
Great Lakes Chapter

Fall/Winter 2019 Chapter Newsletter

President's Message



Aaron Mertens, Microbiologist, STERIS Technical Service Manager, ISPE GL Chapter President

ISPE Great Lakes Chapter, President's Message:

We have already experienced record cold temperatures for November across the United States, and I see a skiff of snow covering the ground as I look out my office window in Cleveland, Ohio. I can only welcome the winter weather, knowing the holidays are around the corner, which bring time spent with family and friends! On that note, I can report on valuable time spent among colleagues in the past few months:

- On September 26th the ISPE Great Lakes Chapter held a social networking meeting at Masthead Brewing Company in Cleveland. I was pleasantly surprised at the turnout, with nearly 30 people in attendance. Thanks to Rovisys and STERIS for sponsoring the event with gift card prizes and plenty of pizza for everyone. There is unanimous interest in another social event in the Cleveland area, so keep your eyes peeled after the New Year.

- The ISPE Annual Meeting and Expo at Caesar's Palace in Las Vegas was held October 27th through 30th. The event was a success – I heard attendance was at a record high. The Expo, Scientific Poster Session, and Technical Presentations were enjoyed by all.
- Newman Sanitary Gasket hosted networking and a facility tour in the Cincinnati area. Please read more about the event later in this newsletter.

I encourage you to take a moment in the coming weeks to vote for the Great Lakes Chapter Board. Three Board positions, along with the Vice President and Secretary Chair positions, are open for voting. I will be serving as President for my second year of the two-year term in 2020, along with Sara Brothers as Treasurer. The ballot for voting will be sent to all ISPE members in good standing within the Great Lakes Region. Thank you in advance for your participation.

Lastly, I am looking forward to the Annual ISPE GL Board Face-to-Face Meeting. The meeting will be held the week of January 5th at the Jacobs Engineering office in Cincinnati. Thanks to Jacobs for opening their space to our Chapter. At this meeting we will review the past year's activities and plan for 2020 events. Please reach out to me directly if you are interested in joining the meeting and getting involved in the upcoming year.

Please contact me at: aaron_mertens@steris.com

Highlights from the ISPE Annual Meeting

The theme of the 2019 ISPE Annual Meeting is Modernize. Globalize. Transform. The Annual Meeting & Expo focused on modernization, globalization, and transformation in pharmaceutical science and manufacturing across the globe, offering pharma professionals the opportunity to engage in industry-critical conversations. This signature event draws pharmaceutical and biopharmaceutical professionals at all levels of the industry from young professionals to the most senior executives in drug manufacturing, supply chain, devices equipment and services, and global regulatory agencies.



The Membership and Awards Breakfast on Tuesday 29 October at the annual meeting saw a number of ISPE members honored with awards, a report on the state of the Society, and new ISPE International Board members taking their places, including the new Chair, Frances Zipp. Breen passed the Chair gavel to Fran Zipp, the 2020 Board Chair. She thanked Breen for his contributions to ISPE. “I love teamwork, precision, and speed,” Zipp said, noting there is a link between these and her two passions: Porsches and ISPE. Both involve “a great team of ‘high performance’ professionals.” She said it was an honor to “take the wheel” of ISPE’s board. About her recent move into the “driver’s seat” of

ISPE as Chair, Zipp noted that an individual “is in reality just one member of a much larger and more important team.”



ISPE’s team is all of its members from around the world, and it is a team “that in order to be effective and successful must consistently operate ‘on all cylinders.’” To do so takes “constant dedication, maximum effort, and sustained involvement. It’s that way with Porsche and I believe it to be the same way with all of us, who together form ISPE.”

Just as the average Porsche 911’s over 28,250 parts all contribute, so does each ISPE member contribute to the whole Society. “Everyone is essential and valuable to the success of our organization,” Zipp said. “Working together—in synch—we learn, we grow, we prosper.” Another commonality between Porsches and ISPE that Zipp noted was that women created the first Porsche 917 race cars in the early 1970s, working as a team and women are still an important part of Porsche’s success today. The same is true for the pharma industry and for ISPE.

“Women in pharma are just as essential and important to our industry’s advancements and successes. We’ve taken on every role and met every challenge, becoming important contributors and leaders at every level. We have done this with the support of every member—men and women working as equals.” In this way, Zipp noted, women have “taken the wheel” in the industry. Zipp noted the great importance of ISPE and its members in her own career growth. “I grew up in ISPE,” she said. “When I started in the industry, I was in the lab. When I was asked to move to an operations role, I turned to ISPE for assistance. The Baseline documents became my bible.” “The networking groups became my family—they accepted my ignorance, they did not judge, and I had a safe place to learn. That is what ISPE is for our members.” She encouraged attendees to become involved. “Join a team, participate in the development of a document, lead a training—you will get more than you give!” For more information and copies of the presentations please go to the ISPE.org website.

ISPE Annual Meeting (cont.)

John Bournas, ISPE CEO, presented the award for Affiliate and Chapter Excellence to Delaware Valley Chapter. There are 39 Affiliates and Chapters worldwide and the first time, ISPE is recognizing excellence in Affiliated and Chapters. The Chapter President Eleanor Small accepted the award for the Chapter. The Delaware Valley has done outstanding work this year, particularly in the areas of membership development and community affairs. The DVC has one of the highest ISPE Chapter membership retention rates at 78%." Through efforts to improve new member rates, DVC reversed a trend of slightly declining membership and brought the total membership up to nearly 900 members. DVC actively supports Young Professionals and worked closely with ISPE YP International to support the 2019 ISPE



NASAAC Meeting at 2019 ISPE Annual Meeting

The NASAAC meeting was held on Sunday before the formal start of the Annual Meeting. There were about 50 chapter and affiliate members attending for all over the world. John Bournas provided a CEO Update and provided highlights of the various international meetings he and other ISPE Board Members attended. A special mention was to announce that the Mexico Affiliate received their formal papers to become the latest international membership. The Japan, Singapore and Brazil Affiliates provide highlights of their past year's accomplishments. The meeting wrapped up with Deborah Geyman passing on the chair position to the two new co-chairs Harry Segner and Brian Vaughn.

COP Committee Meetings at 2019 ISPE Annual Meeting

Many of the ISPE COP leadership committees met in face to face breakout sessions at the annual meeting. As a new member of the HVAC and Sustainable Facilities committee Allen Koester met with other members and will serve as the secretary for the upcoming year. In this meeting members discussed ways of sharing knowledge through training classes, webinars, technical articles, and knowledge briefs. The committee is also making plans to review existing HVAC Good Practice Guidelines for gaps and updates to remain current with updated agency requirements.

Cincinnati ISPE Education & Networking Event

On October 24th, Newman Sanitary Gasket hosted the Great Lakes ISPE Chapter for a networking event and tour. The attendees enjoyed appetizers and drinks provided by Newman Sanitary Gasket. The tour included an overview of the facility including the various types of forming processes used for the manufacture of gaskets for different applications and of different materials of construction. Newman Sanitary Gasket was well set up for the tour, with many viewing windows and areas labeled having gone through the audit process for customers many times annually. The attendees came back together after the tour for more refreshments and networking. A good time was had by all! Thanks again to Newman Sanitary Gasket!



Great Lakes Chapter BOD Elections

The Great Lakes Chapter will be having the elections for new Board of Directors for the 2020 year. Below is the table of ISPE GLC members that have volunteered to run for the 2020 election. There are still several openings that need to be filled. Please contact Aaron Mertens or David McAlonan if you have an interest to serve on the GLC board for next year. The election will take place at the end of November and early December. All GLC members will be asked to vote electronically through an email invitation. We ask that everyone vote.

Name	Current Role	New Position
Aaron Mertens	President	President
Dave McAlonan	Vice President	Vice President
Jordan Rhoades	Board Member	Secretary
Andrea Frazer	Secretary	Board Member
Sara Brothers	Treasurer	Treasurer
Allen Koester	Board Member	Board Member
Joe Robinson	Board Member	Board Member
Tim Fry	Board Member	Board Member
Chris Pardo	Board Member	Board Member
Deborah Geyman	Past-President	Board Member
Open		Board Member
Open		Board Member
Open		Board Member
Open		Board Member

2019 IPSE Great Lakes Chapter Board

Officers

President – Aaron Mertens, Steris, Technical Services Manager

Vice President – Dave McAlonan, Middough, Sr. Project Manager

Treasurer – Sara Brothers, Jacobs Engineering, Senior Project Manager

Secretary – Andrea Frazer, Jacobs Engineering, Process Engineer

Board Members

Director – Mike Carey, Gerfor, National Industry Segment Director

Director – Brian Grimes, Jacobs Engineering, Mechanical Electrical Division Manager

Director – Allen Koester, PCI Skanska USA, Sr. Project Manager II

Director – Tim Fry, JDI Group, President/Principal Architect

Director – Jordan Rhoades, Jacobs, Process Engineer

Director – John Noble, Jacobs Engineering, Vice President & General Manager Life Sciences North America

Member Spotlight: Dave McAlonan

David McAlonan is a Sr. Technical Consultant for Pharma and Biotech with Middough in Oak Brook, Illinois. He retired in late 2018 after 32 years with AbbVie and Abbott as the Associate Director of Global Pharmaceutical Research and Development Engineering in Abbott Park, Illinois. He has a BS degree in Chemical Engineering and has been an active member of the ISPE since 1991. David's career spans 44 years of professional experience developing and implementing projects and strategic programs the food, chemical and pharmaceutical industries. He is considered by the industry to be a technical expert in Operations Management, Program and Project Management and containment for potent and toxic compounds within the pharmaceutical industry.

Great Lakes Chapter welcomes new members!

The Great Lakes Chapter consists of members in the states of Michigan, Wisconsin, Illinois, Indiana, Ohio, and Kentucky. The Great Lakes Chapter of ISPE welcomes 16 new members in August 2019. Please welcome them to the organization and the pharmaceutical industry.

Andrew Abramson, Director - Client Solutions, Grantek Systems Integration

Jackson Achen, Project Engineer, Scientific Protein Laboratories Inc

Anthony C. Barrancotta, Life Science Information Business Manager, RoviSys

Jessica Bartels, Program Manager, CSL Behring

Thomas Biere, Principal Consultant, C3 Consulting Inc

Barbara W. Bloom, IT QA Manager, Abbott Laboratories

Spencer Hirschfeld, Validation Engineer, Commissioning Agents Inc

Tom Hubert, Program Manager, CSL Behring

Ms. Melanie Jackson, President, Essential Quality Solutions, Inc.

Chad Kelly, Industrial Market Leader, PEDCO E & A Services, Inc.

Seth McAlarney, Validation Systems Manager, Roche Diabetes Care Inc.

Lis Nimani,

Jeffrey Nimmo, Associate Director of Maint and Engineering,

Mr. Cornelis Rijnveld, Operational Readiness, CSL Behring

Sandy Rosas, Process Engineer/ Project Manager, CAI

Francesco Tatangelo, Vice President, Engineering, AbbVie

Webinars

ISPE understands your professional needs and is here to help with our new **FREE Pharma Best Practices Webinar Series** available to everyone! Each webinar will feature leading subject matter experts covering critical, relevant topics in pharmaceutical manufacturing.

ISPE Members have the benefit of unlimited access to the webinar recordings - even if you don't sign up for the webinar. Nonmembers that attend a webinar will have access to the recordings for 30 days. So, if you're not a Member - [Join today!](#)

Upcoming Webinars

Overview of the New Baseline Guide for Pharmaceutical Water and Steam Systems

Thursday, 21 November

Time: 1100 - 1200

<https://ispe.org/webinars/ispe-baseline-guide-water-steam-3rd-edition>



Data Science Tools for Successful Technology Transfer

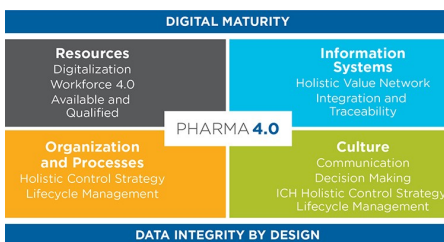
Wednesday, 11 December

Time: 1100 - 1200

Registration Coming Soon

Recordings of Past Webinars

ISPE Members have the benefit of unlimited access to the webinar recordings 30 days after the live webinar.



The ISPE Pharma 4.0 Operating Model – Basis for the ICH Holistic Control Strategy – An Introduction

16 October 2019



Qualification of PAT Based Control Strategies for Batch and Continuous Manufacturing

24 September 2019

See the ISPE Website for links to these and other Webinar recordings (Free to ISPE Members).

Upcoming ISPE Conference



Join us at the [2019 ISPE Global Pharmaceutical Regulatory Summit](#), taking place in North Bethesda, Maryland USA on 5–6 December.

This event packs a fully loaded agenda with two days of expert-led regulatory talks and opportunities for peer-to-peer learning with participants representing global regulatory leaders in an intimate, interactive forum. You will be immersed in collaborative, future-thinking sessions featuring Q&As and insightful case studies with a regulatory focus on innovation and continuous quality improvement.

Janet Woodcock, MD, Director, CDER, FDA, and David Churchward, Deputy Unit Manager, Inspectorate Strategy and Innovation (Expert GMP Inspector), MHRA, will kick off the education program that explores technologies, approaches, and solutions that will drive innovation and quality in today's evolving global regulatory environment.

Additional featured speakers include:

Christine Moore, PhD, Global Head and Executive Director, GRACS CMC Policy, Merck & Co.
Kira Ford, Director, Global Quality - Consumer Product Quality Assurance, Eli Lilly
Lucinda Buhse, PhD, Director, DPA/OTR/FDA
Sau (Larry) Lee, PhD, Director & Emerging Technology Team Chair, Office of Testing and Research CDER, FDA
Thomas Friedli, PhD, Director, Institute of Technology Management, University of St. Gallen (Switzerland)
And more!

This is a unique experience that is invaluable because of the opportunity to ensure you're well-prepared to develop and apply innovative solutions in today's global regulatory environment.

To explore all that this event has to offer you and your team, please visit www.ISPE.org/RegSummit19.

2020 ISPE Conferences



[2020 ISPE Facilities of the Future Conference](#)

30 – 31 Jan 2020
San Francisco, CA USA



[2020 ISPE Aseptic Conference](#)

2 - 3 March 2020
North Bethesda, MD USA

Volunteer Opportunities

Would you like to get involved with other professionals in the Pharmaceutical industry? Do you have a special skill or passion? Would you like to see new or different events to help you in your career? The Great Lakes Chapter of ISPE is looking for volunteers to help with organization of events in your area. If you are interested, reach out to the board members listed .

ISPE Great Lakes Chapter Committees—Get involved with the Great Lakes Chapter

Cleveland Events Committee: This committee plans the Cleveland area chapter events. Contact: Aaron Mertens; aaron_mertens@steris.com

Chicago Event Committee: This committee plans the Chicago area chapter events. Aaron Mertens; aaron_mertens@steris.com, Sara Brothers; Sara.Brothers@hotmail.com

Cincinnati Committee: This committee plans the Cincinnati area chapter events. Contact: Andrea Frazer; Andrea.Frazer@jacobs.com

Indianapolis Committee: This committee plans the Indianapolis area chapter events. Brian Grimes; bgrimes@rossbar.com

Young Professionals & Student Chapter Committee: Jordan Rhoades; Jordan.Rhoades@jacobs.com

Committee involvement is a great way to become more involved with our local chapter and the international organization. Serving on a committee facilitates an expansion of your local network and members involved in committees will be considered for open Board of Director positions .

Technical Articles Wanted:

Do you have a technical discovery or best practices that you would like to share with the Pharmaceutical Industry? This is a great way to get recognized by your peers for the great work that you do every day. We are looking for technical articles for the Great Lakes Quarterly Newsletter> If you have something you would like to contribute, please send to Aaron Mertens, aaron_mertens@steris.com or Allen Koester, allen.koester@skanska.com

Linked In Visit the Great Lakes Chapter Linked-In Page at:

<https://www.linkedin.com/groups/4928599/>

Membership/ Become a member and grow with us!

Discover the advantages of an ISPE Membership for every stage of your career. Whether you are new to the pharmaceutical industry or a seasoned professional, ISPE is your Society of Choice

Networking Opportunities

Whether networking at face-to-face events or collaborating online, the value of ISPE is in the links forged between industry professionals with common work challenges, connecting professionals and companies to practical guidance and dialogue between industry and global regulators.

Membership Directory: Connect with 18,000+ other Members from nearly 90 countries around the world with the Membership Directory.

CoP Online Discussion Forums: Ask questions, find solutions to common problems and share your industry knowledge and expertise with colleagues from around the world.

Affiliates and Chapters: Attend events, collaborate and share best practices in your local geographic region and language.

Networking Events: Interact with fellow industry colleagues at a wide variety of face-to-face networking events at global ISPE conferences and the ISPE Annual Meeting.

Technical Resources

Guidance Documents, industry-leading publications, and on-demand training courses and webinars provide practical information and solutions to real-world problems.

Guidance Documents: Get special savings as an ISPE Member on industry Guides that provide the collective knowledge of leading thinkers on manufacturing best practices, regulatory compliance and international trends and best practices.

Pharmaceutical Engineering Magazine: Your complimentary subscription to Pharmaceutical Engineering magazine gives you access to valuable information on the latest scientific and technical developments, regulatory initiatives and innovative solutions to real-life problems and challenges.

Review and Comment on Regulatory Guidance: Pharmaceutical professionals at all stages of their careers turn to ISPE for the latest regulatory information. Help shape your industry by providing input into ISPE's official industry response to draft guidance from regulatory agencies around the world.

Professional Development

Industry-leading education and training, global volunteer opportunities and industry-focused career solutions allow ISPE Members to grow their professional knowledge and skills.

Education and Training: Save on a variety of education and training programs, including ISPE global conferences, onsite training delivered at your company, online webinars and courses, and professional development and networking events conducted through your local Affiliate or Chapter.

Volunteer Opportunities: Volunteer with ISPE to gain professional experience and recognition in the industry. ISPE Volunteers experience the personal benefits of volunteering while having the opportunity to make a difference and influence the industry we serve. Learn more

Career Solutions: Get noticed by the right people in our industry. Post your resume or job opportunity today to be seen by employers and job seekers specializing in the pharmaceutical and biotechnology industries.

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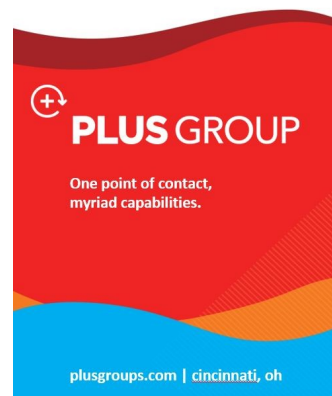
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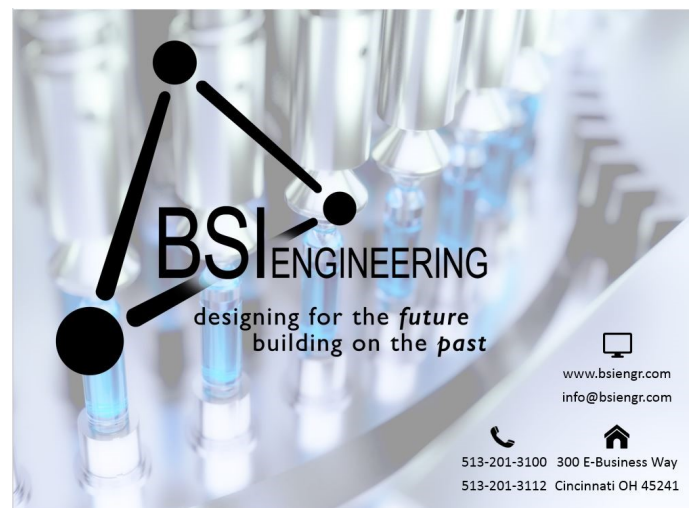
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