

Great Lakes Chapter

Fall/Winter 2018 Chapter Newsletter

President's Message

Deborah Geyman

Quality Principal Auditor (Corp. Quality)

Fellow ISPE Great Lakes Chapter Members,

I would like to extend a special thank you to the GL Chapter Members. It has been a great honor serving as President of this Chapter for the last 2 years. The friendships and relationships have made this such a wonderful experience. The generosity of our Chapter Sponsors and the time volunteered by so many in these busy fast paced times is inspiring!

Aaron Mertens, your new incoming ISPE GL Chapter President, and I have been meeting and sharing ideas to assure a smooth transition. Aaron has many wonderful ideas and I look forward to his leadership in this role.

Meanwhile, we count on your continued support of the Great Lakes Chapter and are always interested in hearing from you on ideas to make the Chapter better. Please contact Aaron or any of the other Board Members for with suggestions or questions about our Chapter activities.

We are also looking for committee members for various committees to launch more events (see the list of committees towards the end of this newsletter). So make it your resolution to get involved and experience firsthand the wonderful experience in being involved with the Great Lakes Chapter!

Feel free to contact me at Deborah.geyman@zimmer.biomet.com or

AaronMertens@steris.com

Join Us! Great Lakes Chapter Webinar

EU GMP draft Annex 1: impact of the changes regarding contamination control program



Webinar presented by
STERIS Corporation

Friday, November 30
12 p.m. EST



Walid EL Azab, Technical Services Manager
Steris Life Sciences

This webinar is free, thanks to the generosity of our sponsor

Offered by



The rationale for Annex 1 “Manufacture of Sterile Medicinal Products” revision is to tide up with current sterile manufacturing processes, reinforce the need for the manufacturer to keep up with current and innovative technologies. There is a clear emphasis on minimizing the risk of microbial, particulate and pyrogen contamination for sterile processes. Manufacturers must control their processes, equipment, and facility by adopting Quality Risk Management (QRM) and ICH Q9 principle. The goal of a QRM is to demonstrate that critical process, equipment, utilities, and personnel, including critical programs such as cross-contamination and sterility assurance, are adequately controlled to ensure product compliance with specification and patient safety. The objective of the presentation is to analyze and assess the impact of the changes that are laid down in the draft Annex 1 regarding contamination control program.

About Our Speaker:

Walid El Azab is an Industrial pharmacist, a Qualified Person and Lean Six Sigma green belt. He is a Technical Services Manager for STERIS Life Sciences. He provides technical support related to cleaning, disinfectants, sterility assurance and process validation. He is an active member of the PDA, ISPE, ECA, and A3P with numerous published articles and book chapters on contamination control. He is also active with the A3P GIC working group on sterilization, and he leads the UPIP-VAPI EU GMP Annex 1 (guidance for sterile manufacturing) working group. He is also part of the ECA task force regarding the revision of the EU GMP Annex 1. He is a planning committee member of the Annual PDA Conference on Pharmaceutical Microbiology (12th and 13th) and biomanufacturing. He is also an Editorial Committee Member of the PDA Letter. Finally, Walid is an observer member of the ISPE Belgium affiliate board and Secretary of the Belgium Qualified Person (UPIP-VAPI) association.

<https://www.eventbrite.com/e/eu-gmp-draft-annex-1-tickets-52283293739>

Questions? Email ISPEGLC@gmail.com

To Register - Hold CTRL and Click or use the link below

Recent Great Lakes Chapter Webinars

On September 20, ISPE Great Lakes Chapter hosted a 1-hour webinar entitled, “Cleaning, Disinfection and Environmental Monitoring after Shutdown of a Controlled Environment”. The webinar content was presented by Joe McCall, Technical Service Specialist and Microbiologist from STERIS Life Sciences, and had over 20 listeners in attendance, with 15 minutes of Q&A discussion at the end. Thanks to Joe for excellent presentation of the educational material and thanks to those in attendance. This webinar was one of many hosted by ISPE GL Chapter, aligning with the Chapter mission to network and educate within the pharmaceutical industry.



On October 24, ISPE Great Lakes Chapter Hosted a 1-hour webinar on Continuous Manufacturing presented by Ed Godek of Glatt. Continuous Manufacturing has moved from a "trend" to reality. As a new form of processing for many in pharmaceuticals it requires new skill sets to overcome its unique challenges compared to traditional batch processes. This session pulled together information from Glatt’s process experts with direct experience in this area to share their lessons learned designing and implementing such systems and then, most importantly, operating actual processes on their installed systems. This event was the most attended webinar of the Great Lakes Chapter with 85 listeners. Thanks to all who helped put the event on and to Ed Godek for his presentation.



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 10 new members in November 2018. Please welcome them to the organization and the pharmaceutical industry.

Chris Abell, Head, Project Management Office - CSL Behring
Keith Clemence, Regional Sales Manager - SAMSON Controls, Inc.
David Engers, Director -Purdue GMP Center
Justin Hopkins, Account Manager -CECS
Scott A. May, Research Fellow-Eli Lilly & Co
Rebecca A. McMullen, Senior Quality Assurance Engineer
Mr. Robert Stephen Opperman, Engineering Manager- Precision Extraction Solutions
Mr. Bill Sauer, Project Engineer -Adare Pharmaceuticals
Matthew Schnell, Operations Vice President -Messer Construction Co.
Sarah Wilson

On Campus - Great Lakes Student Chapter Updates

By Jordan Rhoades, YP & Student Chapter Liason

From the University of Cincinnati:

The University of Cincinnati Student Chapter of ISPE was started this year with 11 active members. The majority of members study engineering, while the minority of members study a life sciences related field. All student members are currently undergraduates. Benjamin Balster is the chapter President, Jacob Sekinger is the chapter Vice-President, Alex Ruiz is the chapter Treasurer, and Cassie Packis is the chapter Secretary. This year, we had presentations from Jacobs Engineering and University of Cincinnati Pharmacy Professors. For the rest of 2018 and 2019, we have interest in covering topics such as biopharmaceutical manufacturing processes, drug delivery devices, and the economics of the pharmaceutical industry. If you have any interest in presenting to our chapter covering any of the above topics, or any other topic not specifically listed, please reach out to balstebn@mail.uc.edu.

From the University of Kentucky:

The University of Kentucky Student ISPE Chapter has roughly 20-25 members from the Colleges of Pharmacy and Engineering, and is made up of both undergraduate and graduate students. The chapter President is Matt Defrese, the Vice President is Hannah Dvorak, the Treasurer is Travis Jarrells, the Secretary is Lucas Timmerman, and Kelley Wiegman is the Historian/Social Chair. So far this year the chapter has had two meetings. The first was to discuss what exactly ISPE and Pharmaceutical Engineering are, and the second meeting was an academic research panel with brief presentations and Q&A over pharmaceutical engineering and graduate school. The University of Kentucky Chapter is interested in organizing a Great Lakes ISPE symposium that would include showcasing student researcher's work and have 2-4 industry and academic presentations. The chapter would like to have other industry and/or academic speakers at their meetings to cover the following topics:

- *Why and how to become a pharmaceutical engineer (what does engineering in the pharmaceutical industry look like, how to get started, and how to connect with employers)?*
- *Overview of a typical pharmaceutical engineering project (product development, scale up, process design, addressing manufacturing difficulties)*
- *How to apply green principles in the industry*

We are also open to other ideas as well, and we are looking for an Industry Adviser for our chapter! If you are interested in helping as an Industry Adviser or in speaking to our chapter, please contact Matt Defrese at mkde225@uky.edu, or (951)941-8887.

Indianapolis Education and Networking Event

On September 27, Jacobs and Wilhelm Construction Group hosted an ISPE Great Lakes Chapter educational and networking event at the CenterPoint Brewing Company in Indianapolis, IN. The objective of this event was to offer an opportunity for ISPE members in central Indiana to network and include an educational component.

Paul Lopolito, Technical Services Senior Manager for Steris Corporation, Life Sciences Formulated Chemistries gave an informative presentation titled “Biofilm and other non-routine microbial events” In this segment, he explained identification and control of biofilms in purified water systems.

Tim Pletcher, Senior Consultant for Ely Lilly provided a short presentation on their project which received the 2017 ISPE Facility of the Year Award.

The event was attended by 38 participants (members and non-members) and raised a total of \$850 for the chapter. The feedback from the event was positive for both the quality of the speakers and the venue.



Member Spotlight : Aaron J. Mertens

Aaron Mertens has been a member of the STERIS Life Sciences Contamination Control Solutions as a Technical Service Manager since January 2015. In this role, Aaron has responsibility for providing global technical support primarily for Critical Environments (i.e. environmental sanitizers, disinfectants, sporicides), Sterility Assurance Products (i.e. biological and chemical indicators), and Barrier Products Solutions (i.e. sterilization wrapping), application and validation.

For nearly 20 years, Aaron has held a number of positions within the Pharmaceutical Industry, specializing in cleaning, disinfection, sterilization and contamination control in paren-

teral drug manufacturing. In these roles, he has gained experience interfacing with industry regulatory agencies (FDA, EMEA, Japan), representing quality assurance programs.

Aaron has been a member of various industry organizations (PDA, ISPE) since 1999, contributing by presenting posters and talks at meetings, as well as participating in local chapter functions. He is the current vice president of the ISPE Great Lakes Chapter. He holds a bachelor's degree in Genetics from the University of Wisconsin – Madison.

Aaron will become the President of the ISPE Great Lakes Chapter in 2019. His contact information is listed below.

Aaron J. Mertens

Technical Service Manager

STERIS Corporation | Life Sciences

440-354-2600 | 800-444-9009

Mobile: 440-530-0060

E-Mail: Aaron_Mertens@steris.com



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.

2019 IPSE Great Lakes Chapter Board

The results are in for the recent election of the ISPE GL Chapter Officers and Board. Please welcome our new Officers and Board Members for the upcoming year!

Officers

President – Aaron Mertens, Steris, Technical Services Manager

Vice President – Tim Fry, JDI Group, Inc

Treasurer – Sara Brothers, CRB, Senior Project Manager

Secretary – Andrea Frazer, Process Plus, Process Engineer

Board Members

Director – Mike Carey, Gerfor, National Industry Segment Director

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

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

Director – Bob Lennon, President, DAKSWAN Automation, Inc.

Director – Dave McAlonan, Abbvie (retired), former Associate Director of R&D Operations Engineering

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

Director – Larry Wessel, Process Plus, Market Segment Director

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

Membership Committee: This committee is responsible to reach out to potential new members and renewal of members to maintain and increase Chapter membership. - Mike Carey; mcarey@gerflorusa.com

Marketing and Communication Committee: This committee shall be responsible for communication to the Chapter membership and to ISPE International on all Chapter activities.

Sara Brothers; sara.brothers@crbusa.com

Cleveland/Kalamazoo Committee: This committee plans the Cleveland and Kalamazoo area chapter events. Deborah Geyman; deborah.geyman@zimmerbiomet.com

Cincinnati Committee: This committee plans the Cincinnati area chapter events. Larry Wessel; lwes-sel@processplus.com

Indianapolis Committee: This committee plans the Indianapolis area chapter events. Brian Grimes; brian.grimes@jacobs.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 .

Contact Deborah Geyman or a Board member if you would like to be on a committee.

Upcoming ISPE Conferences



2018 ISPE Biopharmaceutical Manufacturing Conference

10 - 12 December 2018
Huntington Beach, CA USA



2019 ISPE Aseptic Conference

18 - 19 March 2019
Rockville, MD USA



2019 ISPE Facilities of the Future

7 - 8 February 2019
San Francisco, CA USA



2019 ISPE Biopharmaceutical Manufacturing

18-20 June 2019
Boston, MA USA

For additional articles or what our Great Lakes Chapter can do for you, please contact any of the Board of Directors or your Chapter President, Deborah Geyman at:

Deborah.Geyman@zimmerbiomet.com