
Great Lakes Chapter

Summer/Fall 2020 Chapter Newsletter

President's Message



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

Hello ISPE Great Lakes Chapter. Another quarter of year 2020 has passed us by. I am not sure if time is moving terribly slowly or amazingly fast! The fact is that schools are back in session (both virtually and in person) and some of us are transitioning back to office life. My sincerest hope is that we all stay healthy through these challenging times.

These last few months I have used the new work situation to participate in a number of webinars, including one hosted by our chapter. I am proud to report that STERIS Senior Technical Manager, Jim Polarine, presented an excellent webinar on Contamination Control. Jim focused on recommendations for cleaning and disinfection in the pharmaceutical cleanroom, to minimize microbial contamination and to stay compliant with current Good Manufacturing Practices. Please reach out to me if you attended the webinar and have questions, or if you are interested in learning more about this topic. I will gladly introduce you to Jim, who will share best practices for our industry.

In addition to webinars, I have enjoyed catching up on my reading. In August, ISPE published a new guidance, "Cleaning Validation Lifecycle – Applications, Methods, & Controls", which I found

to be practical guidance for establishing compliant cleaning programs that meet regulatory expectations. Check out ISPE.org to find a good practice guide to ensure your facility is in top shape.

Webinars and articles are the theme, so take a peek in this quarter's newsletter for information on the next webinar hosted by ISPE Great Lakes Chapter. Also, we continue to share excellent technical articles from our membership. I appreciate your contribution to our chapter's goals, bringing pharmaceutical engineering professionals together and providing learning opportunities. Please contact me at: aaron_mertens@steris.com if you have something to contribute or would like to be more involved.

As usual, thanks to the ISPE GL Board and members for making our chapter a success!

Member Spotlight : Chris Timmerman



Chris Timmerman is a Project Manager / Validation Consultant for Commissioning Agents Inc., in Madison, WI. He has been a member of ISPE since 2018. Chris's career spans 22 years of military and professional experience in nuclear power plants, radioactive materials and licensing and emergency response training to the public living within 10 miles of commercial nuclear power plants.

In addition, over the last 5 + years Chris has been involved in multiple types of CQV & CSV pharmaceutical and biotechnology projects while employed at CAI. Chris's strengths include risk assessments, root cause analysis, data analysis, software quality testing, project management, contract management and troubleshooting.

Chris has 3 girls, 24, 15 and 10. His oldest daughter has just started her graduate studies at George Washington University in St. Louis, MO to obtain her Law Degree. His younger daughters enjoy going tubing, skiing, knee boarding, and swimming on the lakes around Madison, WI.

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 4 new members in June-July 2020. Please welcome them to the organization and the pharmaceutical industry.

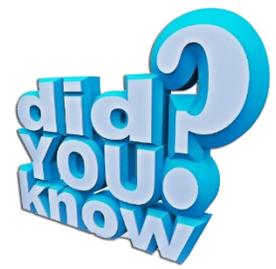
Christian H. Jaeger, Engineering Director, Process Alliance LLC, Carmel, IN

Mr. Blaine Krause, Global Senior Executive Account Manager, Nalco Company, Naperville, IL

Akshay Ramnikbhai Mavani, Post-Graduate Research Assistant (Volunteer Learning), Wayne State University, Detroit, MI

Mr. Harshil Patel, Terre Haute, IN

Jeff Pettet, Consultant Scientist, Plainfield, IN



Particle Counter Quick Reference Guide

Airborne Particle Counters:



Count and size particles in the air and are used to determine how clean a cleanroom is and relate the level of cleanliness to cleanroom standards based on the number of particles per cubic meter of air sampled. ISO14644-1:2015 is one of the most used standards in Pharma and Electronics controlled environments. It also specifies the standard method of testing to determine cleanliness class, including selection of sampling locations.

Flowrates:

CFM = Cubic Foot per minute

1cfm = 28.3 Liters per minute

0.1cfm = 2.83 Liters per minute

Sample Volumes:

A cubic meter (m³) is 1000 Liters

A cubic foot (ft³) is 28.3 Liters

Sample Times:

0.1cfm flowrate will take over 350mins to sample 1³m of air

1cfm flowrate will take just over 35mins to sample 1³m of air

50 Liters per minute (L/min) flowrate will take just over 20mins to sample 1³m of air

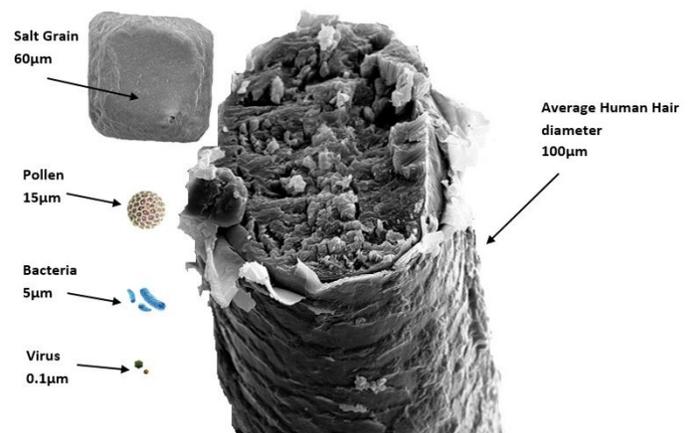
100L/min will take just over 10mins to sample 1³m of air

Particle Sizes:

1µm is a micrometer", or a millionth of a meter. Particles in Cleanrooms are measured in microns. Particle Counters size and count particles at sizes not visible to the human eye.

Provided by: Lighthouse Worldwide Solutions, Inc.

Human hair under a microscope



ISPE GLC Webinar - Date and Registration Coming Soon

See our LinkedIn page: [linkedin.com/company/ispe-great-lakes-chapter](https://www.linkedin.com/company/ispe-great-lakes-chapter)

WEBINAR: COMPLIANT MANUAL DATA ENTRY TO OSI PI HISTORIAN

This seminar will discuss the use case for and development of a Part 11 compliant solution to support manual data entry into an OSI PI Historian.

Who Should Attend the Webinar:

- Validation
- Automation
- Operations
- Engineering
- Data Analytics/IT

Speaker Bio:

David Stauffer, Vice President of Automation Services, Aztec Technologies

David joined Aztec in 2016 as Director of Automation Services where he provided lead consulting services to a major biotech company building a new manufacturing facility in Switzerland. In this project, David led an international team of Aztec and client resources responsible for overseeing the PCS and MES design. Currently, as Vice President of Automation Services, David is responsible for providing technical leadership for our DCS, MES, and Data Analytics resources supporting our life sciences client base.

Dave holds a master's degree in chemical engineering and has 20 years of professional experience. His experience includes process and lab automation and data management in the life sciences industry for both existing and greenfield facilities. Over the last 20 years, Dave has worked for system vendors, integrators, and directly for end users such as Bristol Myers Squibb and Johnson & Johnson. His responsibilities have ranged from day to day support of site automation systems to the development of global standards to support standardization of platforms and solutions across the manufacturing network.

He has managed, lead and developed teams, in the US and other geographies, having responsibility for technical design, implementation, commissioning and validation of a variety of systems.

Webinars



Join us for a virtual conversation with Sandy Chamber on how to convert fear to confidence as we encounter change, as well as on defining your own personal brand.

Presents

Mentor of the Month



Sandy Chambers

Senior Director,
Global Supply Chain Brand Management
Abbvie

September 24th, 2020
9:00 - 10:00 AM (CST)

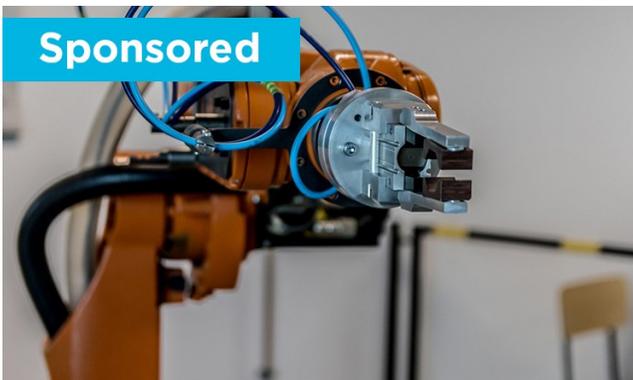
Registration: <https://us02web.zoom.us/meeting/register/tZwocOurrjstvGdxrFOgv6YPluaEt1f6j-YRA>

<https://us02web.zoom.us/meeting/register/tZwocOurrjstvGdxrFOgv6YPluaEt1f6j-YRA>

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 ISPE Webinars



[More Than Just Technology: A Holistic Approach To Pharma 4.0 Webinar](#)

Tuesday, 22 September 2020
Time: 1100 - 1200 EDT

Complimentary

Sponsored By:



2020 ISPE Conferences



[2020 ISPE Biotechnology Virtual Conference](#)

7 - 8 October 2020
Virtual Conference



[2020 ISPE Annual Meeting & Expo](#)

2 - 6 November 2020
Virtual Conference



2020 ISPE Europe Pharma 4.0™ Virtual Conference

17 - 18 November 2020
Virtual Conference



[2021 ISPE Aseptic Virtual Conference](#)

15 - 17 March 2021
Virtual Conference

[BUY ON DEMAND SESSIONS](#)



[2020 ISPE Continuous Manufacturing Virtual Workshop](#)

3 - 4 June 2020 (Buy on Demand)



[2020 ISPE Biopharmaceutical Manufacturing Virtual Conference](#)

1 - 2 June 2020 (Buy on Demand)

Interested in sponsoring the ISPE Great Lakes Chapter? Check out our new sponsorship strategy!

Sponsorships	Cost	Benefits
Newsletter Advertising		
Business Card Size	\$75 per issue or \$250/year	Advertisement in each newsletter (4 issues per year)
1/2 Page	\$100/issue or \$350/year	
1 page	\$150/issue or \$550/year	
Webpage Advertising		
https://ispe.org/great-lakes-chapter	\$250/6 months or \$500 /year	Logo on banner at bottom of ISPE.org page. GLC LinkedIn page will share requested company content ¹ .
Single Event Sponsorships		
Platinum	\$600	2 minute company introduction at event, table top display with representative, company logo on event advertising, 3 free passes to event
Gold	\$400	Table top display with representative, company logo on event advertising, 2 free passes to event
Silver	\$200	Company logo on event advertising, 1 free pass to event
Webinar	\$200	1-hour webinar. Company logo on slide deck and webinar advertising
Chapter Sponsor		
Number of Chapter Sponsorships Limited to 6 Companies	\$1200/year	½ page Newsletter Advertising and Website Advertising for year
		Silver Level Event Sponsorship for every event ISPE Great Lakes Chapter Hosts ²

¹Content to be shared on LinkedIn must be approved by member of GLC board. Limited to 2 posts/month. Post will start with "SPONSORED CONTENT".

²If sponsorship company wants to be a Gold/Platinum level sponsor, an additional \$200 / \$400 will be required per event to move from Silver to Gold/Platinum. Number of events held is not guaranteed and may change year to year.

Please contact Sara Brothers and Joe Robinson to set up your sponsorship!

Sara.Brothers@jacobs.com
Joe.Robinson@cagents.com

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. Contact: David McAlonan, McAlonDW@Middough.com

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

Young Professionals & Student Chapter Committee: Chris Pardo, Cpardo@biotech.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

2020 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 – Jordan Rhoades, Jacobs Engineering, Process Engineer

Board Members

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

Board Member– Tim Fry, JDI Group, President/Principal Architect

Board Member– Andrea Frazer, Jacobs Engineering, Process Engineer

Board Member—Joe Robinson, CAI, Regional Manager, Midwest

Board Member– Chris Pardo

Board Member—Chris Timmerman, CAI, Project Manager / Validation Engineer

Board Member—Rick Corbett, Process Plus, Director-Pharmaceutical Project Management

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.

2020 Chapter Sponsors

QUALITY INTEGRATED SOLUTIONS & SERVICES



WHEN YOU NEED
TO MEET A
HIGHER STANDARD™

www.cagents.com

PROJECT 
PROCESS 
PEOPLE 
FACILITY 
QUALITY 



Whether your capital project involves building new facilities and processes or repurposing existing ones, Middough has the engineering and project management expertise to assure successful implementation from concept to validation.

Contact us today to discuss your pharma and bio-tech project needs.

Mark Jablonski

630.280.5092

JablonME@Middough.com

Dave McAlonan

630.756.7034

McAlonDW@Middough.com

PERFORMANCE YOU TRUST™

Middough Inc. - 1901 E. 13th Street - Cleveland, OH 44114

www.Middough.com