

APRIL 2018 ISSUE

PDA[®]

Parenteral Drug Association



Missouri Valley Chapter

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Please take a moment to visit our [website](#) to learn more about the Missouri Valley Chapter of the

PDA! You will find information about the chapter, presentations from past events, chapter news, information on how to get involved, chapter sponsors and sponsorship opportunities.

Missouri Valley Chapter of PDA Newsletter

Welcome to the latest issue of the Missouri Valley Chapter of the PDA Newsletter. We provide this newsletter as a communication tool to accomplish our mission of connecting people, science and regulation within our Chapter. We are excited about the possibilities for the Missouri Valley Chapter for the remainder of 2018. Within this newsletter, you will find pertinent information regarding personnel, upcoming events, and opportunities related to our chapter.

Mark Your Calendars!

PDA Missouri Valley Chapter CAPA, Change Management, & Risk Management Event

April 09, 2018 | Hilton Kansas City Airport | Kansas City, MO

April 2018

SU	MO	TUE	WE	THU	FRI	SAT
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

PROGRAM

- 5:00 pm – Cocktail/Social
- 6:15 pm – Introduction of Sponsors & Vendors
- 6:30 pm – Dinner
- 7:00 pm – Speakers

PDA's Missouri Valley Chapter is pleased to announce our first event for 2018 on **Monday April 9th** at the Hilton Airport Hotel Kansas City, Missouri. Will you be there to hear Industry and Regulatory Experts discuss the top items firms are cited for In 483's? Will you hear our local FDA Districts opinions and be able to ask direct questions preparing your firm for its next audit?

Will you have the opportunity to network and develop peer relationships across firms in our area laying the groundwork for future benchmarking. YES...you will have all of these and more by attending our regional Chapter meeting next Monday!

[REGISTER HERE](#)

PDA- Missouri Valley Semi-Annual Fall 2017 Meeting

The Missouri Valley PDA Chapter's Fall Semi-Annual 2017 meeting was held in St. Louis on October 2, 2017. The guest speakers for this event included Carl A. Huffman, Supervisor in Pharmaceuticals at the FDA who discussed the FDA's perspective on aging facilities, and Chris Troutt, Reliability Engineer at Curium Pharmaceuticals who shared a presentation on Curium's predictive maintenance facilities program.

Event attendees were provided with the opportunity to go on a behind the scenes guided tour of Curium's radiopharmaceutical manufacturing plant outside of St. Louis, MO. Curium is recognized as a world class nuclear medicine solutions provider with over 100 years of industry experience serving more than 14 million patients per year. The two-hour facility tour started with a welcoming presentation that listed several key aspects of the plant as well as details into the patient population who benefit from Curium's high quality nuclear medicine products. After the introduction and overview, the chapter members were split into several tour groups that showcased three key areas of manufacturing operations including: Cyclotron Production, Reactor Production, and Cold Products (non-



Carl Huffman, FDA, 2017 Fall Meeting—St. Louis, MO

radioactive) Production.

The Cyclotron group uses several particle accelerators to produce four different forms of radioactive raw materials. Most of the components are ultimately used in a multitude of diagnostic imaging procedures that help detect cancer and other serious diseases and conditions.

The Reactor group is specifically centered on the production of the Molybdenum Mo-99/Technetium Tc-99 generators (the workhorse of nuclear medicine). Material from these generators are used in nearly 80% of nuclear medicine procedures annually.

Finally, the Cold Products Production group aseptically manufactures a variety of non-radioactive lyophilized products that, when mixed with radioactive isotopes, are used in various diagnostic imaging procedures, each aimed at evaluating a specific organ or area of concern in patients.

Throughout the tour, the group also observed several world class cultural initiatives that help make Curium the center for Nuclear Medicine Excellence. In the end the tour was an outstanding experience and demonstrates Curium's dedication to product safety and improving the lives of patients. As a Chapter, we hope to replicate this wonderful behind the scenes tour and learning experience at other manufacturing sites across the Midwest.



Chris Troutt, Curium, 2017 Fall Meeting—St. Louis, MO

MO Valley PDA Biome School Event

On October 10th 2017 the MO Valley Chapter had Dr. Fred Williams III, DVM, DACVP speak to the Biome Charter School in St. Louis as part of the MO Valley's community outreach to help stimulate students to consider Science fields as a career path. The Biome Charter School is an inner city St. Louis MO school making a difference. It offers customized, project based and student-centered learning opportunities with an emphasis on growth mindset and STEAM (Science, Technology, Engineering, Art and Mathematics) education.

Dr. Williams brought many items for interactive learning including a horse's hoof, which is actually only one toe that the horse is standing on. He spoke on what it was like being a Veterinarian and the importance of staying in school, studying, and getting good grades. The children loved his presentation (what 9 year old doesn't think a bat skeleton is cool?) and he had a question and answer ses-

sion with the students that was very interactive and fun for the children. You could tell the children were inspired by the questions they asked.

The MO Valley donated over \$1,300 towards certain supplies that were needed by the school to further enhance the already

outstanding education the school offers. The MO Valley coupled the charity event with their annual meeting they hold in St. Louis. Dr. Williams is a professor at the University of Missouri, Columbia and teaches Pathology.



Dr. Fred Williams III, DVM, DACVP speaking to the Biome Charter School in St. Louis on October 10th 2017

MO Valley Chapter of the PDA New Board Members

Erin Patton

[Senior Product Specialist at Charles River]

Erin Patton has been a member of the Missouri Valley Chapter of the PDA for five years, and in that time has benefitted from participating in PDA meetings and events at the national level as well as with other regional chapters.

Erin is a Senior Product Specialist for Charles River's Microbial Solutions division and is responsible for providing tech-

nical support and expertise to Charles River colleagues and clients alike, primarily in the areas of rapid micro solutions for microbial detection and identification, environmental monitoring, endotoxin testing, and the compounding pharmacy market. She has over 16 years' experience in molecular biology research, microbiology QC, Quality Assurance, and regulatory compliance.

Erin has an M.S. degree in Cell and Molecular Biology from

University of Illinois, Urbana-Champaign and a B.S. degree in Biology from Xavier University.

Erin resides in St. Louis, Missouri and enjoys spending time with her daughters, volunteering with their school and leading a Girl Scout troop.

Whitney Sandberg is a Senior Director Quality Operations at Patheon Biologics, part of Thermo Fisher Scientific, in St. Louis, MO. In this role she has responsibility for oversight and management for all of Quality including QA, QC, Validation, and Regulatory.

Prior to this role, Whitney was the Senior Director of Quality and Operations at Mallinckrodt Pharmaceuticals where she was responsible for implementing the integration strategy for mergers and acquisitions. She also served as the Site Director of Quality at the Mallinckrodt Maryland Heights Nuclear Medicine facility, the Covidien

Greenville, IL API facility, and was the Quality leader for the External Manufacturing organization for Covidien.

Whitney has over 20 years of pharmaceutical industry experience, the majority of which has been focused in Quality. She began her career in Quality Control as an analytical chemist and later transitioned into Quality Assurance. During her time in the industry, Whitney has worked at various pharmaceutical companies including, Centeon, Wyeth-BioPharma and Bristol Myers-Squibb, where she's served in roles of increasing responsibility and led key initiatives including

Whitney Sandberg

[Senior Director Quality Operations at Patheon Biologics, part of Thermo Fisher Scientific]

quality systems development, compliance enhancement, and Lean implementation.

Whitney earned her Certified Quality Auditor (CQA) and Certified Quality Engineer (CQE) designations from ASQ and is Lean Leader certified. She is an active member of PDA and has a bachelor's degree in Chemistry from Southern Illinois University in Carbondale, Illinois.

MO Valley Chapter of the PDA New Board Members

cont...

Ioana Gruchevska

[Clinical Research Associate at Boston Scientific]

After attending regional PDA meetings and events for three years, Ioana joined the Missouri Valley Chapter of the PDA board in December, 2017.

Ioana is a Clinical Research Associate at Boston Scientific's Cardiac Rhythm Management division and is responsible for monitoring clinical trials data

for medical devices. She has prior experience coordinating clinical research studies at Washington University of St. Louis where she also oversaw the department's cleanroom activities. She also served the university's Institutional Review Board (IRB) for nearly four years.

Ioana holds a M.S. in Clinical Trials Management from Washington University of St. Louis

and a BFA in Studio Arts with a Minor in Art History from University of MO – St. Louis. She is also SOCRA-certified clinical research professional and has retained her pharmacy technician PTCB certification active. Ioana resides in St. Louis and enjoys traveling, art & architecture, and appreciates home improvement projects other than yardwork.

Missouri Valley Chapter of the PDA

Meet All the Chapter Officers

Gary Klaassen [President]

Jim Polarine
[President Elect]

Valerie Welter
[Treasurer]

Bryan Lowery
[Secretary]

Keith Koehler

Ben Frey

Denise Maddox

Erin Patton

Jeff Kisslinger

Jeff Wiegers

Ioana Gruchevska

Whitney Sandberg

Meet our Annual Sponsors:



Azbil North America, Inc.
Jamie Diamond
 Director, Global Business Development

BioVigilant Division
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 Tucson, Arizona 85705
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Trying to get noticed? We offer vendors, consultants, operating companies and other organizations the opportunity to promote themselves and also support the Missouri Valley Chapter of the PDA. We offer advertising opportunities within the newsletter as well as sponsorship opportunities for chapter events.

Our direct e-mail distribution reaches over 1,176 contacts throughout Missouri, Kansas, Nebraska, and Iowa. Our membership includes people from manufacturing, research, QA, QC, engineering, contract manufacturers/laboratories, consultants, and regulatory.

Our semi annual Missouri Valley Chapter meetings are a great forum for promotion and sponsorship opportunities. We offer business card sized add space in our semi annual newsletters for as little as \$200 per year.

Please contact Gary Klaassen for information:
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