ISPE®
Connecting Pharmaceutical Knowledge

Great Lakes Chapter

Summer/Fall 2018 Chapter Newsletter

President's Message

Deborah Geyman
Quality Principal Auditor (Corp. Quality)

Fellow ISPE Great Lakes Chapter Members,

Can you believe summer is almost over and school has started?!!!!

I would like to thank you for your continued support of our Great Lakes Chapter through your membership and interest in our many activities. As you may already know, you Chapter held a facilities education and networking event in Cincinnati in June. You can read more about this successful event in this newsletter. Your Chapter has also produced a Dust Hazard Analysis webinar and has two more in the works for 2018 with special Subject Matter Experts speaking on topics that are of interest to you and your everyday working lives. Read on in this newsletter for announcements for both webinars and a technical article teaser!

We also have another education and networking event planned for September 24 in Indianapolis at Centerpoint Brewing Company - you can find the announcement in this newsletter. We are really looking forward to this event and hope to see you there!

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 me or any of the other Board Members for any suggestions or questions about our Chapter activities.

We are also looking for committee members for various committees to launch more events like the successful event in Cincinnati. So make it your resolution to get involved and experience firsthand the wonderful experience in being involved with the Great Lakes Chapter!

Contact me at Deborah.geyman@zimmer.biomet.com

Join Us! Indianapolis Education and Networking Event

Microbials and Microbrews

Come learn about microbial events while enjoying a locally brewed beer

Centerpoint Brewing Company
1125 E Brookside Avenue, Suite 2B
Indianapolis, IN 46202

Monday, September 24th
6:30 p.m. EDT

$25 for members
$30 for non-members

Click to Register

Offered by ISPE® Great Lakes Chapter

JACOBS™

WILHELM CONSTRUCTION

Tim Pletcher, Senior Consultant Engineer at Eli Lilly and Company, will be making a 15 minute presentation on the 2017 ISPE Facility of the Year Award.

Questions? Email ISPEGLC@gmail.com

Speaker Bio:

Paul Lopolito Manager, Sr. Technical Services STERIS, Paul Lopolito is a senior technical services manager for the Life Sciences Division of STERIS Corporation (Mentor, Ohio). He currently manages the Process and Cleaner Evaluation (PACE® Evaluation) program and provides global technical support related to process cleaning and contamination control, which includes field support, site audits, training presentations and educational seminars. Paul has specific expertise in managing cross-functional projects with over 20 years of experience. Paul has held positions as a technical services manager, manufacturing manager and laboratory manager. Paul is a frequent speaker at industry events and has published numerous articles and book-chapters related to cleaning, cleaning validation and contamination control. He earned a B.A. in Biological Sciences from Goucher College in Towson, MD.

STERIS
Life Sciences

Join Us! Great Lakes Chapter Presents Two Webinars

September 20, 2018 (12:00 EDT) — **Cleaning, Disinfection, and Environmental Monitoring after Shutdown of a Controlled Environment** presented by Steris Corporation.

Steris representatives will expand upon the technical article presented in this newsletter. Bring questions to be addressed by industry experts.

Additional details coming soon.

October 24, 2018 (12:00 EST) —**Continuous Manufacturing** presented by 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 pulls 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. The format will be a design overview followed with some actual operations experience so attendees will leave with a deeper understanding of what to expect and how to prepare for actually engineering continuous processes. It will become clear which design aspects drive value for the end user and which features are critical success factors. Attendees are expected to come with a basic knowledge of continuous processing, related unit operations and integration requirements.

Additional details coming soon.

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 11 new members in July 2018. Please welcome them to the organization and the pharmaceutical industry.

Benjamin Patrick Balster, Cincinnati, OH

Tyler R. Friedl, Senior Project Engineer, Project Farma - CHICAGO, IL

Jordan Houston, Technical Development Engineer, Akorn Pharmaceuticals

Ms. Tamara D. Jordan, Principal, Compliance Consulting Partners, Inc.

Amy Kamai, Director, IT Compliance & Risk Management, AbbVie

Gage Kramer, Cincinnati, OH

Miss Cassie Packis, Student, University of Cincinnati

Mr. SCOTT PATTERSON, VP Commercial Sales, ILC Dover

Beau Pieper, Tech Development Engineer, Akorn Pharmaceuticals

Lukas Renker, Akorn Pharmaceuticals

Mr. Aaron Secrist, Vice President of QA, NOW FOODS

08/13/18

STERIS
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Cleaning, Disinfection, and Environmental Monitoring after Shutdown of Controlled Environments

Authors - Aaron Mertens and Joe McCall, STERIS Life Sciences.

Performing preventive maintenance (PM) as well as facility and equipment repairs within pharmaceutical, biotechnology and medical device manufacturing facilities during active commercial production is likened to doing engine repair on a locomotive as it barrels down the tracks at top speed. There is no tolerance for risk. For these manufacturers whose processes reside within cleanroom conditions, the ability to perform necessary maintenance and repairs is restricted by the systems that establish those cleanroom conditions; this is especially true for aseptic processing operations where the personnel gowning requirements make the performance of repair work cumbersome. As well, many types of repairs and maintenance are microbiologically "dirty" and simply cannot be performed while still maintaining aseptic conditions. For these reasons, manufacturers schedule planned "shutdown" periods, where commercial production is halted and the cleanroom controls and systems (e.g., HVAC differential pressures, HEPA filtration, aseptic gowning requirements) are stopped, allowing repair and maintenance work to be completed without risk of contamination. Often companies schedule shutdowns on an annual or semiannual basis. Contrary to the meaning of the term outside of industry, a shutdown period is not a time of relaxation for manufacturers, rather these are periods of intense around-the-clock activity. Adherence to timelines and project management is critical to a successful shutdown. The adage "time is money" is apt; completing maintenance activities and returning to commercial production as quickly as possible is the driving factor for scheduling shutdowns. Extensive resources are spent in planning and executing the work conducted during a shutdown. There is little room for inefficiency, mistakes or unplanned events. More critical than meeting the timeline however, are the processes by which the manufacturing area(s) are returned to suitable cleanroom conditions. This article summarizes the key steps for returning cleanroom environments to suitable levels of cleanliness and microbiological control after shutdown events.

Whether a shutdown is planned or unplanned (i.e., the result of a power loss or other breach), the processes for bringing a cleanroom facility back to sufficient levels of control must be described in a written plan based on sound scientific principles. It is understood that cleanroom conditions have been lost during a shutdown. The steps to bring the cleanroom(s) back on line after the event need to be carefully considered and understood by all personnel involved.

The initial stage is a gross manual cleaning of all surfaces using a detergent solution. This is sometimes referred to as "construction cleaning". This is that rare opportunity to perform a robust round of cleaning without the typical restrictions required by aseptic practices in cleanrooms. In other words, this is the time to use some "elbow grease", get down on hands and knees to scrub clean surfaces that wouldn't normally be touched during aseptic processing. Production personnel are typically not engaged in operations at this time and are a valuable source of labor to complete the cleaning quickly and thoroughly. Floors, walls, ceilings, equipment, furniture, etc., all are brought back to a new state of physical cleanliness. The cleaning crew are assigned tasks and areas to clean systematically ensuring no areas are neglected. The focus for this first stage of cleanroom recovery is not disinfection, but rather the removal of soil and debris left behind by the shutdown activities. Personnel do not require aseptic gowning, but some level of gown-control is recommended: shoe covers, head / beard covers, non-shedding facility scrubs, gloves, etc. are considered. The goal is to remove all dirt, debris, soil and restrict further addition of these contaminants into the cleanroom environment.

Once the first stage of cleaning is complete, standard personnel gowning requirements are reinstated and the facility HVAC (i.e., HEPA, differential pressures) controls are reestablished. This is an opportune time to collect baseline environmental monitoring (EM) data on the cleanroom environment. Viable microbial surface sampling by the EM department provides a picture of the "before" condition of the facility, which is assessed against the "after" EM sampling done once the final round of disinfection is complete.

The next stage is a full facility treatment of all surfaces with a broad-spectrum disinfectant. A combination cleaner/disinfectant product is optimal to enhance the pre-cleaning done during the first stage. This surface disinfection is conducted by fully trained personnel with experience performing disinfectant cleaning. The same quality tools (e.g., mops, buckets, wipes, sprayers, etc.) and agents that are used during normal production periods are used at this stage. All applicable standard operating procedures for disinfectant cleaning are followed as well.

A second full round of disinfectant cleaning is often included after the prescribed "dwell" or wet-contact time of the first round of disinfectant cleaning.

The final stage utilizes a sporicidal agent applied to all applicable cleanroom surfaces. The presence of endospore-forming bacilli and molds are reduced during the previous recovery stages, simply by mechanical action on the surfaces, but this final round of treatment ensures that microorganisms that are not killed or removed by the broad-spectrum disinfectant are effectively eliminated by the sporicide.

With full gowning, aseptic behavior standards, and environmental controls (i.e., HVAC, DP, HEPA reimplemented), the cleanroom is now at a suitable level of cleanliness and microbial control. This is the time to gather the "after" EM viable samples, which demonstrate in-situ effectiveness of the cleaning and disinfection strategy for shutdown recovery.

Cleanroom recovery from a shutdown must be thoughtfully developed and executed correctly; given the stakes (i.e., product quality and patient safety) there is zero tolerance for risk. This article highlights the major considerations to return a cleanroom operation to sufficient levels of cleanliness and microbial control after a loss of aseptic conditions, either planned or unplanned. Additional details and elements, specific to each unique manufacturing environment, must be in place to achieve an effective shutdown recovery plan.

In our industry there are unfortunate examples of manufacturers waiting too long to enter a shutdown, postponing them in favor of higher production numbers. Often this results in disastrous and unacceptable outcomes. Given the nature of our products and customers, the "locomotive" must be stopped every now and again to facilitate repairs.

Please join a one-hour webinar, "Cleaning, Disinfection, and Environmental Monitoring after Shutdown of Controlled Environments", hosted by the ISPE Great Lakes Chapter, to expand upon the aforementioned concepts. Bring your questions to be addressed by industry experts at the conclusion of the webinar.

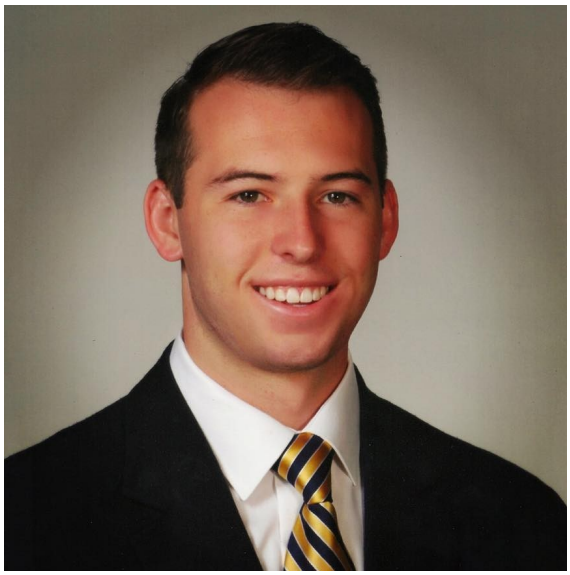
About the authors: Aaron Mertens and Joe McCall are Microbiologists on the STERIS Life Sciences, Technical Services Team, where they support the pharma, biotech, and med device industry regarding contamination control concepts, global regulations, and best practices. Together they have over 40 years of industry experience.

Cincinnati ISPE Education & Networking Event

On June 27, Plus Group hosted an ISPE Great Lakes Chapter educational and networking event at the Great Wolf Lodge Conference Center in Mason, Ohio (a suburb north of Cincinnati). The objective of this event was to repeat and expand on the successful networking event held last year in downtown Cincinnati by adding an educational component. A survey of the members in Ohio, Indiana and Kentucky was sent out prior to the event to solicit feedback on the topics as well as the location and logistics of the event. Based on the survey, the event featured two facilities topics: "Facility of the Future: Trends in Drug Substance Facility Design", presented by Jim Savage of Jacobs Engineering; and "Facility Master Planning", presented by Ken Popham of Process Plus, a Plus Group Company.

The event was attended by 71 participants (members and non-members) and raised a total of $1000 for the chapter. It was sponsored by several companies including event host, Plus Group; GE Booth, Jacobs Engineering, and Performance Validation at the Platinum Level; and Ketchum & Walton, Maetrics, and Wilhelm Construction at the Gold Level. There was a 30 minute discussion session after the presentations where several participants asked questions, showing a high level of interest in the content presented. The feedback survey after the event showed an overall positive response and included some suggestions for events in the future. Suggestions included adding more in-depth presentation content and concurrent tracks to address different attendees' interest areas. This is understandable as the Great Lakes region does not have national training offered within the region, therefore chapter events provide members with an economical solution to receive education. The Cincinnati regional events team is excited to continue this annual event!

Member Spotlight : Jordan Rhoades



Jordan's desire to work in the Pharmaceutical Industry stemmed from his first co-op experience during school. As a freshman at Purdue University, he joined the Cooperative Education Program and was fortunate to receive a position in validation at Cook Pharmica. Once he began working, he quickly realized the profound impact that working in the industry had on patients' lives.

In addition to working at Cook Pharmica, Jordan spent a summer interning with Process Plus, an engineering firm in Cincinnati. He then graduated from Purdue University in May of 2018 with his B.S. in Chemical Engineering, and now works as a Process Engineer for Jacobs at their Cincinnati office.

Jordan joined ISPE a year ago as a student in order to learn more about the industry and to grow his professional network. He enjoys reading the Pharmaceutical Engineering Magazine and takes advantage of the resources available through ISPE. Attending networking events has been very beneficial to him and created relationships that have led him to where he is today.

Jordan has recently taken on the role of Young Professional Liaison for the Great Lakes Regional Chapter of ISPE. In this position, he hopes to create a stronger relationship between the chapter and young professionals as well as student chapters. In order to enhance these relationships, he wants to ensure younger members feel comfortable and welcomed at networking events, increase awareness about events, and help student chapters find facility tours and set up industry speakers at their meetings on campus. Jordan would love to hear from anyone with ideas, recommendations, or questions! Please reach out to him via email (jordan.rhoades@jacobs.com).

Jordan grew up around Indianapolis and enjoys not being too far from his family now that he has moved to Cincinnati. He likes to spend weekends with friends and family at the lake, and loves playing basketball, golf, and tennis. He is huge sports fan and enjoys cheering for the Indiana Pacers and Indianapolis Colts, and is a die-hard Purdue fan. He also loves watching the TV shows *NCIS* and *Suits*, as well as reading books, especially ones written by Dan Brown.

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.

Our Board

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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; lwessel@processplus.com

Indianapolis Committee: This committee plans the Indianapolis area chapter events.

Brian Grimes; brian.grimes@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 Annual Meeting & Expo
04 - 07 November 2018
Philadelphia, PA USA

2018 ISPE Biopharmaceutical Manufacturing Conference
10 - 12 December 2018
Huntington Beach, CA USA

2019 ISPE Aseptic Conference
18 - 19 March 2019
Rockville, MD 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