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Thursday, October 24, 2019

Current Good Manufacturing Practices (cGMP)



cGMPs per the FDA (abstract)

We will be presenting the current Good Manufacturing Practices (cGMP) per the Food and Drug Administration (FDA), and how these directives are practiced in a pharmaceutical manufacturing facility making parenterals in a Final Dosage Form (FDF). This process operation has the strictest regulations from the FDA relative to any other production areas. This is due to the direct injection of the parenterals into the human blood stream with no barriers of protection from any potential risk of contaminants or pyrogens that may cause fever or infection.

Mr. John R. Juchnowski (biography)

Mr. Juchnowski has recently graduated from the Cleveland State University, Washkewicz College of Engineering in the Department of Chemical and Biomedical Engineering with a Bachelor of Science in Chemical Engineering as well as having a minor in Chemistry. He has been employed at Xellia Pharmaceuticals since his graduation in June 2017. Mr. Juchnowski is also the Young Professionals Chair with the AIChE Cleveland Section. He has hosted several Trivia Challenge nights with the AIChE YPs at various locations across Cleveland. During his tenure at Xellia he has presented several topics at Cleveland State University with the Washkewicz College of Engineering during the Xellia / AIChE Lunch & Learn 12 part series on cGMP Design for Pharmaceutical Facilities. He has also participated in several panel reviews of Capstone Internship Projects on Water For Injection (WFI) spreadsheet dynamic simulations of process operations with senior students from Case Western Reserve University, Department of Chemical and Biomolecular Engineering. Mr. Juchnowski has been responsible for the complete qualification of several laboratory instruments and is gown qualified for entrance into production rooms that are Grade C and D Qualified. He also has 133 SOP training modules he is current (GMP) on each 90 days.

Meeting Location: Bahama Breeze Restaurant, [Bahama Breeze 3034 - Cleveland](https://www.bahamabreeze.com/locations/oh/beachwood/cleveland-orange-village/3034)
3900 Orange Place
Beachwood, OH 44122
(216) 896-9081
<https://www.bahamabreeze.com/locations/oh/beachwood/cleveland-orange-village/3034>

Social Hour: 5:30 – 6:30 pm, **Dinner:** 6:30 pm – 7:30 pm, & **Presentation:** 7:30 pm – 8:30 pm

Cost: (all people attending dinner are responsible for their meal as ordered from the menu)

Menu: <https://www.bahamabreeze.com/menu-listing/food/>

RSVP by October 17th with Michael Galgoczy at Michael.galgoczy@lubrizol.com

AIChE Cleveland Section Steering Committee Appreciation Corner

Let us take this time to thank Dr. Charles Roe for his time, diligence, and dedication to our AIChE Cleveland Section. Dr. Roe has faithfully served our section since 2010. During his tenure he helped improve many of the ways we operated our meetings, helped increase our section's recognition with his food protein algae work, and most of all helped increase member participation. We are very fortunate to have had Dr. Roe as one of our leaders, as well as to have retained his talents on our steering committee as our "Past Chair."

Charles, thank you many times over!

