

September 2018 Issue

PDA®

Parenteral Drug Association



Missouri
Valley

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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.

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.

Connecting People, Science and Regulation

MO VALLEY CHAPTER COMPOUNDING (503B) DINNER EVENT

September 20 | Cheshire Inn | St. Louis, MO

September 2018

SUN	MON	TUE	WED	THU	FRI	SAT
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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

- 2:30 pm—Transportation to Dynalabs tour
- 5:00 pm—Cocktail/Social
- 6:00 pm—Introduction of Sponsors and Vendors
- 6:15 pm—Dinner
- 6:45 pm—Speakers

[REGISTER HERE](#)



Connecting People, Science and Regulation®

PDA MO Valley Semi-Annual Spring 2018 Meeting

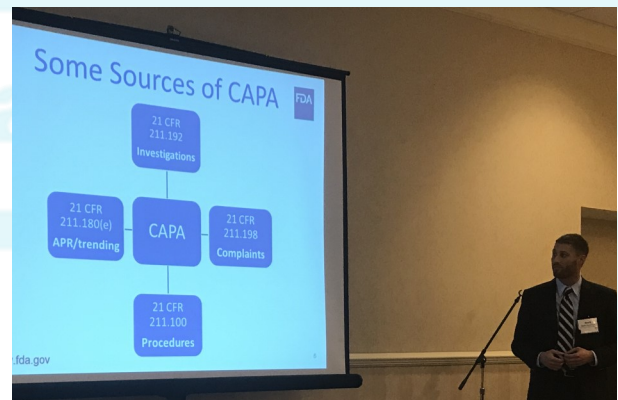


David Bergeson, Parexel Senior Compliance Consultant

The Missouri Valley PDA Chapter's Spring Semi-Annual 2018 meeting was held in Kansas City on 09 April 2018. The guest speakers for this event included Brett Havranek, FDA Consumer Safety Officer & Michele Obert, FDA Drug Specialist / Pre-Approval Manager with the Division of Pharmaceutical Quality Operations who discussed Effective CAPA, Change Management, and Risk Management to Mitigate Regulatory Enforcement Risks, and David Bergeson, Parexel Senior Compliance Consultant who provided a thorough review of industry guidance of Quality Systems Approach to Pharmaceutical cGMP Regulations.

Attendees were provided with the opportunity to meet the presenters and ask questions pertaining to the topics discussed. David Bergeson kicked off the highly anticipated event with a

thorough review of ICH Q8 (R2) Pharmaceutical Development Annex; ICH Q9 Quality Risk Management; and ICH Q10 Pharmaceutical Quality System guidance documents followed by practical examples of their implementation and execution.



Brett Havranek, FDA Consumer Safety Officer

Brett Havranek reviewed CAPA definitions and frequent misinterpretations of the term, its concepts, and the parts of the CFR that pertain to FDA investigations and procedures. A thorough discussion was held regarding CAPA compliance,



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PDA MO Valley Semi-Annual Spring 2018 Meeting cont.

and its stages of implementation. Specific case studies were presented and their resulting CAPA resolutions or lack thereof. The importance of robust company SOPs development was emphasized by all three presenters throughout the evening. Michele Obert closed off the discussions by providing insight to her extensive experience in leading inspections throughout the United States and addressing questions from attendees.



Michele Obert, FDA Drug Specialist / Pre-Approval Manager

In addition to the presentations, the 15th Annual Capitol Graduate Research Summit winners Erika Nolte, PhD Candidate representing University of Kansas, Pharmacology and Toxicology Department, and Ren Bean, MS Candidate at Pittsburg State University, Chemistry Department were in attendance. Both are the recipients of \$1000 scholarships. Erika Nolte's poster titled

"Turning Back Time: Reversing Alzheimer's Disease Progression", and Ren Bean's poster "Personalized Drug - Cocktail Nanomedicine for the Treatment of Prostate Cancer" were on display throughout the evening and the two scholarship winners gladly discussed their research projects with the event attendees.

		2018 PDA/FDA Joint Regulatory Conference	Sept. 24-26, 2018 Washington, DC #2018PDAFDA	
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Missouri Valley Chapter Provides Scholarships

Thanks to the outstanding support of the vendors and members who attend our meetings we are able to provide scholarships to encourage college and high school students to pursue science. This year we partnered with BioKansas and provided scholarships to the winners in the High School and College Graduate Competitions.

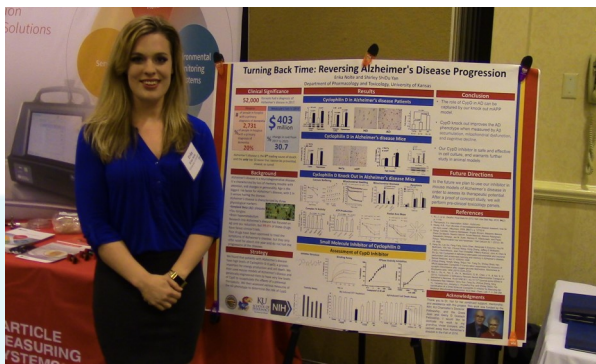
KANSAS BIOGENEUS FINALS

Winner received a \$500 Scholarship

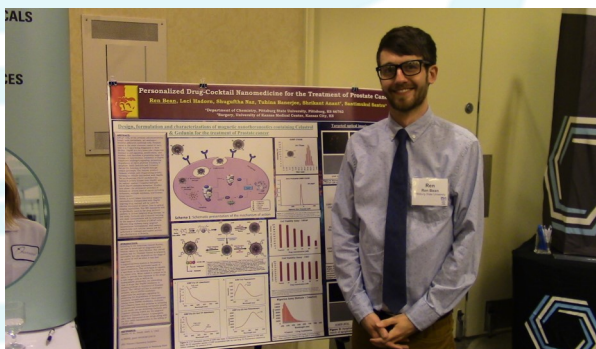
- Luann Jung (Manhattan High) – Genomic Indicators of Type II Diabetes
- Luann Jung is the winner of the 2018 Kansas BioGENEius Challenge, the premier competition for regional high school students conducting research in biotechnology. Luann will advance to Boston, MA, to compete against other peers in the International BioGENEius Challenge at the BIO International Convention on June 4 – 7, 2018.

CAPITOL GRADUATE RESEARCH SUMMIT WINNERS

Each winner received a \$1000 Scholarship



- Erika Nolte, PhD Candidate – University of Kansas, Pharmacology and Toxicology
Turning Back Time: Reversing Alzheimer's Disease Progression

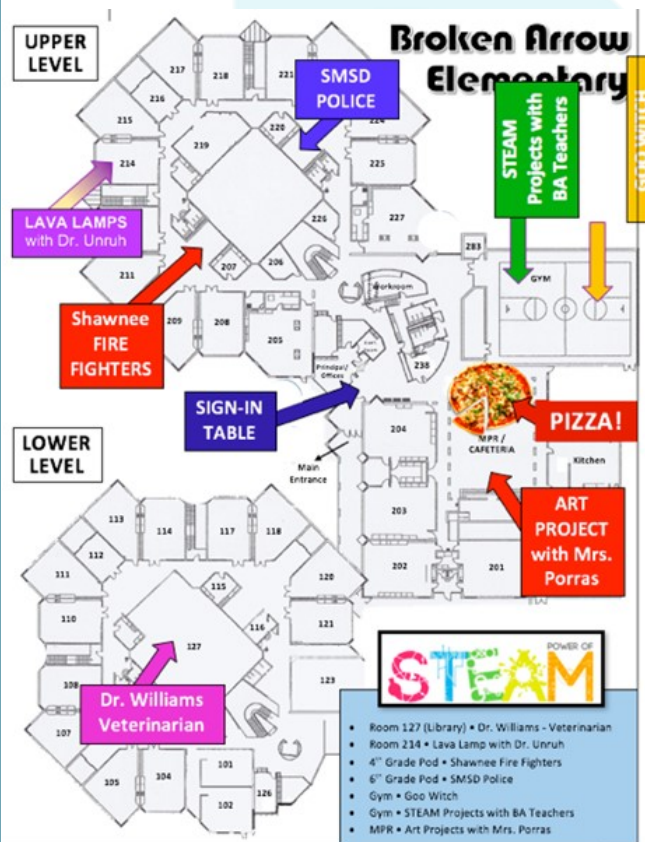


- Ren Bean, MS Candidate – Pittsburg State University, Chemistry
Personalized Drug-Cocktail Nanomedicine for the Treatment of Prostate Cancer

MO Valley Chapter STEAM Night at Broken Arrow Elementary School

On Tuesday March 6, 2018 the Mo Valley Chapter was honored to provide an all school assembly and participate in STEAM Night at Broken Arrow Elementary School in Shawnee as part of our community outreach program to help stimulate students to consider Science fields as a career path. The Chapter coordinated the participation of Dr. Fred Williams III, DVM, DACVP an honored veterinarian and professor at the University of Mo Columbia.

the students about the value of staying in school, finding your passion, and the importance of good grades. He awed the kids with a horse's hoof, a bat skeleton, and the highlight... a 10 inch hairball from a cow! L The kids were encouraged to pursue science and to come back that evening for the STEAM night event.



Students at Broken Arrow Elementary School

This STEAM event was a great opportunity for the Mo Valley chapter of the PDA to directly touch the lives of young students in our community and to provide tools for their continued development in Science and technology. This event is an example of the great work the Chapter can do with the continued support of our membership and sponsors. A big Thank you to all from the students of Broken Arrow Elementary

The day began with the presentation of 10 Bluetooth enabled Microscopes to the schools STEAM Program and an all school assembly where Dr Williams talked to



Dr. Fred Williams III, DVM, DACVP, University of MO Columbia

MO Valley Chapter of the PDA New Members

Erin Shannon Whaley

[Account Manager at Charles River Microbial Solutions]

Erin Shannon Whaley has a Master's in Food Science with a focus on food safety and microbiology. Following graduate research on natural antimicrobials for inhibition of *Listeria monocytogenes*, Erin worked as a Sr. Application Technologist for DuPont Nutrition and Health. In this role, Erin supported food companies in transitioning from chemical antimicrobials to clean label options, primarily in the meat, pet food, bakery, and

beverage industry. Using her background in microbiology and processing, Erin served as an account manager for Viva 5 corporation, focusing on probiotics and custom formulations for the supplement industry. In 2017, Erin joined Charles River Microbial Solutions as an Account Manager 2 for the South-Central US. This role has provided an opportunity to explore microbiology and processing applications in the pharmaceutical industry, while continuing to balance customer needs with regulatory requirements. With

a passion for learning and teaching, Erin has served as a guest lecturer at the University of Arkansas, University of Wisconsin (Madison), Penn State University, Mississippi State University, and local STEM programs, and serves on the board of the Arkansas Association for Food Protection (IAFP Chapter). Erin has found PDA to be an invaluable tool for education and networking in the pharmaceutical industry and looks forward to continued career development.

Don LaChance

[Capital Account Sales Account Manager at STERIS Corporation]

Don LaChance from STERIS Corporation has recently joined the PDA Missouri Valley Chapter. Don has been with STERIS Corporation for 40 years. Don served 10 years in sales support prior to the STERIS Corporation purchase of Calgon Vestal. Don

served 15 years as a Consumable Account Manager in the Midwest for STERIS Corporation. Currently, Don has been a Capital Account Sales Account Manager at STERIS Corporation for 15 years. Don has been very active in the Pharmaceutical,

Biotech, and Medical Device industries for his entire career at Steris Corporation.



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Meet the Chapter officers and members...

Missouri Valley Chapter of the PDA

Gary Klaassen [President]

Jim Polarine
[President Elect]

Valerie Welter
[Treasurer]

Bryan Lowery
[Secretary]

Keith Koehler

Ben Frey

Denise Mad-
dox

Jeff
Kisslinger

Jeff
Wiegers

Erin
Patton

Ioana
Gruchevska

Whitney
Sandberg



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Meet our Annual Sponsors:



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 news-