily adapt to those incremental gains and the efficiencies that come along with them. We think our POD concept with skid-based processing equipment allows us to embrace those incremental changes as they occur. We think we have a sustainable model to keep pace with the technology evolution that we anticipate will occur," says Blackwood.

As Pfizer works toward GMP capabilities later this year, its PCMM platform has the potential to be a transformative technology for both the company and the industry as a whole. "We have created an integrated factory that is capable of making smaller-scale clinical supplies, yet it's also capable of running 24/7 to make high-volume supplies in a commercial environment. And as a mobile facility, we were able to incorporate this technology into a former warehouse in a rapid time frame," concludes Blackwood. ■



In-line powder mixer



Floor plan view of the PCMM POD

What the FOYA Judges Had to Say

Bringing breakthrough medications to patients faster that are affordable and reliably supplied is one of Pfizer's key objectives. To deliver on these objectives by creating the next generation of OSD processing technologies and to address the rapidly changing requirements of pharmaceutical drug manufacturers, Pfizer, GEA, and G-CON Manufacturing formed a consortium to design and build a portable, autonomous manufacturing environment for continuous OSD production using GEA's ConsiGma-25 system and G-CON's modular POD system. Installed at Pfizer's labs in Groton, Connecticut, the current prototype transforms raw materials into uncoated tablets in minutes. The equipment fits into a portable facility called a POD, which can be shipped to any location to produce medications when and where they are needed.

Portable, continuous, miniature, and modular development and manufacturing for OSD forms is a platform technology that can be utilized in product development and commercial manufacture; a key innovative advantage is being able to use the same equipment throughout the entire product life cycle and to shorten development timelines and technology transfer.

One factor critical to the success of the design effort was the close coordination between Pfizer, G-CON Manufacturing, and GEA engineering design teams. To meet the schedule, both the process equipment design and POD designs had to be conducted in parallel. Throughout the design process, innovative approaches were incorporated to increase speed, enhance quality, and reduce overall project costÐall ultimately aimed at benefiting patients globally. Significant contributions to the pharmaceutical industry include:

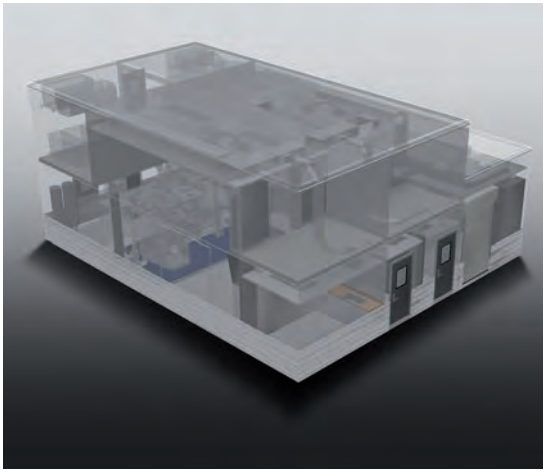
- Increased project speed significantly reduced timelines for facility design and construction. The design of the customized air-bearing and POD lifting system allowed the PODs and process equipment to be positioned and installed into a gray space warehouse within one week of receipt at the landing location.
- Integration of a new vertical, in-line powder mixer for continuously blending pharmaceutical powder streams; integration of five process analytical technology (PAT) sensor systems within the continuous wet granulation and continuous direct compression process equipment; and integration of an advanced process control capability to integrate signals from process and PAT sensors into a real-time monitoring and control system all enhanced quality.
- Lower up-front investment cost (compared to traditional facilities) and up to 35% energy and resource savings reduced overall project costs and environmental footprint.
- Additional benefits: Efficient experimental study of the process equipment with an estimated 10 times less material usage and 10 times faster batch equipment, multiple formulations and flexible batch sizes, reduction in wash-in-place materials as powder is converted to tablets within minutes, increased overall equipment effectiveness and no scale-up from R&D, and clinical supply to full-scale commercial production.

Pfizer will use the PCMM prototype unit for current GMP (cGMP) manufacture clinical supplies of immediate-release tablets for various new chemical entities. Today, the PCMM prototype produces uncoated tablet cores via direct compression and wet granulation processes. In the immediate future, POD-based installations containing continuous tablet-coating technology are envisioned. A key feature of the POD-based installation is that significant construction/expansion activities can occur without disrupting the ongoing operations within the prototype unit.

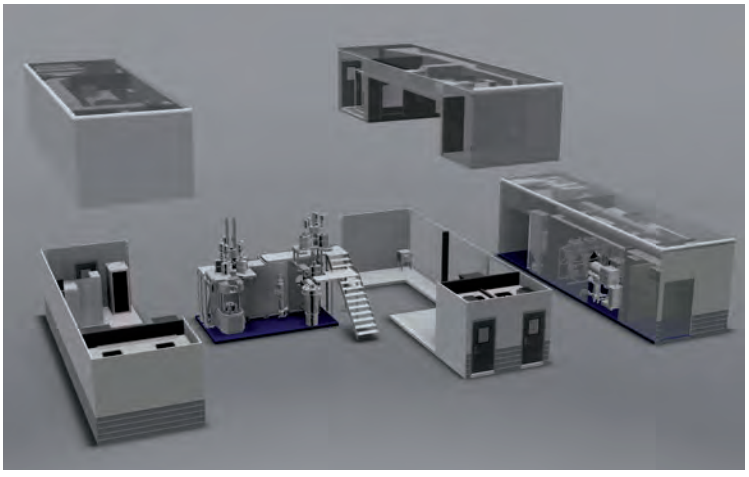
The PCMM ConsiGma-25 contains a continuous direct compression and continuous high-shear granulation and drying system that converts active pharmaceutical ingredients and excipients into tablets for development, pilot, clinical, and production in a single, compact unit. The system can be configured into a direct-compression mode that allows for gravimetric feeding and in-line mixing of these powder streams and direct conversion into tablets. Alternatively, the operation can be reconfigured for wet granulation so that powder streams can be wet granulated, dried, milled, and compressed into tablets. There is minimal waste during start-up and shutdown. Batch size is determined simply by how long the machine operates. The system can operate at rates of 5–30 kilograms per hour [kg/hr [11–66 pounds per hour)]. Quality is measured throughout the process, with five integrated PAT instruments. The integrated advanced process control system and PAT tools enable monitoring and control during production.

Facility of the Future

Pfizer, G-CON, and GEA anticipate the opportunity for significant expansion of the platform itself and expect that PCMM will become the industry platform for OSD manufacturing. The miniaturization of the equipment allows it to fit inside a cGMP enclosure—a POD—that can then be placed inside a cost-efficient structure. The modular and portable components allow unit operations to be "plugged in" when needed. Modularity and portability will also minimize construction issues. Lastly, risks associated with stranded assets/facilities are mitigated due to the modularity and portability of these designs. PCMM truly represents a breakthrough platform for facilities of the future.



Exterior image—3D CAD version of PCMM POD



Expanded 3D CAD of PCMM PODs and equipment

In Their Own Words

The PCMM installation represents a collaboration between three companies (Pfizer, GEA, and G-CON Manufacturing) that:

- Conceptualized, designed, fabricated, installed, and commercialized a novel facility to continuously manufacture pharmaceutical OSD forms using a POD-based installation that is portable, continuous, miniature, and modular;
- Utilized investments of company resources, talents, and capital from all three entities to create an OSD platform technology;
- Created a new paradigm to develop and commercially manufacture OSD forms that does not use traditional batch pharmaceutical processing;
- Developed and integrated novel in-line vertical continuous powder-mixing technology, customized PAT interfaces, and advanced process control systems into this facility; and
- Lastly, with the help and support of many diverse scientists and engineers, Pfizer today has a working OSD cGMP continuous tableting operation that produces at rates of 5–30 kg/hr inside a former warehouse space.

Together, these features will transform the pharmaceutical industry and bring medications faster and more cost-effectively to patients.

Key project participants

Manufacturer/Owner	Pfizer, Inc. Eastern Point Road Groton, Connecticut 06340
Designer/Architect	TLB Architecture, LLC 92 West Main Street Chester, Connecticut 06412
Engineer	Hallam ICS 575 West Street, Suite 220 Mansfield, Massachusetts 02048
Main/General Contractor	Harry Grodsky & Co., Inc. 4 Fort Hill Road Groton, Connecticut 06340
Major Equipment Supplier(s)/ Contractor(s)	G-CON Manufacturing, Inc. 8800 Health Science Center Parkway Bryan, Texas 77807 GEA Process Engineering N.V. Keerbaan 70 B-2610 Wommelgem, Belgium
POD Engineering	Amec Foster Wheeler 7 Penn Center 1635 Market Street Philadelphia, Pennsylvania 19130 Whitman 7 Pleasant Hill Road Cranbury, New Jersey 08512
POD Structural Engineering	Mainstay Engineering Group, Inc. 212 North Main Street North Wales, Pennsylvania 19454
POD Automation and Control Supplier	Rockwell Automation 4325 West Sam Houston Pkwy N #100 Houston, Texas 77043

FOYA 2016
Facility of the Year Awards
CATEGORY WINNER
Facility Integration

Takara Bio Inc.

"The innovative use of integration to house cell products, viral vectors, and recombinant proteins within the same facility, makes this a practical, efficient model for future biopharmaceutical facilities."

Project:
Center for Gene and Cell Processing Construction Project

Location:
Kusatsu, Shiga, Japan

Project mission:
To provide products and/or investigational agents for biopharmaceuticals, gene therapies, and cell therapies, in combination with quality checks, by establishing the Center for Gene and Cell Processing.

Total facility floor area:
71,824 sq ft (6,675 m^2)

Center for gene and cell processing (CGCP)


CGCP and the surrounding environment


Dry type hydrogen peroxide sterilization system (in machine room, second floor)) (newly developed in the project)

One-Stop GMP Facility for Cells, Viruses, and Proteins

Seeing a growing demand for their R&D expertise and contract manufacturing capabilities, the team at Takara Bio had a choice to either grow their capacity the traditional way or innovate. They chose innovation, and in doing so may have developed a concept that has the potential to become a new global standard.

Takara Bio of Shiga, Japan, is a leader in three core business sectors: bioindustry, agribio, and gene therapy. For the past 20 years, the company has been developing new products in the fields of stem cells, regenerative medicine, and cell therapy. Its product RetroNectin, a recombinant protein that enhances gene transfer, is used by gene therapy companies and scientists worldwide.

Spurred by the Japanese government's policy to encourage the development of regenerative medicines, the company's bioindustry division is researching stem cells and developing regenerative medicine and gene therapy products. The company also decided to expand its contract development and manufacturing organization (CDMO) business under which biopharmaceuticals are developed and manufactured under contract.

"We have four pipelines of gene therapy projects for cancers and AIDS worldwide," says Junichi Mineno, PhD, Managing Director, Takara Bio. "In Japan, there were no facilities that could manufacturer viral vectors at GMP [good manufacturing practices] grade. Many customers asked us to manufacture viral vectors and cells at GMP grade, so we decided to build new facilities."

As part of this effort, in June 2012 Takara Bio initiated a project to construct its Center for Gene and Cell Processing (CGCP) to serve as a core facility for the CDMO business. The facility was designed to manufacture and test biopharmaceuticals as well as investigational products for gene and cell therapies—a single facility that would meet all of the company's manufacturing and R&D needs while reducing production time and saving costs and energy.

A one-stop GMP manufacturing facility

TTo produce three product types—proteins, viral vectors, and cells—the traditional industry approach would be to build a separate facility for each one. There are several good reasons for this, not the least of which is that the raw materials and the production processes are different for each type. "Viral vectors are produced by transfection of the DNA manufactured by *E. coli*," says Mineno. "Normally, we would manufacture the plasmid DNA by *E. coli* in one facility and then the DNA is moved to another facility to manufacture viral vectors. And then gene-engineered cells are made by retroviral vector transfection, so to make gene-engineered cells we move viral vectors from one facility to another. So, to produce the gene-engineered cells, we normally use three kinds of facilities and the materials are moved among them."

But Mineno and his team decided to look at things a little differently: What if all of those processes could be done in a single facility? "Before designing our CGCP facility, I asked some overseas companies making viral vectors whether we could integrate the *E. coli* production area and the cell production area," he says. "Everyone said that if they are physiologically separate, it should be OK. The question then became 'What is physiologically separate?' That became our most important homework."

Discussions about how to proceed took place between the company and its engineering provider, Daikin Applied Systems Co., and the Pharmaceuticals and Medical Devices Agency (PMDA), Japan's regulatory drug agency. They concluded that to mitigate the possibility of contamination, each functional area needed separate airflow, drainage systems, and flow of materials and personnel. In essence, they set out to design a single facility that would house three independent, separate facilities.

One floor per function

The building concept that Mineno and his team designed contains three floors, each housing a specific function. "The first floor is mainly for the *E. coli*-handling area, the second is mainly for viral vector production, and the third is mainly for the cell-processing areas," he says.

Construction began in May 2013 on the new CGCP facility in Kusatsu, right next to the company's head office. The first floor was designed for the upstream culture area, with three bioreactor suites for manufacturing recombinant protein and plasmid DNA. The second floor was designed for the virus manufacturing area, with six suites having flexible manufacturing capability for a variety of viruses and viral vectors (retroviral vectors, adenoviral vectors, adeno-associated viral vectors, lentiviral vectors, and herpes simplex virus); a purification area with two purification rooms for recombinant proteins, antibodies, and plasmid DNA; and an aseptic filling area with three aseptic filling rooms. The third floor was designed for the cell-processing area, with five cell-processing suites (plus three for future expansion) for manufacturing gene-modified cells or regenerative medicines, and a quality and safety testing area with 16 rooms for testing vectors and cell products.

To reduce any risk of contamination between functional areas and to improve the efficiency with which materials moved from one area to another, the company selected the best practices to achieve their goals. "We selected vaporized hydrogen peroxide (VHP) to clean up the rooms to avoid contamination of each functional area," explains Mineno. "We also selected single-use systems in the case of the *E. coli* cultured as well as gowning systems that best fit our facility and the air lock systems between functional areas to reduce contamination."

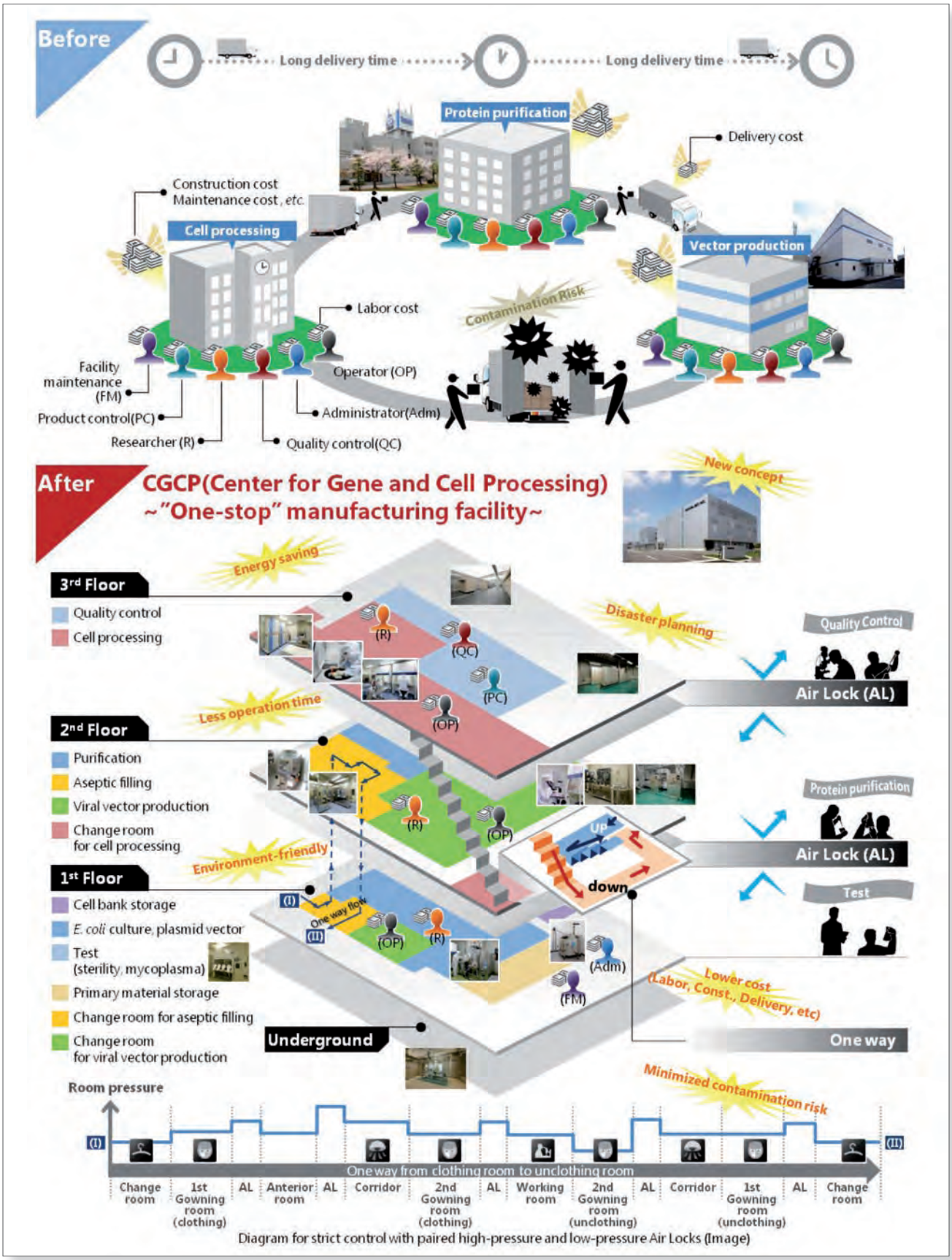


Diagram for strict control with paired high-pressure and low-pressure Air Locks (Image)

Top and bottom—Restricted access barrier system, second floor

Sterilzation booth, second floor—Three sterilization methods: 1) autoclave, 2) dry-heat sterilizer, and 3) dry-type VHP

The project team met weekly, and the construction phase of the project was completed in April 2014, approximately 11 months after that phase began. Performance lots were produced in September 2014 and the first products produced in February 2015. The CGCP facility was certified by Japan's Ministry of Health, Labour, and Welfare for cell processing in May 2015.

"We expect to contribute more to the development of gene therapy as well as regenerative medicine, especially in Japan, and we believe we can contribute to those kinds of developments through this facility," says Yoh Hamaoka, PhD, Senior Executive Officer, Business Development, Takara Bio. Mineno says that the CGCP project's win of the ISPE Facility of the Year Award Facility Integration category is a true honor. "The big pharmaceutical companies, such as Pfizer, Baxter, and Janssen, won awards in other categories, but Takara Bio is a small gene therapy company in Japan, and we are very proud to win this award." ■

What the FOYA Judges Had to Say

To support its R&D partners and contract manufacture commercial biopharmaceutical products, Takara Bio constructed the Center for Gene and Cell Processing (CGCP) in the city of Kusatsu, in Shiga, Japan. This unique facility is being recognized for its innovative use of integration to house cell products, viral vectors, and recombinant proteins within the same facility.

Industry traditionally places these three functions in separate facilities to eliminate any risk of cross-contamination, thereby accepting significant inefficiencies associated with the operation of multiple facilities. Takara Bio, however, needing to improve operational and cost efficiencies, departed from tradition by incorporating well-considered facility and operational containment measures to lessen the risk of cross-contamination between the three dissimilar manufacturing processes.

Each of the three functional areas, under the appropriate pressure cascade, has a separate entrance for personnel and raw materials via one-way paths lessening the risk of cross-contamination. Rooms were constructed with double ceilings and full-height partitions to close that contamination pathway. The air-conditioning systems are completely segregated, with exhaust filtered through high-efficiency particulate air filters and an uninterruptible power supply system with backup generator to significantly reduce the risk of airborne materials contaminating the other areas.

Processes include single-use systems, dedicated equipment, and restricted access barrier systems (RABS). The RABS sterilization process uses a dry-type VHP sterilization. The air-conditioning system ensures uniform dispersal once the hydrogen peroxide is fully vaporized. This sterilization process provides fully automated control of the interior temperature and humidity during sterilization and VHP concentration. The facility was certified by Japan's Ministry of Health, Labour, and Welfare for cell processing in May 2015.

The judging panel recognizes the facility innovations and the reasoned acceptance of risk required to combine three dissimilar biological processes into one facility, and looks for ongoing success with additional regulators and manufacturing campaigns to further support this approach as a practical, efficient model for future biopharmaceutical facilities.

In Their Own Words

The facility can become a new global standard

We constructed the CGCP facility unlike any other in the world; it can handle upstream bacterial culture as well as manufacture different types of gene therapy products and regenerative medicines such as viral vectors, recombinant proteins, antibodies, and cell products within the single facility.

- There are separate entrances in each area for personnel and raw materials to eliminate any intersecting between areas.
- There is also an excellent air-conditioning system that eliminates the intersection of air from different areas.
- The operation system satisfies the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), cGMP, EU GMP, and Japan GMP standards, resulting in manufacturing processes and a quality testing environment that meet global standards.

The CGCP has the potential to become a global standard for one-stop manufacturing facilities in the pharmaceutical and regenerative medicine industries.

The facility greatly reduces operating costs, time, and risk

This one-stop manufacturing facility can manufacture proteins, viruses and cells, thereby greatly reducing operating costs for facility maintenance, transportation and movement, personnel, and operation time. It also completely eliminates contamination risks inherent in existing facilities. Compared to existing facilities, this one-stop manufacturing facility:

- Reduces about 20% of personnel expenses
- Reduces filling operation time by approximately 80%, thanks to faster product filling
- Eliminates the contamination risk from transporting product materials between existing facilities

The sterilization process does not use highly toxic formalin

Formalin is toxic to humans and damages facilities. Hydrogen peroxide, however, breaks down rapidly and is harmless to the environment. This facility uses a new dry-type VHP sterilization process that is highly effective and reduces facility damage. This provides a consistent, high-quality sterilization process with fully automated control of VHP concentration, interior

temperature, and humidity during sterilization. Moreover, the air-conditioning system ensures uniform dispersal once the hydrogen peroxide is fully vaporized.

The facility can rapidly manufacture small lots of a variety of products

Employing the above-mentioned new technology for the changeover system in each room, and furthermore providing multiple manufacturing rooms in each area and an independent air-conditioning control system (a system that provides strict control of room pressure, temperature, and cleanliness level), made it possible to produce small quantities of products in a wide variety of categories for gene therapy and regenerative medicines, including cell products and viral vectors that do not constitute large-scale lots, at a speed that could not be achieved with conventional technologies.

- Comparison with conventional technology in terms of time needed for changeover: reduced to one-seventh that of the formalin system and reduced to one-fifth that of the hydrogen peroxide heating evaporation system.

The facility can accommodate disasters, environmental contamination, and other risks

- Previously, the pharmaceutical industry did not have facilities that could preserve at temperatures of –80°C or below, which is needed for gene therapy products and regenerative medicines. The CGCP provides a stable preservation of regenerative medicines, which can also contribute as a center for risk diversification in the event of a disaster or the like.

- The CGCP installed a kill tank system to prevent the spread of genetically modified microorganisms into the surrounding environment, a system in which effluent is stored temporarily to inactivate any genetically modified microorganisms in the effluent.

Key project participants

Manufacturer/Owner	Takara Bio Inc. Nojihigashi 7-4-38, Kusatsu Shiga 525-0058, Japan
Designer/Architect	Daikin Applied Systems co., Ltd. Kawashima, Kazuo (First-Class Registered Architect) MS Shibaura Building, Shibaura 4-13-23, Minato Tokyo 108-0023, Japan
Engineer	Daikin Applied Systems Co., Ltd. Hiruma, Takaharu, (Engineering Manager) Katsura, Fumihito, (Engineering Manager) MS Shibaura Building, Shibaura 4-13-23, Minato Tokyo 108-0023, Japan
Construction Manager	Daikin Applied Systems Co., Ltd. Hosono, Takatoshi (Construction Manager) MS Shibaura Building, Shibaura 4-13-23, Minato Tokyo 108-0023, Japan
Main/General Contractor	Daikin Applied Systems Co., Ltd. Miyazawa, Osamu (Project Manager) MS Shibaura Building, Shibaura 4-13-23, Minato Tokyo 108-0023, Japan
Piping Subcontractor	Hirayamasetsubi Co., Ltd. Nagamine, Toshio (Heat Source Piping) 13-11-13, Shinkotoni 10 Jo, Kita, Sapporo Hokkaido 001-0910, Japan Toho Industrial Co., ltd. Yamaguchi Katsuya (Interior Piping) Awaji-machi 2-6-6, Chuo Osaka 541-0047, Japan
HVAC Subcontractor	Sankikogyo Co., Ltd. Kamei, Shoji Ohno 1-5-12, Nishi-Yodogawa Osaka 555-0043, Japan
Automation and Control Supplier	Kinden Corporation Iemura, Shinya (Instrumentation Works) Nojihigashi 7-4-39, Kusatsu Shiga 525-0058, Japan
Major Equipment Suppliers/Contractors	Ngk Insulators, Ltd. Awai, Akihiro (WFI, PS Equipment) Midosuji Mitsui Building 11F, 4-1-3 Bingo-machi, Chuo Osaka 541-0051, Japan Santasalo & Steri-pro Solution Corporation ICHIHARA Hironobu (Vaporized Hydrogen Peroxide Generator) KDC Kobe Building 5F, Kyo-machi 83, Chuo Kobe 650-0034, Japan Seeder Co., Ltd. Komaki, Koichi (Automatic/Manual Vial Filler) Usui 302-1, Sakura Chiba 285-0863, Japan ULVAC, Inc. Komiya, Takumi (Vacuum Freeze Dryer) 2500 Hagisono, Chigasaki Kanagawa 253-0071, Japan
Construction Company	Obayashi Corporation Ushita, Takaya Beppo 1-15-38, Otsu Shiga 525-0835, Japan

FOYA 2016
HONORABLE MENTION

FOYA 2016
Facility of the Year Awards
Honorable Mention

Greater Pharma Manufacturing Co., Ltd.

"This the first facility of its kind to apply Western standards to design, build, and operate a pharmaceutical facility to produce tablets, capsules, sachets, and liquids for the local Asian market."

Entrance

Dispensing booth

Raw material transferring into IBC with recovery cyclone in dispensing booth

Project:
Greater Pharma Manufacturing New Facility

Location:
Bangkok, Thailand

Project mission:
New facility for oral solid dosage, liquids and semisolids

Site information:
Reinforced concrete shell with cleanrooms fitted inside made from cleanroom panels, floor area 6,000 m^2 (64, 583.46 sq. ft.)

Model Production Facility in Thailand

Pharmaceutical production companies in Thailand do not typically adopt Western standards when designing, building, and operating their facilities. That has been the state of the industry in the country for the past 30 years. Bangkok's Greater Pharma Manufacturing Co., Ltd., however, has taken the advice of organizations like ISPE and created a facility that is the first of its kind in Thailand to apply Western pharmaceutical standards.

Greater Pharma Manufacturing is a leading Thai pharmaceutical manufacturer whose objective is to manufacture quality products at an affordable price for the health of the public. It applies strict quality standards along with modern techniques and equipment to ensure both product safety and manufacturing efficiency.

An overview of the Thai pharmaceutical market

The pharmaceutical industry in Thailand dates back to the 1930s; it was not until the 1970s, however, that the Government Pharmaceutical Organization was established to make Western-style medicines.

Approximately 30 years ago, a number of multinational pharmaceutical companies invested in the region and established their own manufacturing bases. Meanwhile, local companies developed medium-sized private and family-owned businesses with some knowledge transfer and sharing from the multinationals.

But about 25 years ago, tax privileges and government incentives in other Asian locales began to draw multinationals to those regional hubs. Singapore, for example, offers pharmaceutical companies long-term tax incentives combined with an international financial and legal system that provides an attractive infrastructure to foreign investors.

All of this led to stagnation in the Thai pharmaceutical industry. There was little international experience, processes were manual, and good manufacturing practices were comparable to what was considered standard in Europe or the United States more than 30 years ago.

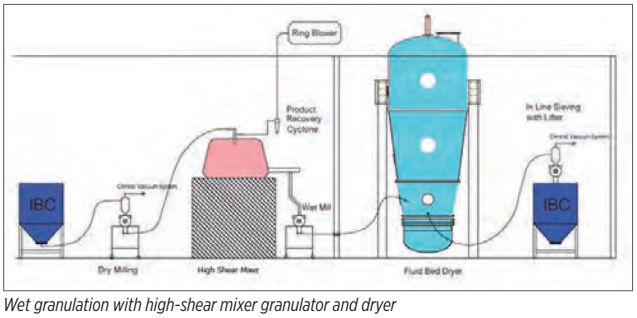
It was in this context that a typical medium-sized pharmaceutical production company in the region would produce formulated product and packing. It would distribute its products to hospitals, wholesalers, and major retail outlets, often through government contracts.

Adopting new standards

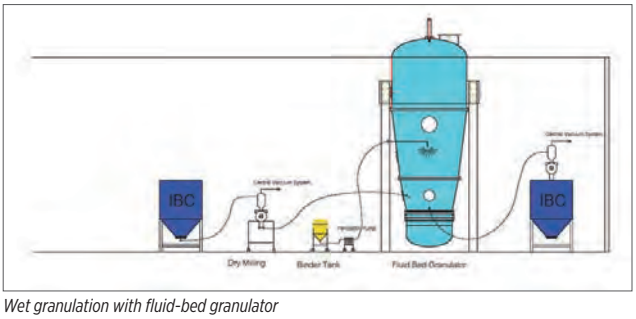
In the 13 years since the formation of the ISPE Thai Affiliate, Greater Pharma Manufacturing received many visits and training courses from noted ISPE Member and trainer Gordon Farquharson. The message from Farquharson and other industry representatives was strong and clear: Manufacturing operations must improve, particularly by moving from open to closed processing.

Open processing for oral solid dosage (OSD) products is problematic because it produces dust (a major concern for cross-contamination); it can also adversely affect operator health and block HVAC systems.

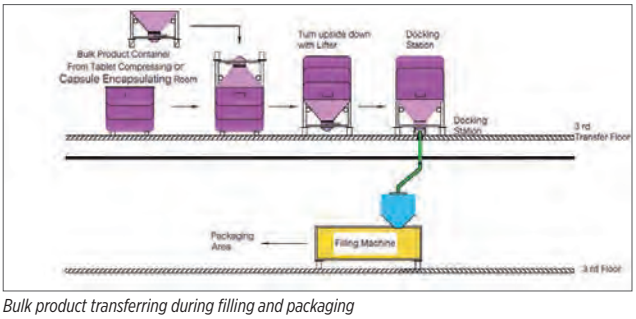
Greater Pharma Manufacturing's new Bangkok facility became the first plant in Thailand to use closed processing for OSD production through all process stages until primary packing. Four types of OSD processes are used at the facility: wet granulation with high shear mixer and dryer, wet granulation with fluid-bed granulation, dry granulation with roller compactor, and



Wet granulation with high-shear mixer granulator and dryer



Wet granulation with fluid-bed granulator



Bulk product transferring during filling and packaging

direct compression. Each process type has closed transfer for charging, closed process, and closed transfer for discharging. The transfer steps use intermediate bulk containers that are made in the region.

Gravity flow processing

The new facility is the first plant in Thailand to use a gravity flow concept throughout the operation. The building has six floors for processing and three technical floors. Each OSD process is designed to use gravity transfer on the facility's six processing floors:

- First floor: warehouse and dispensing
- Second floor: liquid and semisolid
- Third floor: tablet coating, OSD filling and packaging
- Third transfer floor: OSD bulk product transferring
- Fourth floor: OSD granulation, tablet compression, capsule encapsulation
- Fourth transfer floor: granule transferring

Gravity feed requires connections through the floors; these are sourced locally as they are more cost-effective than imported ones.

Cost- and energy-saving features

The plant was designed by Greater Pharma Manufacturing's production manager in collaboration with design and engineering firm, Global Tech Co., Ltd. Together, they employed local solutions to solve problems. The theme for the project was "Keep it simple and get back to the basics."

To combat Thailand's tropical climate—an average temperature of 95°F (35°C) with 90% relative humidity—the company installed an energy-efficient cooling/heating generation system consisting of a water-cooled chiller, primary and secondary loops for both cold and warm water, a cold-water tank, and a warm-water tank.

The primary cold water is pumped from the cold-water tank at 53.6°F (12°C) to the chiller, where it is cooled to 44.6° F (7°C). If there is no load on the system, the chiller will stop. The secondary cold-water loop supplies cold water to the air-handling unit (AHU) to cool and dehumidify the circulating air.

The main purpose of the insulated cold-water tank is to keep the chilled-water temperature at a constant and stable 44.6°F (7°C) during full or partial loads without using sophisticated automation. The tank also helps the chiller and chilled-water pump, condenser water pump, and cooling tower avoid start/stop situations during load demand. The tank stores the cooling energy so that in low load condition all chillers and components in the primary loop will stop entirely but cooling energy is still available for a few hours before chiller restart is required. Moreover, this cold-water storage system is suitable for future cooling media clathrate hydrate slurry, which has cooling capacity storage two to three times that of water and is promoted by the Thai government as the new thermal energy storage air-conditioning system under the country's energy-conservation program.

The primary warm water transfers the heat from the chiller to the cooling tower, which disperses the heat to the outside air. The secondary warm-water loop transfers the heat from the warm-water tank to the AHU to reheat the circulating air to room temperature.

Incoming fresh air is treated in the outdoor AHU for initial filtration and to remove latent heat. The incoming air is then mixed with the recirculating air from the process rooms in the AHU. There, the cooling coil chills the air to 51.8°F (11°C) to control relative humidity. The heating coil uses the warm water to heat the air to a room temperature of 71.6°F (22°C).

All told, this system allows the site to realize 65% energy savings per year when compared to traditional designs, and has a return on investment of only 1.5 years. ■

Tablet compressing set, granule transfer tube, tablet deduster and bulk product IBC

What the FOYA Judges Had to Say

Greater Pharma Manufacturing Co. Ltd., located in Bangkok, Thailand, is the first facility of its kind to apply Western standards to design, build, and operate a pharmaceutical facility to produce tablets, capsules, sachets, and liquids for the local Asian market. Prior to this, a typical facility would have a staff of 300 and produce 100 generic products employing the open processes and methods used in the United States and the European Union 30 years ago. Greater Pharma Manufacturing took initiatives to change that outdated mindset and built a pharmaceutical facility similar to what we typically see in the West today.

This facility will be recognized as a model in Thailand, allowing other companies in the region to emulate and develop similar facilities to improve the quality of medicines for the majority of the patient population. The local regulatory agency also benefited from the inspection of and interactions with this facility. Therefore, ISPE will honor this facility and its team with the Honorable Mention award.

In Their Own Words

The ISPE Thailand Affiliate began in 2003; since then, many lecturers from the West have emphasized the importance of using closed processes.

- This is the first plant in Thailand to use closed processes, from raw materials to the finished product.
- This is the first plant to use the vertical concept.
- It is the first pharmaceutical facility to use an energy-conservation design concept.
- The plant uses locally sourced design solutions and equipment.
- Capital cost is at the low end of plant cost in Thailand, but it has a more efficient running cost.

Key project participants

Manufacturer/Owner	Greater Pharma Manufacturing Co., Ltd. 55/2, 55/7, 55/11 Moo. 1, Salaya-Nakhonchaisri Rd., Salaya, Phutthamonthon, Nakhonpathom 73170 Thailand
Designer/Architect **Engineer** **Construction Manager** **Main/General Contractor** **Piping Subcontractor** **HVAC Subcontractor** **Automation and Control Supplier**	Global Tech Co., Ltd. 35/51 Soi Ladprao 124 Kwaeng Phlabphla Wangtonglang District Bangkok 10310 Thailand
Major Equipment Supplier	CTC Machinery Co., Ltd. 90/137 -139 Moo., 10 Phutthamonthon 4 Rd., Amnoi Katumban, Samutsakorn, Thailand
Major Equipment Supplier	N. R. Narong Group Co., Ltd. 768 Moo. 3 Soi. Thanpuying, Teparuk Rd., Muang Samutprakan 10270 Thailand

FOYA 2016
HONORABLE MENTION

FOYA 2016
Facility of the Year Awards
Honorable Mention

University of Strathclyde, CMAC

"This project demonstrates the exemplary collaboration between industry, academia, and government, and represents the future of pharmaceutical manufacturing and the supply chain R&D framework."

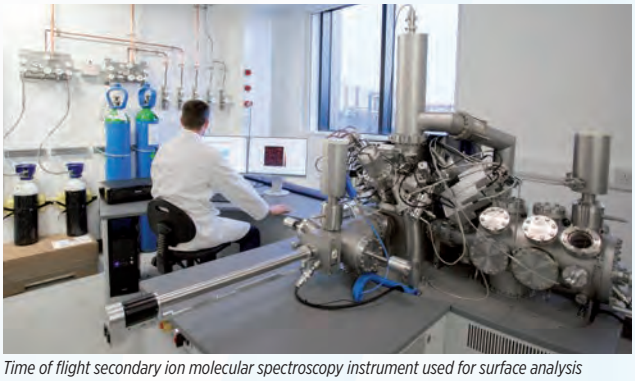
Project:
Technology & Innovation Centre

Location:
Glasgow, Scotland

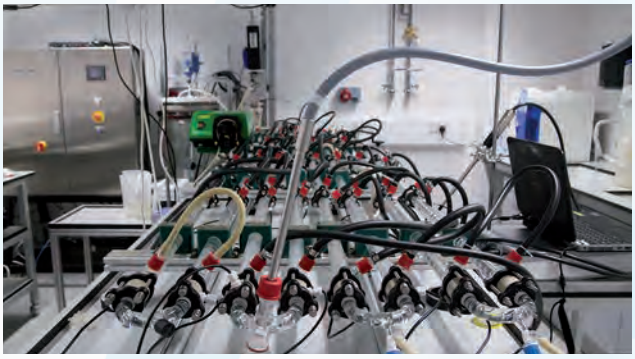
Project mission:
World-class research and knowledge-exchange facility

Site information:
280,000 sq. ft.

Aerial View of North Elevation



Time of flight secondary ion molecular spectroscopy instrument used for surface analysis



Continuous crystalliser

Bridging the Gap between Academia and Industry

The University of Strathclyde in Glasgow, Scotland, has earned a worldwide reputation for working well with businesses. Building on this reputation, the university recently completed its Technology & Innovation Centre (TIC), a collaborative research and conference facility located in the heart of the city.

The TIC, a nine-story triangular steel-frame building constructed between mid-2012 and early 2015, provides research space, collaborative meeting areas, and laboratories for around 900 staff. It also provides conference facilities and meeting rooms, including a 150-seat lecture theater and a 450-seat auditorium. Its mission is to support partnership between business, industry, academics, and the public to solve to economic, technological, and societal challenges.

The university undertook the ambitious project in early 2010. Construction began in May 2012 and was completed in February 2015. With a value of approximately $140 million, it was, at the time, the single-largest project in the Scottish education sector.

Seeing the TIC as its most significant build project in the foreseeable future, the university aimed to make it a landmark building that evoked a sense of permanence, timelessness, and technological innovation.

The TIC is unique in that it is not directed at undergraduate teaching; in fact, "teaching" in the traditional sense plays no part in the TIC program. Instead, it is dedicated to bridging the gap between academia and industry, which the university believes will strengthen collaboration and encourage innovation in practical research.

CMAC

A key partner in the TIC is the Centre for Continuous Manufacturing and Crystallisation (CMAC), a world-class international center for research and training in advanced pharmaceutical manufacturing. Working in partnership with industry, the center will transform current manufacturing processes into the medicine supply chain of the future.

CMAC's vision is to accelerate the adoption of continuous manufacturing processes, systems, and plants to produce high-value, high-quality pharmaceutical and fine chemical products more sustainably and at lower cost. CMAC's vision and research program have been shaped through close collaboration with industry and the input of its initial tier 1 partners: GlaxoSmithKline, AstraZeneca, Novartis, and Bayer. CMAC is led by the University of Strathclyde and involves six additional universities: Cambridge, Edinburgh, Bath, Glasgow, Heriot-Watt, and Loughborough.

CMAC is also a cofounder of the International Institute for Advanced Pharmaceutical Manufacturing (I2APM), in collaboration with the Center for Structured Organic Particulate Systems in the United States and Research Center Pharmaceutical Engineering GmbH in Austria. I2APM aims to bring together academic expertise from around the globe to deliver end-to-end continuous manufacturing capabilities that will transform global medicine supply chains.

CMAC has $20 million in funding form EPSRC to be a UK national manufacturing center. With more than $100 million in secured funding and an annual operating budget of about $7.5 million, CMAC comprises 14 investigators (academics), 20 postdoctoral researchers, 60 PhD students, 17 MSc students, and a 15-person central resources team. CMAC currently houses 80 active industry and research projects.

The facility's primary output is collaboration, research, and knowledge exchange. Research themes include:

- Laboratory-scale continuous process capabilities to support end-to-end manufacturing
- Tools and workflows for rapid product assessment and continuous process selection
- Product-process archetypes that will support supply chains of the future

Since the CMAC labs were completed in 2015, the center has worked on 1a portfolio of company projects, research publications, and conference proceedings; the labs operate with a fully integrated electronic lab notebook system; and the first cohort of MSc students in advanced pharmaceutical manufacturing has graduated. In 2014, CMAC and MIT organized the very successful first international symposium on continuous manufacturing and pharmaceuticals , with the second planned for September 2016.

As a national center, CMAC works with and on behalf of the wider research community by influencing policy, facilitating and supporting workshops, meeting on topics within scope, supporting feasibility studies, and developing national expertise. CMAC also holds an important position in the United Kingdom's collaborative research and innovation landscape, and has been influential in developing strategy and policy in the area of continuous manufacturing.

Industry collaboration and knowledge exchange

The shared vision, scope, and program for CMAC have been developed through close collaboration with industry, including strategic partners from the United Kingdom and the European Union who provide significant input and support: GlaxoSmithKline, AstraZeneca, Novartis, and Bayer Healthcare.

Continued support from industry partners is at the core of CMAC's success. The Industry Technical Committee continues to provide coordinated and sustained support for the center's training and outreach programs. In addition to publicly funded basic and applied research, CMAC also delivers a range of contract research programs on a confidential basis for company spending processes, understanding development, and batch processing to continuous flow.

Strong academic and industrial partnerships are the foundation of CMAC, and a key part of its success depends on successful user engagement. It continues to develop excellent relationships with end users and technology providers.

CMAC labs within the TIC

CMAC's location within the TIC provides shared facilities such as cleanrooms, workshops, conference rooms, knowledge-exchange areas, and exhibition space. CMAC also has access to over 9,687 square feet (900 square meters) of laboratory facilities, including:

- Primary processing lab: The largest in TIC, this laboratory houses 12 walk-in fume cupboards. These highly configurable bespoke units meet the needs of current research and will also be able to meet future demand as the center's research grows.
- Secondary processing suite: A purpose-built collection of rooms houses the entire formulation capability. These rooms are equipped with flexible exhaust ventilation, twin screw extruders and a mini-injection molder, bin blender, high-shear wet granulator, fluid bed dryer, conical/hammer mill, dry granulator, and tablet press.

- X-ray analysis suite: A dedicated X-ray suite houses three Bruker D8 XPRDs, D8 Venture single-crystal, new Bruker powder XRD and PANalytical, as well as X-ray Nano-CT.
- Process development lab: This lab provides for regular 2-meter-wide fume hoods for smaller-scale activities.
- Material characterization lab: The largest analytical lab houses all of CMAC's capability in understanding and characterizing materials via powders, tablets, slurries, etc.
- Wolfson pharmaceutical surfaces lab: Time-of-flight secondary ion mass spectrometry provides elemental, chemical state, and molecular information from the surfaces of solid materials.
- Microscopy suite: CMAC houses its microscopy capability in a vibrationally sensitive laboratory, a step change in imaging and chemically analyzing physical samples; it also represents the first piece in the workflow around surface imaging. ■

What the FOYA Judges Had to Say

The project did not meet the criteria for consideration in the awards, as it is not intended to manufacture materials for commercial or clinical trials. The FOYA judges, however, felt the project was well worthy of an Honorable Mention due to the exemplary collaboration between industry, academia, and government, which represents the future of pharmaceutical manufacturing and the supply chain R&D framework. In addition, the students working with such technology and in such a collaborative environment are the pipeline for the pharmaceutical professionals of the future.

In Their Own Words

- Home of internationally recognized cutting-edge research and development of novel process manufacturing technology in continuous manufacturing, process automation, and characterization.
- Exemplary collaboration between industry, academia, and government, which represents the future of pharmaceutical manufacturing and the supply chain R&D framework.
- Superb integration of design and planning that embodies CMAC's aspirations and the university's vision and strategic objectives.
- Sustainable design and construction methodology, which reduces waste and energy use.
- Flexible/adaptable research lab and office space that will accommodate the changing landscape of the pharmaceutical supply chain and manufacturing technology research and collaboration.

Key project participants

Manufacturer/Owner	University of Strathclyde 99 George Street Glasgow, Scotland, UK G1 1RD
Designer/Architect	BDP 15 Exchange Place Glasgow, Scotland, UK G1 3AN
Project Manager **Cost Consultant** **CDM Consultant**	Gardiner & Theobald G1 Building, 5 George Square Glasgow, Scotland, UK G2 1DY
M&E Design Engineer/ Consultant	KJ Tait Engineers Ltd. 15 Woodside Terrace Glasgow, Scotland, UK G3 7XH
Structural Engineer	Struer Consulting Engineers Ltd. Moorpark House, 11 Orton Place Glasgow, Scotland, UK G51 2HF
Construction Manager **Main/General Contractor**	Lend Lease 33 Bothwell Street Glasgow, Scotland, UK G2 6NL
Piping Subcontractor **HVAC Subcontractor**	FES Limited Forth House, Pirnhall Business Park Stirling, Scotland, UK FK7 8HW
Automation and Control Supplier	Honeywell Control Systems Worthington House, 856 Wilmslow Road Didsbury, Manchester, UK M20 2HY
Concrete Works	Carey Group Plc Carey House, 21 Shairps Business Park Houstoun Road, Livingston, EH54 5FD
Curtain walling and Glazing	Glassolutions Saint-Gobain House, Binley Business Park Coventry, CV3 2TT
Rainscreen Cladding	Lakesmere Group Ltd The Ring Tower Centre, Moorside Road Winnall, Winchester, Hampshire, UK SO23 7RZ
Structural Steel Frame	Fisher Engineering Ltd. (Severfield-Rowen) Ballinamallard, Enniskillen, County Fermanagh Northern Ireland BT94 2FY
Lab Furniture	Romero Muebles de Laboratorio, S.A. Calle Verano 17, 28850 Torrejón de Ardoz Madrid, Spain

FOYA 2016
HONORABLE MENTION

FOYA 2016
Facility of the Year Awards
Honorable Mention

West Pharmaceutical Services, Inc.

"This facility upgrade and expansion is an industry-leading effort to align the primary-component manufacturing process with current industry trends and standards."

Kinston facility exterior

Customer view of Westar RS final packaging

Westar lab area with customer view from corridor in background

Project:
Kinston, North Carolina
Ready-to-Sterilize (RS) Expansion

Location:
Kinston, North Carolina, USA

Project mission:
Develop Westar ready-to-use production capacity at West's Kinston site

Site information:
22,000 sq. ft. (addition) and 33,000 sq. ft. (renovation)

Expansion Enhances Customer Experience and Compliance

It began as a response to increasing customer demand. West Pharmaceutical Services, Inc., identified the need for additional manufacturing capacity for its Westar® ready-to-sterilize (RS) product. What began as a simple expansion of the Kinston, North Carolina, facility became a quest to ensure "excellence in the project through the last 5%" and create the ultimate customer experience.

West is a leading manufacturer of packaging components and delivery systems for injectable medicine and health care products. The 200,000 square foot Kinston facility manufactures a variety of rubber components that serve the injectable drug and health care markets. The facility has the capability to bring in basic rubber components and produce finished rubber products with B2 Coating and Westar RS component processes.

In the Westar RS process rubber components are put through a pharmaceutical washer that prepares the product for sterilization, which is required for most pharmaceutical applications. Historically, this work was done by the pharmaceutical customer, but over the years West was able to partner successfully with its customers to assume this part of the production process.

"In 2011, because of its superior performance, labor capacity, facility capacity, dedicated team members, and proximity to a few of our key customers West decided to launch a project to expand the RS capacity to our Kinston facility," says Ed Hill, Senior Program Manager, West. "The project team developed a concept for the facility expansion that was based on best practices for both West and the pharmaceutical industry where customers could feel that it was at or above the level of one of their own facilities. West leveraged this opportunity to provide a superior facility that raises the bar for component manufacturing in the pharmaceutical industry."

The Kinston facility is unique in its ability to allow customers to see the manufacturing processes without interruption. "We have many customers for the RS process with a need to regularly audit the facility," says Hill. "We designed a production space that is easily accessible for customers to tour and very transparent to the process. We developed the flow for customers to tour without being gowned and be able to see all the processes, from molding through trimming, B2 coating, RS wash to final packaging."

"Devotion to excellence"

Early in the design the team realized that there were no glass-wall systems available to meet their demand for a superior customer experience while keeping the manufacturing process transparent. "The team looked at different systems for glass and construction, and we really weren't happy with what we reviewed," explains Hill. "We ended up developing our own floor-to-ceiling glass system with minimal visual obstructions that makes the customers feel like they're totally immersed in the process."

Visitors are able to walk down a tour aisle and view all of the rubber extrusion, molding, and Westar processes; video screens show additional process information. Phones have been placed strategically so that customers can communicate the team members during audits, if necessary. The transparency of the process has added to customer confidence in West's capabilities, making the facility itself an additional marketing tool.

HVAC and environmental monitoring systems were also enhanced to allow the facility to tightly control its production environment and ensure quality products for customers. Special care was taken to introduce a cleanroom design that has become the standard within the West manufacturing network. Lean techniques and principles were used during design to optimize flow, eliminate waste, and facilitate quality and compliance.

Customer view of Westar RS final packaging.

WFI system

CONGRATULATIONS
2016 Facility of the Year
Honorable Mention

West Pharmaceutical Services, Inc.
Kinston, NC Ready-to-Sterilize (RS) Expansion

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HorstConstruction.com

The 22,000 sf Westar facility expansion and 33,000 sf renovation was designed with transparency and compliance in mind. A new glass wall system makes the process visible to customers eliminating the need for visitors to gown and enter controlled areas minimizing production interruptions and contamination concerns.

Congratulations to West Pharmaceutical Services, Inc. and the entire Design-Build team for winning Honorable Mention for industry leading efforts to align primary components manufacturing process with current industry trends and standards.

Transparency of Westar RS processing for customers.

As the expansion project continued, Hill explains, modifications were necessary to ensure the best customer experience; the company even repeated the installation of glass walls because the caulking was not done properly and the team didn't feel it presented well. "It was a constant challenge, and when came down to that last 5% of the project that we kept being a stickler about proper fit and finishes. The difference between a good and great project is attention to detail" says Hill. "Even at the end, when we were pushing to get into production, we strived to keep true to the design and the vision of a superior transparent and visible facility."

Looking back at the project, which concluded in July 2015 as the facility entered production, Hill credits the employees at the Kinston site for its success. "There is a superior group of West team members at the site," he says. "They are very excited about their future—from a rubber products supplier to a full pharmaceutical solutions provider—and West is definitely positioned Kinston, NC for a lot of great things in the future." ■

What the FOYA Judges Had to Say

Biopharmaceutical companies continue to bring new molecular entities to the market, addressing unmet medical needs for the benefit of patients all over the world. As the industry evolves, there is the realization that components enabling the delivery of new as well as old molecular entities play a significant role in preserving the integrity and efficacy of drugs. Increasingly, regulators are paying more attention to not only the properties of the drugs but also the components that may come into direct contact with them. If components such as vials, stoppers, and syringes are not properly manufactured, processed, packaged, and shipped, they have the potential to render pharmaceutical products adulterated or contaminated. Regulators are requiring drug manufacturers to collaborate with raw-material and primary-component suppliers to raise the standards by which these important components are manufactured.

West's Kinston site is a primary-component supplier that is raising the bar on how these components are manufactured. While expanding to introduce new ready-to-sterilize product capabilities, it took the opportunity to upgrade its facilities to align with industry trends as well as meet drug manufacturer and regulators requirements. The facility expansion was designed with transparency and compliance in mind.

FOYA is recognizing West's Kinston facility with an Honorable Mention for its industry-leading efforts to align the primary-component manufacturing process with current industry trends and standards.

In Their Own Words

The development of a glass-wall system provided a revolutionary customer experience and transparency.

The team felt that existing glass-wall concepts were too practical and not visually appealing. The project team developed a custom floor-to-ceiling glass design with minimal visual obstructions. The result of the unobstructed view from the corridor is that the visitor feels fully immersed in the process.

The design team paid attention to detail.

"The difference between a good project and a great project is not cost; it is the design team paying attention to detail and being innovative."

This statement exemplifies West's commitment to excellence and inspires confidence in West as a supplier.

The facility design and layout provides customers with superior process transparency.

The Westar component area was designed to make the process visible to customers without gowning and disruption to production. The visitor is able to walk down a tour aisle and view all of the rubber extrusion, molding and Westar processes.

The transparency of the process inspires customer confidence in West's capabilities, making the facility an additional marketing tool.

The team leveraged the early development of building information management into basis of design, which proved invaluable throughout the construction process.

The extensive development work done early to define the project set the path to success. The team had a clear, optimized design concept before construction began. The up-front work was validated by the fact that it closely matched the final result.

The facility layout utilizes a modular design to allow for future expansion.

The Westar RS addition is laid out to integrate seamlessly with the existing plant and allow for future expansion. The process flow from molded product through to shipping is lean. Foresight was used in the design phase so processes can be added with minimal interruption.

RS final packaging

Key project participants

Manufacturer/Owner	West Pharmaceutical Services 530 Herman O. West Drive Exton, Pennsylvania 19341
Designer/Architect	Eric Walker, AIA, CCS 419 Rohrerstown Road Lancaster, Pennsylvania 17603
Engineer	DME Alliance Inc. Two Windsor Plaza 7540 Windsor Drive, Suite 311 Allentown, Pennsylvania 18195
Construction Manager Main/General Contractor	Horst Construction P.O. Box 3310 Lancaster, Pennsylvania 17604-3310
Cleanroom Contractor	Hodess Contruction 100 John L Dietsch Sq Attleboro Falls, Massachusetts 02763
Piping Subcontractor HVAC Subcontractor	Gamewell Mechanical 3195 Airport Blvd., Suite G Wilson, North Carolina 27896
Automation and Control Supplier	Siemens P.O. Box 2134 Carol Stream, Illinois 60132
Major Equipment Supplier/ Contractor	Temtrol, Inc. 15 E. Oklahoma Avenue Okarche, Oklahoma 73762 MECO 12603 Southwest Freeway Suite 500 Stafford, Texas 77477 Carrier Commercial Services 4110 Butler Pike Plymouth Meeting, Pennsylvania 19462

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