Connecting Pharmaceutical Knowledge

Great Lakes Chapter

Summer/Fall 2019 Chapter Newsletter

President's Message

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

ISPE Great Lakes Chapter, President's Message:

Amazing that the 4th quarter of 2019 is starting already! Let's take a few minutes to reflect on what the ISPE Great Lakes Chapter has accomplished in the first three quarters of the year.

- We kicked the year off right with the face-to-face Chapter Board Meeting in Indianapolis – I think we are on track with accomplishing the goals we established in January.
- NASAAC involvement on the Chapter level has been great – I anticipate NASAAC support to engage owner companies, assist members who are geographically isolated, and succession planning.
- Unfortunately, the event planned for the fall in Northern Illinois has been postponed, but this will free resources to present a few technical webinars in the coming months.
- We have had some turnover on the Great Lakes Chapter Board due to a retirement and a job change. I welcome David McAlonan as the Vice President and Jordan Rhoades on to the Board.
- Lastly, the event held in Cincinnati on July 30th was a success. Thanks again to our speakers, sponsors, planning committee and attendees. Read more about it in this quarter's newsletter.

There are exciting activities yet to come this year. Plans are progressing for a Thirsty Thursday social in Cleveland. Rumor has it, a group is meeting for appetizers, drinks, and networking at Masthead Brewing Company on September 26th. Please keep an eye out for the event flier to be distributed soon. October 27th through 30th brings the ISPE Annual Meeting and Expo at Caesar's Palace in Las Vegas. I will be in attendance and would like to opportunity to meet some of you in person. Please reach out to me directly to arrange a few minutes to chat. Enjoy the last weeks of summer and I hope to see you soon in sunny Las Vegas!

Cincinnati ISPE Education & Networking Event

On July 30, the Great Lakes Chapter hosted an educational and networking event at the Great Wolf Lodge Conference Center in Mason, Ohio (a suburb north of Cincinnati).

The event was attended by 53 participants (members and non-members). The event raised money that was used to raffle ISPE Annual memberships and Good Practice Guides to the attendees. It was sponsored by several companies including Plus Group, BSI Engineering, Jacobs Engineering, Newman Sanitary Gasket Company, and Wilhelm Construction at the Platinum Level; and Performance Validation and Steris at the Gold Level. There was a presentation by Joanne Barrick of Ely Lilly titled *"Process Validation Lifecycle Implementation Update—Progress, Application to New Product Types and Available Tools".* Michael Rutherford of Syneos Health presented "*Current Trends and Guidance on Data Integrity for Manufacturing Records".* Elizabeth Rivera of Steris presented on *"Cleaning Agent Screening: Key Aspects in Selecting a Suitable Cleaning Agent for GMP cleaning Procedures*". The educational presentations were followed up by two networking sessions where the attendees had a chance to enjoy food and drinks and make connections with fellow attendees and with the sponsors.

2019 ISPE WIP Mentor Circle Program

WIP MISSION

ISPE Women in Pharma® (WIP) provides women in the pharmaceutical industry a forum for connecting and collaborating on technical and career advancement topics. WIP's inclusive community leverages a network of mentors, role models, and resources across all levels to foster balanced professional success.

This program is being led by Christa Myers (Pharma Chair) and Jennifer Clark (Pharma Co-Chair).

WIP GOAL

The WIP goal is to promote an inclusive culture. We:

- Provide toolkits and approved formats for WIP functions;
- Facilitate a collaborative mentorship program;
- Sponsor students and young professionals;
- Offer webinars;
- Host educational and networking events;
- Encourage and celebrate success.

It is the goal of ISPE to see all our affiliates and chapters engaged by 2021.

PROGRAM DESCRIPTION

Mentor Circles are a way to promote growing relationships and career development for women scientists and engineers in the pharmaceutical industry. The circles will be groups of roughly 10 people that will meet 4-6 times per year. Half of the time the groups meet will be spent networking and half of the time will be spent discussing a relevant career advancement topic with a guest speaker that may or may not be one of the mentors part of the regular group. The teams will be made up of 2-4 Mentors per team and the remaining people will be mentees and mid-career people. Ultimately the group make up will differ slightly between groups based on interest.

The discussion topics will rotate throughout the year based on the topics the recruited speakers are knowledgeable about and based on feedback on issues that group members may be facing and would like feedback on. As this is a new program, the format is subject to change based on feedback from the group.

VOLUNTEERS

Regional Mentor Leads: The regional leaders will recruit other mentors, mentees, and guest speakers. They will also make sure that guest speaker mentors have the resources they need to lead meetings, which may include booking a location for the meetings. They will also report back to the program leaders and promote the events via email and LinkedIn. The time commitment for this role will likely be a few hours per month.

Mentor Leaders in Mentor Circle (could be regional or teleconference leads) – The mentor leaders in each circle will be a consistent presence and make sure that the guest speakers understand the group and have the resources they need. They will lead the meetings and report back to the program leads on how things are going and what resources they need. In many cases they will also be the regional leads.

Guest Speakers for Mentor Circles - An expert senior level pharmaceutical person will be brought in for each meeting to lead the topic discussion for the group. Sometimes this will be the group leader. The idea behind

having the guest speakers is to give senior level executives that may not have the time to participate quarterly the opportunity to participate. The time commitment here can be as little as an hour to two for the actual mentor circle meeting.

Mentor Program Ambassadors: For people that don't have time to participate formally we still benefit from you spreading the word and keeping an eye out good speakers, future mentor leaders and mentees for future programs. This can take as much or as little time as people can make for it. If people want to officially help in spreading the word, information will provided for them to distribute.

Sponsorship chair: Initially regional chairs will make sure that they have a location to host meetings. In the long term, the program may benefit from having someone specific to recruit companies to sponsor some of the face to face meetings and host at their facilities

If you are interested in joining the WIP Program, please contact David McAlonan at mcalodw1@yahoo.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. Aaron Mertens; aaron_mertens@steris.com, Sara Brothers; Sara.Brothers@crbusa.com

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

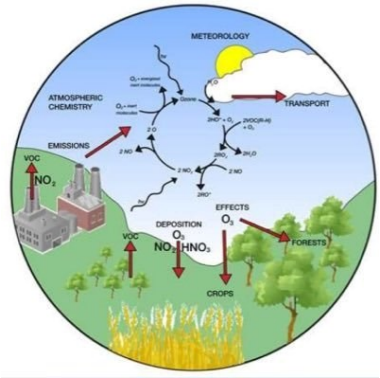
Committee involvement is a great way to become more involved with our local chapter and the international organization. Serving on a committee facilitates an expansion of your local network and members involved in committees will be considered for open Board of Director positions .

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

A Discussion of the Analysis and Implementation of VOC Abatement Technologies

Volatile Organic Compounds, or VOC, are widely used in pharmaceutical and biotech manufacturing. These include: alcohol extraction processes, chemical synthesis operations, chromatography purification, tableting granulation and coating, even in bench top cleaning. The code of federal regulations defines a VOC as *any compound of carbon which participates in atmospheric photochemical reactions*. Common VOC chemicals used in the pharmaceutical industry include (but are not limited to) ethanol, methanol, toluene, methylene chloride, benzene, acetonitrile; the list is extensive. These chemicals may be entrained in the vapor phase of effluent waste from a manufacturing facility, healthcare facility, or laboratory as a part of normal operations. The release of VOC to the atmosphere represents a pollution concern that can have negative effects to the environment and those who reside in that environment; therefore, the emission of VOC is regulated by federal law.



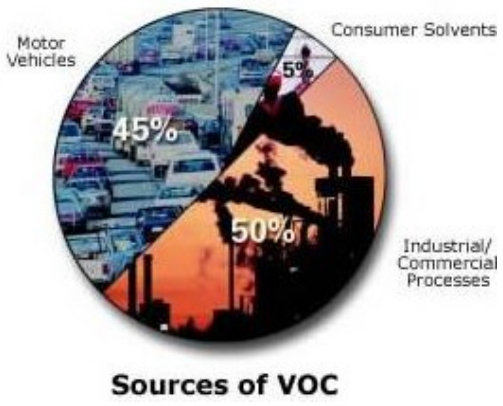
Consultation with the state's EPA agency in which the facility resides is necessary to first define if VOC are present in the waste effluent. The EPA maintains lists of VOC chemicals requiring treatment. On any new facilities a site-wide analysis must be conducted to determine the expected amount of VOC emissions. This is typically done through the development of an Air Permit as required by federal law under the Clean Air Act and is best developed in partnership with the local EPA or governmental permitting authority. This analysis will determine if emissions controls are required to remove pollutants from the vapor effluent stream in order to be compliant with environmental law and avoid hefty fines. Be aware, there may also be county or even municipality level requirements that go beyond the state regulated levels. These local regulations must also be considered as part of the analysis process. Typically, the allowable limits set by the EPA are in terms of tons of emissions per year. For example, in the state of Indiana the allowable limit of VOC emissions before the application of controls are necessary is 90.7 megagrams (100 tons) per year (Indiana EPA Rules for Handling Volatile Organic Compounds Section 8-6-2.a found at www.epa.gov/in). However, this does not preclude an operator from enacting their own, more conservative restrictions in order to practice a "good neighbor" policy particularly if the operating facility is located within a highly industrialized area with a high concentration of other VOC producers, an area where the surrounding environment is particularly sensitive to VOC emissions, or nearby any residential area.

If VOC abatement is determined to be necessary to meet regulatory and/or good neighbor requirements there is a wide variety of technologies to choose from to meet the specific site's needs. The four most commonly utilized technologies are:

Activated Carbon Adsorption

Activated carbon adsorption is the most commonly used method for removal of contaminants in both liquid and vapor streams because of its ease of use, high efficiency, and low initial capital expenditure for implementation. Activated carbon beds are modular and typically leased from a vendor who then is responsible for remediation of saturated beds and disposal of the target contaminant thus releasing the end user from performing disposal activities on their site. The most effective use of activated carbon are on effluent streams containing a single contaminant or contaminants that are relatively similar in molecular weight as there is a relationship between molecular weight and pore size in the activated carbon granules. Consult with the vendor as they will have available detailed data tables for the proper selection of the type of activated carbon for the process.

Thermal Oxidization: A thermal oxidizer (TO) decomposes hazardous effluent gases at high temperature releasing only the products of a typical combustion reaction; carbon dioxide and water. Thermal oxidation is useful when the effluent stream contains multiple VOC species in the stream with a wide variation in molecular weights. The advantage of TO is the complete reduction of the target contaminant with no secondary disposal required as is the case with other abatement technologies. In the case of Regenerative Thermal Oxidizers (RTO) the process is very efficient using a heated ceramic bed for the oxidative reduction. Implementation of TO requires a significant capital investment for installation and may not be consistent with end uses who are attempting to reduce their overall carbon emissions.



Sources of VOC

Chemical Scrubbing: Chemical scrubbers are widely used across the manufacturing industry for a variety of applications from removing entrained particulates from a high velocity gas stream to acid/base neutralization from process venting. Chemical scrubbers utilize contact of a falling film scrubbing fluid (such as water) flowing counter-current with a waste gas effluent stream for the removal of contaminant particles. Waste fluid is then treated by way of a site's process waste system or collected for treatment by a third party. Compared to thermal oxidation, the initial capital investment for implementation and long-term operation is comparable; however, chemical scrubbing does not increase a site's carbon emissions.

Cryogenic Condensation: Cryogenic condensing takes advantage of the liquid-vapor equilibrium principle in multi-component mixtures. Utilizing liquid nitrogen as a coolant, the temperature of the gas stream can be lowered to decrease the saturation capacity of the carrier gas thus allowing contaminant VOC vapors to condense into liquid. This process is highly efficient with low energy input. Cryogenic condensing works best on VOC compounds with a low boiling point but can achieve a high level of control to condense almost any organic solvent. Dependent upon the process, the recovered solvent can potentially be reused. However, as with other abatement technologies the initial capital investment for cryogenic condensing is significant and still requires secondary treatment of the waste.

Determination for the need of VOC abatement is straight forward, the technologies are established and well understood, and implementation is almost novel. The treatment of vaper emissions for the removal of VOC contaminants is not only the law both national and international, but it's important in order to make us good stewards of our corner of the planet.

About the Author: *J.T. Cochran received his Chemical Engineering degree from the University of Missouri-Rolla (now called the Missouri School of Science and Technology) and has been with CRB Engineers for 21 years doing both automation and process design. During that time J.T. has worked in the areas of cell culture and fermentation operations, protein and oligonucleotide chemical synthesis, biofuels, and oral solid dosage. J.T. is currently located at AstraZeneca in Mt. Vernon, IN working as a contract engineer in the Capital Projects Group at that site. He resides with his wife in New Harmony, IN and in his spare time enjoys watching Star Wars movies and doing cosplay.*

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

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 – Dave McAlonan, Middough, Sr. Project Manager

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, PCI Skanska USA, Sr. Project Manager II

Director – Tim Fry, JDI Group, President/Principal Architect

Director – Jordan Rhoades, Jacobs, Process Engineer

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.

Dean Arneson, Concordia University Wisconsin

Nicholas Blacklock, Exelead

Nick Cartwright, Covance

Arthur Gildea, BMS ChE, MS ChE, Lead Engineer I, Alkermes Inc

Mr. Daniel Heaton, Senior Architect, Seven Generations Architecture & Engineering LLC

Mr. David Henderson, Jr., Sr Director, Process Engineering and Technical Operations, Oakwood Labs

Mr. Scott James, Process Engineer, CSL Behring - 1201 N Kinzie Ave Bradley, IL 60915 USA

Andrew Rellinger,

Nathan Lee Richardson, Associate Director of Facilities, Engineering, and Maintenance, Piramal Pharma Solutions

Mr. Christian Sprunger, Site Manager-Stoughton, WI, Colorcon

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

Thank you to our Sponsors