Missouri Valley Chapter Holds First Event, Plans Second

Thomas Pamukcoglu, SAFC Biosciences

On Monday, April 25, the PDA Missouri Valley Chapter hosted its inaugural chapter meeting at the Kansas City Airport Hilton hotel. Following a networking/vendor reception and buffet dinner, the meeting included talks from three distinguished speakers representing industry and the U.S. FDA. The event attracted over 70 industry professionals, including many potential new PDA members and was supported by the following sponsors:

- cGMP Validation
- Regulatory Compliance Associates
- ACH Foam Technologies
- ProPharma Group

Richard Johnson, President, PDA, attended to help kick-off the inaugural event. Richard welcomed the new chapter into the PDA fold and gave an informative presentation on the business climate of the pharmaceutical industry and manufacturing environments as well as some insight into current industry regulatory trends.

Richard then introduced **John Thorsky** District Director, U.S. FDA, from the

Kansas District Office, who provided remarks echoing many of the issues identified in Richard's presentation along with insight to the FDA's current thinking on issues and the challenges that it is facing as an agency. With the emphasis on developing core competencies, John described the requirements and challenges associated with retention of the Pharmaceutical Inspectorate. He graciously answered questions from the audience on all topics related to compliance and other topics of interest.

It is not often that one gets to ask a Director questions directly!

Following John's remarks, we were fortunate to have **Nadine Nanko**, Supervisory Investigator, U.S. FDA, who also is from the Kansas District Office. Nadine's presentation interjected some levity and also helped us to better understand the anatomy and inner workings of the District Office and the broad range of products FDA regulates.

The session opened our eyes to the types of challenges FDA is facing. Namely, more firms to inspect, rapidly changing technologies and diminishing funds. But, with consumer safety being paramount, we can expect FDA's current emphasis on compliance enforcement to continue.

With the successful completion of the first Missouri Valley Chapter event, the chapter is now planning a similar event to be held in the St Louis area. The planned date is targeted for mid-September, and the chapter is reviewing input received from the inaugural event to discuss agenda topics, identify speakers and to secure a suitable venue.

We are anxious to hear from our chapter membership about how we can make our next event even more successful!

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