President’s Message

ISPE Great Lakes Chapter, President’s Message:

2019 marks the 20th anniversary of my involvement in ISPE and is the start of my tenure as ISPE Great Lakes Chapter President. I am grateful and humbled by this opportunity! First, I would like to thank Deborah Geyman for her term as GL president. Under Deborah’s leadership, the chapter is thriving, with new focus on regional activities and events. I am excited for this year, where I see my responsibility as simply guiding the ship that has already set sail.

Our chapter will focus on supporting our members through professional networking and educational events. We held our annual board meeting (10 members in attendance) in early January 2019 and agreed to continue where we left off in 2018. Last year we hosted four technical content webinars and two face-to-face events in Cincinnati (spring) and Indianapolis (fall). The webinar series will continue this year and a third face-to-face event will be added in the Chicago area (timing to be determined). To do this, volunteers have been added to fills roles as webinar coordinator, social media chair, newsletter email coordinator, sponsorship coordinator, and women in pharma liaison. I am thrilled to have new energy on the team.

In addition to these volunteer roles, we are looking for technical content for the GL Chapter Quarterly Newsletter. If you have a short article on a hot industry topic, please submit directly to me for possible publication. This is a great way to share your expertise and become more involved!

Lastly, I would like to thank all ISPE members and the Great Lakes Chapter Board. Your continued support and involvement guarantee another successful year ahead.

Please contact me at: aaron_mertens@steris.com
Walid El Azab, Technical Services Manager of STERIS Life Sciences, presented the impact of the changes regarding the EU GMP draft Annex 1 contamination control program. Over 50 individuals attended the webinar on Nov 30, 2018 and asked several insightful questions during the Q&A portion.

Walid is an industrial pharmacist, a Qualified Person and Lean Six Sigma green belt. He provides technical support related to cleaning, disinfectants, sterility assurance and process validation.

It was apparent in the webinar that Walid’s technical knowledge was well suited for the analysis and assessment of the impact of the changes laid down in the draft Annex 1. Walid articulated the emphasis of the draft Annex 1 to minimize the risk of microbial, particulate and pyrogen contamination for sterile processes.

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.

**Great Lakes Chapter welcomes new members!**

- Dr. Hamza Alshannaq, PhD Student, University of Cincinnati
- Dr. Bernard Gadagbui, Toxicologist, TERA
- Elissa Hilton, Consultant Chemist, Eli Lilly & Co
- Mr. Daniel Keelin, , Omega Plastics, Inc.
- Mr. Lex Konko, Validation Manager, American Regent
- Jennifer Moore
- Nick O'Hare, Client Relations Manager, StructureTec
- Xandra Olmedo, Quality Systems Specialist III,
- Mr. Kevin Raymond Papp, Architectural/Engineering, Stonhard
- Nathaniel C. Smart, Process Specialist, CRB
- Mr. John Swibes, President, PharmAseptic Inc
Member Spotlight: Sara Brothers

Sara Brothers has more than 23 years of experience in the design and construction of advanced technology, academic, healthcare and corporate facilities. With advanced degrees in both architecture and construction management, Sara has served in construction engineering, architecture and project management roles across various industries. In her current position at CRB as a Senior Project Manager, she oversees the design of biotechnological facilities, with a growing involvement in the science and technology field. She has contributed to projects at Patheon – A Part of Thermo Fischer Scientific, Scientific Protein Laboratories, DSM Food Specialties USA, Washington University School of Medicine, Mercy, and BJC Healthcare.

A member of AIA St. Louis, Sara founded a subset organization called the AIA St. Louis Women in Architecture Forum. This group serves women in architecture and related fields by providing both professional development and networking opportunities. Additionally, Sara sits on the Ranken Technical College Building Systems Advisory Board and the St. Louis Children’s Hospital Patient and Family Centered Care Council.

Sara joined the ISPE Great Lakes Chapter as a Board Member in 2018 and led the marketing, communications and webinar coordination efforts. In 2019, she was elected in as Treasurer of the Chapter.
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@crbusa.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; 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

Your Opinion Counts:

The Great Lakes Chapter board would like to encourage you to have your voice heard and get involved by filling out our events survey by March 28. You can find the link to the survey in your email or below. Link: Begin Survey
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.
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** – Larry Wessel, Process Plus, Market Segment Director
- **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/](https://www.linkedin.com/groups/4928599/)
Upcoming ISPE Conferences

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

2019 ISPE Biopharmaceutical Manufacturing
18-20 June 2019
Boston, MA USA

2019 ISPE Process Validation Workshop
20 - 21 June 2019
Boston, MA USA

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