



PDA Missouri Valley Chapter Spring 2012 Event

The Missouri Valley Chapter of PDA held its Spring Event on March 26, 2012. The dinner meeting was held at the Kansas City Airport Hilton Inn on the topic “Current Industry and Enforcement Trends.”

Following a networking/social time and dinner, the Chapter was addressed by two excellent speakers:

- Mr. Miguel Hernandez – Director, Compliance Branch at KAN-DO FDA spoke on “Compliance and Enforcement Issues and What is New in the KAN-DO.” Mr. Hernandez recently joined the FDA’s Kansas City Office to lead the compliance organization from the Honolulu Office where he was Supervisory Investigator. He provided an overview of FDA’s current approach to compliance enforcement and provided some background on how the Compliance Branch of the District Office collaborates with the Investigations team to ensure compliance. Mr. Hernandez mentioned that the FDA is applying risk management in assessing GMP compliance of firms. By that he stated that a key element of their assessment involves the potential risk to the patient. When patient risk is high, FDA action will be more direct and swift. When risk is low, FDA will generally exercise more flexibility unless repeat issues are noted. Mr. Hernandez emphasized that his philosophy (and FDA’s in general) is to work closely with industry – the earlier, the better when issues or concerns are noted. The Missouri Valley Chapter welcomed Mr. Hernandez to his new post in Kansas City.
- Mr. Jim Polarine – Technical Services Manager, Steris Corporation spoke on “Current Industry Trends, including Cleaning and Disinfection, Disinfection Validation, and Current Warning Letter Activity.” Mr. Polarine provided an excellent overview of current issues and topics in cleaning, disinfection, and disinfection cleaning in industry today. He provided a number of excellent examples of typical cleaning/disinfection issues experienced and approaches to resolve these issues. He also shared recent FDA Warning Letters on this topic, some of the background behind the citation, and means to be proactive in preventing similar issues in our operations. Mr. Polarine also provided a number of excellent reference materials that are shared with our chapter members through a posting of his presentation. Several members noted that his comments directly address current issues with which they struggle in their operations.

Each sponsor was introduced and provided an opportunity to share brief information on their products and/or services. These sponsors included:

- cGMP Validation, LLC (represented by Laura Gillikan)
- Stantec (represented by Kishore Warriar)
- Regulatory Compliance Associates (Mike Silvola)
- Commissioning Agents, Inc. (David Shenberger)
- Particle Measuring Systems (Mark Hollworth and Beth Lyons)
- ACH Foam (Keith Baechle)
- ProPharma Group (Ben Frey)

We thank our sponsors for their continued support of our chapter.

Finally, the new chapter officers were introduced:

- Eldon Henson, President
- Jeff Hargroves, Vice-President
- Gary Klaassen, Secretary
- Keith Kohler, Treasurer
- Valerie Welter, Board Member
- Luann Wolfgram, Board Member

Approximately 65 members, sponsors, and guests attended. Our next chapter event is tentatively scheduled for mid-September in the St. Louis, Missouri area.