

## *Great Lakes Chapter*

### Spring/Summer 2019 Chapter Newsletter

#### President's Message



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

ISPE Great Lakes Chapter, President's Message:

Recently I have had the pleasure of joining the ISPE North and South American Affiliate Council (NASAAC) meetings, where this year's focus has been to address specific challenges in the organization. The NASAAC committee conducted a poll on the Chapter level to determine the challenges faced within each region. The results were compiled nationally and a task force was created for the following top four challenges identified

- Increasing engagement of operating / owner company members
- Geographic spread of territory and isolation of members
- Board and chairperson succession planning
- Communicating Community of Practice information from the National to Chapter level

Interestingly enough, the first two challenges are inline with the results from the Great Lakes Chapter – we are not alone in our thoughts and feelings! I am pleased that as a Chapter we have already demonstrated improvement in these areas, as evidenced by the Third Annual ISPE GL Chapter to be held in the Cincinnati area on July 30th. Representatives from owner companies (Eli Lilly and Syneos Health) will be presenting on two hot topics in our industry. Great job to the Cincinnati Event Planning Committee in securing these speakers.

To help address the large geography of the Great Lakes Chapter territory, in September we are hosting a second event in northern Illinois. This is a joint event planned with CSL Behring to highlight their facility expansion. Technical presentations, a facility tour and a job fair are among the activities planned for what promises to be another exceptional event. Details are forthcoming.

As you can see, a lot is in the works and I haven't mentioned the fall Indianapolis event, webinars, Women in Pharma Committee, Thirsty Thursday Social, etc. None of this could be possible without our Chapter Board, which continues to impress. If you would like to learn more, please reach out to me directly for information on how to join the GL Chapter monthly meetings.

Thanks again for your support and engagement and I look forward to seeing you in Cincinnati.

Please contact me at: [aaron\\_mertens@steris.com](mailto:aaron_mertens@steris.com)

# JOIN THE ISPE GREAT LAKES CHAPTER

## Third Annual

### Cincinnati ISPE Networking & Education Event

Register at  
[cincy-ispe.  
eventbrite.  
com](http://cincy-ispe.eventbrite.com)

#### Event Details:

Tuesday, July 30

4-7:30 pm

Great Wolf Lodge

2501 Great Wolf Drive,

Mason OH 45040

\$25 for ISPE Member

\$30 for Non-ISPE Member

\$10 for Student with Valid ID

**Joanne Barrick** of Eli Lilly will be giving a presentation titled Process Validation Lifecycle Implementation Update - Progress, Application to New Product Types and Available Tools.

**Michael Rutherford** of Syneos Health will present Current Trends and Guidance on Data Integrity for Manufacturing Records.

**Elizabeth Rivera** from Steris will present on Cleaning Agent Screening: Key Aspects in Selecting a Suitable Cleaning Agent for GMP Cleaning Procedures.

Enjoy 2 beer/wine tickets, appetizers, the presentations and networking time with other industry professionals! Questions may be directed to Jordan Rhoades and Andrea Frazer at [jordan.rhoades@jacobs.com](mailto:jordan.rhoades@jacobs.com) and [AFrazer@plusgroups.com](mailto:AFrazer@plusgroups.com).



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# Member Spotlight : Tom Kerker

Tom Kerker has over 35 years in the construction industry. He joined FA Wilhelm Construction in 1988 and became the Account Manager of Wilhelm's construction services at Eli Lilly & Company in 1996. Tom has served as operations manager for Wilhelm's pharmaceutical clients since 2000. As project executive, his responsibilities include the oversight and management of large capital projects and on-going clients throughout the Midwest. Specifically, Tom involved in projects from inception to turn-over; and is responsible for the business development and marketing, budgeting and bid review, project cost control, project safety, quality and schedule, staffing and staff support, client and customer satisfaction on each project.

Tom's projects have ranged from pharma to biotech to Level 3 containment facilities, Research and Development, GMP warehouses to the corporate headquarters and parking structures that support these facilities. Throughout the years. Tom has worked under several different contracting methods of construction delivery including general construction, design-build, construction management and most recently integrated project delivery.

Tom's passion is providing GMP facilities for clients in the most cost and schedule efficient manner meeting their needs and expectations. After years of hands on experience of building and maintaining pharma facilities; he works hard to support clients and to mentor project teams to the success of the project and our Life Sciences industry.

A graduate of Purdue University, Tom has remained involved as an active alumnus serving on the Executive Council of the Construction Advisory Council for a number of years. He continues to work with Purdue students through internship opportunities and advising students. Tom has been a member of ISPE since 1993, having been a member since the inception of the Great Lakes Chapter and has attended several national conferences over the years. He is been active with the Construction Industry Institute (CII), Mid-West Minority Supplier Diversity Council and the Association of General Contractors.



## 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](mailto:aaron_mertens@steris.com)

**Chicago Event Committee:** This committee plans the Chicago area chapter events. Aaron Mertens; [aaron\\_mertens@steris.com](mailto:aaron_mertens@steris.com), Sara Brothers; [Sara.Brothers@crbusa.com](mailto:Sara.Brothers@crbusa.com)

**Cincinnati Committee:** This committee plans the Cincinnati area chapter events. Contact: Andrea Frazer; [AFrazer@plusgroups.com](mailto:AFrazer@plusgroups.com)

**Indianapolis Committee:** This committee plans the Indianapolis area chapter events. Brian Grimes; [bgrimes@rossbar.com](mailto:bgrimes@rossbar.com)

**Young Professionals & Student Chapter Committee:** Jordan Rhoades; [Jordan.Rhoades@jacobs.com](mailto: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](mailto:aaron_mertens@steris.com) or Allen Koester, [allen.koester@skanska.com](mailto:allen.koester@skanska.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 – Open Position

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

## Linked In

Visit the Great Lakes Chapter Linked-In Page at:

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

## 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 May 2019. Please welcome them to the organization and the pharmaceutical industry.

**Mr. Dallas S. Barber, Manager, Engineering Alkermes Inc**

**Suresh Bhamidi, Manager**

**Jonathan Cook, Vice President, Manufacturing, Nexus Pharmaceuticals**

**Jim Kelley, Engineer, MSKTD & Associates, Inc.**

**Robert Nolan**

**Corey Lee Povaleri, High Purity Water Engineer, Eli Lilly & Co**

**Jeremy Sheldon, National Sales Manager, Life Sciences, LJ Star**

**Randall Specht, Validation Engineer, CAI**

**Chris Timmerman, Validation Engineer, CAI**

**Mr. Phillip Aaron Wagner, Validation Engineer, CAI**

**Mr. Glen Wheeler, Principal Engineer, Alkermes**

# Upcoming ISPE Conferences



## 2019 ISPE Annual Meeting & Expo

27 - 30 October 2019  
Las Vegas, NV USA



## 2019 ISPE Regulatory Conference

05 - 06 December 2019  
North Bethesda, 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, Aaron Mertens at:

[Aaron\\_Mertens@steris.com](mailto:Aaron_Mertens@steris.com)