



PDA Missouri Valley Chapter Fall 2012 Event

The Missouri Valley Chapter of PDA held its Fall Event on September 17, 2012. The dinner meeting was held at the Embassy Suites Conference Center in St. Charles, MO. The topic of the evening was “The Cost of Non-Compliance.”

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

- Mr. Jason Sapsin, JD, MPH – Jason is currently a member of Polsinelli Shughart's Life Sciences group, leading its FDA law practice based in Denver, Colorado. He previously served as Associate Chief Counsel in the FDA's Office of Chief Counsel in Washington, D.C. He provided an excellent history and overview of the FDA. Jason also shared recent metrics regarding FDA's inspectional activities and provided an insider's viewpoint of enforcement philosophy and approaches. In short, FDA's emphasis on enforcement has resulting in increasing numbers of Warning Letters and more significant regulatory actions. According to Jason, most of these actions relate to “fundamental failures to follow long-standing cGMP requirements.” He concluded his remarks with the recommendation that firms re-emphasize good product safety/supply chain management, verify and update quality control procedures, ensure adequate quality resources, adequately investigate and address discrepancies, and implement marketing controls to prevent unlawful product promotion.
- Eric Good, PhD – Eric is currently Vice-President, Quality at KV Pharmaceutical. He provided an industry perspective on the cost of non-compliance. Eric shared his experiences with three different firms under consent decrees and the associated corporate and human costs. He provided a summary of the requirements included in consent decrees at Centeon (Aventis-Behring), Wyeth, and KV Pharmaceutical. In all three cases, the actual financial costs were significant and in one case (KV Pharmaceutical) resulted in the near shutdown of the company. The consent decree actions are long-term and can actually result in a quality-to-production headcount ratio of 1:1. Eric also shared the significant human impact of a consent decree – exceedingly long hours, loss of pay/bonuses, loss of job satisfaction, and high turnover. Eric's recommendation is that the time to invest in quality and quality resources is BEFORE issues are identified by the FDA. Prevention is the key and, in this day of enforcement, will pay off both in manufacturing performance and regulatory compliance.

Both speakers also mentioned FDA's use of the Park Doctrine to specifically target members of management and their responsibility to identify and prevent compliance issues. In short, the take-home message to all participants was that prevention is the key – once compliance issues are elevated within FDA, it is often too late.

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 Jeremy Theys)
- TSI (represented by Troy Tillman)
- Envirotainer (represented by Diane Knight)
- Biovigilant (represented by Peter Noverini)
- Laboratory Validation Specialists (represented by Carolyn Brown)
- Rapid Micro Biosystems (represented by Susan Schilling)
- ProPharma Group (Ben Frey)

Commissioning Agents, Inc. (David Shenberger) was a table sponsor. We thank our sponsors for their continued support of our chapter.

Approximately 40 members, sponsors, and guests attended. Our next chapter event is tentatively scheduled for spring in the Kansas City, Missouri/Kansas area.