Featuring in-depth panels and presentations by top FDA and industry experts!

FDANEWS PRESENTS THE

PHARMACEUTICAL QUALITY CONGRESS

BUILDING A CULTURE OF QUALITY

JUNE 14-16, 2017

DOUBLETREE BETHESDA HOTEL • BETHESDA, MD

AGENDA

Pre-Conference Workshop, June 14

12:00 p.m. – 1:00 p.m. Registration

1:00 p.m. – 4:00 p.m. **Pre-Conference Workshop: Data Integrity Problems on the Rise**

Data integrity issues have become a common — and ever increasing — problem over the last few years and are often symptoms of system-wide failures.

Uncovering data integrity issues within your operations or partner networks can be challenging. And once data integrity issues come to light, remediating them can be even more difficult.

Drug companies need a system for assessing the way their staff or partners create, record, process and maintain data.

Quintiles consultant Leo Dodds has developed a new and effective approach to rooting out and solving data integrity issues. Now they're ready to share it with you. You'll learn…

- Recent case histories highlighting data integrity lapses
- Proven tools and techniques used to uncover data integrity issues
- How to characterize the scale and scope of issues using methodologies like the Maturity Curve Model
- How to design and deploy a remediation strategy
- Best practices for tailoring solutions to the problems identified — One size does not fit all
- How to implement 5 leading solutions for data integrity issues
    - Investigating and remediating data integrity issues through CAPA and other quality systems
    - Creating a culture of quality
    - Developing visible, engaged leadership that is committed to sound GMP and GDP practices
    - Recruitment and retention strategies that support sound GMP & GDP practices
    - Practical balanced performance management

Leo Dodds, Principal Consultant, Quintiles IMS

Day 1, June 15

8:00 a.m. – 8:45 a.m. Registration and Continental Breakfast

8:45 a.m. – 9:00 a.m. **Welcome and Introduction by Chairperson**

Susan Schniepp, Fellow, Regulatory Compliance Associates Inc.

9:00 a.m. – 9:45 a.m. **FDA Keynote Speaker: Update on OPQ and CDER's Quality Initiative**

The goal of CDER's Quality Initiative is clear: Modernize the regulation of the pharmaceutical quality of drugs. But, like all agency programs, it's the details that matter. In this keynote, you'll hear the latest CDER developments on product quality, good manufacturing practices, FDASIA enforcement, risk-based surveillance, and performance measures. Specifically, you'll be better able to determine whether your facility is up to snuff when it comes to manufacturing standards, such as sterility and cross-contamination. In addition, you'll hear what the Office of Pharmaceutical Quality will be doing in 2017 to streamline drug application review, post-approval improvement, surveillance, and inspections.

Alex Viehmann, Operations Research Analyst, Quality Intelligence Branch, OS, OPQ, CDER, FDA (Invited)

9:45 a.m. – 10:30 a.m. **Quality Metrics: What Do You Have To Report?**

The FDA is working on the final guidance for the collection of quality drug metrics. What's the status of that guidance? When will you have to begin reporting data and what data will you have to report? Come hear Sanofi Pasteur's Chief Quality Officer update you on where the effort stands.

Anders Vinther, PhD, Chief Quality Officer, Sanofi Pasteur

10:30 a.m. – 10:45 a.m. Refreshment Break

10:45 a.m. – 12:00 p.m. **Panel Discussion: 21st Century Cures Act — Impact on Quality**

The passage of the 21st Century Cures Act means drug manufacturers will be scrambling to meet new mandates. Do you know how to accelerate approval of your new uses for drugs and but still stay in compliance with current FDA regulation and guidance on quality? And do you know how to develop cutting-edge strategies to maximize opportunities for more rapid drug development under the Cures Act but still adhere to quality measures?

Anders Vinther, PhD, Chief Quality Officer, Sanofi Pasteur

Alex Viehmann, Operations Research Analyst, Quality Intelligence Branch, OS, OPQ, CDER, FDA (Invited)

Susan Schniepp, Fellow, Regulatory Compliance Associates Inc.

Anil Sawant, Global Quality Management Systems & External Affairs, Merck & Co.

12:00 p.m. – 1:00 p.m. Lunch Break

1:00 p.m. – 1:45 p.m. **Data Integrity: A Warning Sign for Investigations**

FDA officials have made it clear that data that are not valid and trustworthy is a sign that an entire operation or facility is out of control and cannot assure the quality of its medicines. Don't get caught in this thorny thicket. In this uber-important session, you'll learn how to make sure your data is up to snuff.

Anil Sawant, Global Quality Management Systems & External Affairs, Merck & Co.

1:45 p.m. – 2:30 p.m. **Top 5 Annual 483 Observations: The Cycle of Quality**

This session breaks down 483 letters issued by the FDA and finds the trends that affect your daily activities in drug quality and compliance. No spoiler alerts here. Don't miss this session that's practical to the max for anyone who understands the impact of a 483.

Susan Schniepp, Fellow, Regulatory Compliance Associates Inc.

2:30 p.m. – 2:45 p.m. Refreshment Break

2:45 p.m. – 4:00 p.m. **Panel Discussion: PDA Quality Culture Assessment Pilot Program**

The purpose of the pilot is to work with assessors from up to 20 different pharmaceutical companies to refine a quality tool.

During the pilot, the task force developing the tool will assess:

- Reproducibility—is the tool objective and verifiable?
- Differentiability—can the tool differentiate sites?
- User-friendliness
- Training effectiveness

After attending this panel, you'll find out more about the current status of the pilot and the survey that the FDA is conducting with stakeholder companies.

Denyse Baker, Senior Advisor of Scientific and Regulatory Affairs, PDA

4:00 p.m. – 4:45 p.m. **Ask the Experts: Real-World Advice on Running Quality Programs**

Three top quality professionals will talk about the day-to-day running of a quality program. What does it take to make a program run successfully? What can you do as quality managers to make your process better?

4:45 p.m. – 6:00 p.m. Adjournment and Networking Cocktail Reception

Day 2, June 16

8:00 a.m. – 8:45 a.m. Registration and Continental Breakfast

8:45 a.m. – 9:00 a.m. **Welcome and Introduction by Chairperson**

Susan Schniepp, Fellow, Regulatory Compliance Associates Inc.

9:00 a.m. – 9:45 a.m. **FDA Keynote Speaker: Creating a Quality Culture to Aid Risk Management**

The FDA expects a quality culture in which risk management and quality are integrated and proactive in their approach. After attending this panel, you'll learn about the quality/risk management culture the FDA wants to see in play this year.

Tara Gooen Bizjak, Senior Science Policy Advisor for Pharmaceutical Quality, CDER, FDA (Invited)

9:45 a.m. – 10:30 a.m. **Pharmaceutical Supply Chain Integrity in 2017**

The U.S. drug supply chain remains one of the safest in the world and also one of the most complex. Threats to the supply chain such as counterfeiting, diversion, cargo theft and importation of unapproved or otherwise substandard drugs haven't gone away. What can you do this year to improve your supply chain?

Wes Schmidt, Divisional Vice President, Operations Quality Assurance, AbbVie

Gerard Pearce, Rx360, Executive Vice President, SQA Services, Inc.

10:30 a.m. – 10:45 a.m. Refreshment Break

10:45 a.m. – 12:00 p.m. **Panel Discussion: Quality Regulation Harmonization — The US and EU Mutual Recognition of Drug Manufacturing Inspections**

After almost three years of negotiations, the U.S. and the European Union have agreed to recognize each other's drug GMP inspections. What does this mean for you? Can regulators opt out of accepting documents? Will the agreement allows the regulators to accept GMP documents for facilities outside of their geographical territories? What system is in place to notify authorities of quality defects, counterfeit or falsified products, or potential shortages across borders?

After attending this panel will have the answers and understand what this agreement will do in your world.

Rick Friedman, Deputy Director, Science & Regulatory Policy, OMPQ, CDER, FDA (Invited)

David Churchward, Expert GMP Inspector, Medicines and Healthcare Products Regulatory Agency (Invited)

David Elder, Executive Vice President, Regulatory Compliance, Greanleaf Health

12:00 p.m. Closing Remarks and Conference Adjournment