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PDA Midwest Chapter Holds Event Focusing on QbD & CMOs

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On October 17, the PDA Midwest Chapter held a training event at the Eli Lilly and Company Manufacturing and Quality Learning Center in Indianapolis, Ind. More than 90 attendees from 36 companies and 5 different states gathered to hear talks on Quality by Design (QbD) in the morning and Contract Manufacturing Organizations (CMO) in the afternoon. The two sessions featured presentations and panel discussions from experts from the industry.

The morning session of the event began with the presentation "Product Commercialization and Quality by Design Implementation at Lilly," by **Joanne R. Barrick**, which highlighted some of the driving forces behind the QbD initiative and some of the steps Eli Lilly has taken in their commitment to QbD.

Next, **Steven Nail**, PhD, presented, "A Quality by Design Approach to Development and Scale-Up of Freeze Dry Cycles." Steven provided general comments about QbD and discussed ways in which Baxter has begun to apply QbD in their operations with freeze dryer and spectroscopy technology.

The final presentation in the morning session was by **Paula Hudson**. Paula discussed how Eli Lilly has implemented QbD in product and process development. Reviewing the product lifecycle from the patient profile to the process design review, she highlighted ways in which applying QbD effectively will provide knowledge and flexibility to efficiently manage and support products throughout their lifecycle.

Following the presentations, **Richard Van Doel** joined the speakers on the stage to take part in a panel discussion. The discussion included numerous questions about the participant's experiences with the application of QbD. Specific topics of discussion included: future trends for QbD, additional examples of the application of QbD, and application of QbD by CMOs.

After lunch and networking, the afternoon session on CMOs began with a presentation by **Lisa Schuster**, entitled, "Overview of Regulatory and Quality Requirements of Contract Manufacturers." She reviewed the requirements for these organizations, sources of these requirements, and common considerations for selecting a CMO.

Next, **John Steichen** presented "Contract Manufacturing Organizations: Auditing & Oversight." As a part of this discussion, he reviewed common deficiencies with quality systems, material systems, product systems, facilities and equipment, laboratory control systems, and packaging and labeling.

John Lockwood provided the final presentation of the afternoon session. His presentation, "Selection & Qualification of Contract Manufacturers," expanded on the earlier discussion of considerations for selecting CMOs, to include advantages of using a CMO, common complaints about working with CMOs, and finally, key selection criteria such as experience, reputation, price, customer service, and quality.

James Copp and **Steve Thomas** joined the speakers on the stage to participate in a panel discussion. Specific topics of discussion included: frequency of audits, audit certificates and auditor certification, managing the CMOs, dealing with compliance and quality issues, and an additional discussion of common audit deficiencies.

The PDA Midwest Chapter holds monthly dinner events in Northbrook, Ill., an annual golf outing in Chicago, Ill., and an annual event in Indianapolis, Ind. For more information about these events, or to get involved as a volunteer, please contact **Peter Noverini** at peter_noverini@baxter.com, or **Scott Hartman** at shartman@safis-solutions.com. 🍷