QUALITY ASSURANCE IN PHARMACEUTICAL MANUFACTURING

Maintaining Compliance with Evolving Quality Standards on a Global Level while Implementing & Enhancing Quality Systems that Ensure the Highest Level of Quality in Pharmaceutical Manufacturing

DISTINGUISHED PRESENTERS INCLUDE:

Penny E. Hylton, PhD, MBA  
Executive Director, Quality  
NOVAVAX

Jeffrey Hartry  
Director, Quality Systems & Information  
CANGENE CORPORATION

Sandra Roque  
Director, Manufacturing QA  
NOVEN PHARMACEUTICALS

Jason Koral  
Partner  
COOLEY LLP

Michael G. Beatrice, PhD  
Vice President Quality & Regulatory  
ABBOTT

Melissa Gilmore  
Senior Counsel  
McGUIREWOODS LLP

James A. Boiani  
Associate  
EPSTEIN BECKER GREEN

Colleen Juliano  
Vice President, Quality Assurance & Regulatory Affairs  
NEPHRON PHARMACEUTICALS

Kenneth Ray  
Director, Global Quality Systems & Continuous Improvement  
CELGENE CORPORATION

Jason Koral  
Partner  
COOLEY LLP

Michael G. Beatrice, PhD  
Vice President Quality & Regulatory  
ABBOTT

Melissa Gilmore  
Senior Counsel  
McGUIREWOODS LLP

James A. Boiani  
Associate  
EPSTEIN BECKER GREEN

Colleen Juliano  
Vice President, Quality Assurance & Regulatory Affairs  
NEPHRON PHARMACEUTICALS

Kenneth Ray  
Director, Global Quality Systems & Continuous Improvement  
CELGENE CORPORATION

Stephen Shields  
WWQA Director, Computer System Compliance & Quality Assurance

PROGRAM OVERVIEW

Within Pharmaceutical and Biotechnology manufacturing operations, maintaining a rigorous level of quality assurance is of the utmost importance. Outside of the strenuous and ever increasing FDA and international regulatory standards, there is also the need to maintain the highest possible level of product quality. As corporations work to adapt to increasingly complex products, along with ever evolving regulatory guidance, learning from other organizations that have successfully grappled with these issues is of the utmost importance. This program will provide the pharmaceutical and biotechnology industries an open forum for discussion and debate amongst leading organizations on how to maintain the highest level of quality within manufacturing facilities.

The first area that will be addressed during the conference program are the evolving quality regulations with the FDA. With a number of high-profile cases of non-compliance with serious consequences, the FDA is continuing to increase their surveillance and scrutiny of manufacturing facilities. As many areas of warning letters and consent decrees address lack of quality assurance and quality systems in place, it is critical that manufacturers focus on these areas of improvement. Sessions focusing on agency regulations will also highlight processes for preparing for internal audits through the implementation of strong standard operating procedures, as well as internal auditing plans to prepare for planned and unanticipated audits by the FDA.

The implementation and expanded use of quality systems is also an area of concern for many pharmaceutical manufacturers. While there are considerable challenges in the initial implementation of a quality system, or the upgrade of existing quality systems, the use of these systems is invaluable as organizations work to maintain rigorous levels of quality, as well as easy reporting for both internal and external examiners. Implementing and fostering an internal culture where quality systems are valued, and where standard operating procedures are clearly outlined for staff members will greatly enhance the level of quality within facilities.

Conference Sponsors:

Media Partners:
9:10 OPPORTUNITIES IN THE IMPLEMENTATION OF QUALITY SYSTEMS

Initiating, reviewing and updating quality systems regularly and making sure the proper SOPs are in place ensures that a quality system is on track with FDA requirements & standards. Implementing a culture of quality from top down through quality training and setting high expectations of manufacturing plant employees limits the deficiencies caused by human error. Designing clear, smart systems that can be easily communicated to employees will facilitate a quality system’s sustainability.

- Ensuring that your quality systems meet FDA’s standards
- Aligning SOPs with CAPAs to prevent deficiencies
- Designing ICH Q10s that are sustainable

Penny E. Hylton, PhD, MBA
Executive Director, Quality
NOVAVAX

10:00 ESTABLISHING RISK MANAGEMENT IN THE QUALITY SYSTEM

Installing and regularly reviewing quality risk management ensures that a company stays within appropriate risk levels to meet regulatory standards. Control measures should be established through validation, standardized procedures, employee training and assessment of existing quality risk management. It is imperative for a company to prove its credibility on a regular basis to regulatory bodies. It is imperative for organizations to regularly validate their quality systems and establish with regulatory bodies that risk management initiatives in place are appropriate and well defined.

- Integrating ICH Q9 and ICH Q10 at each level of manufacturing
- Establishing QRM team to monitor activity daily
- Communicating clearly and efficiently
- Managing risk to patient, physicians & the stakeholders

Jeffrey Hartry
Director, Quality Systems & Information
CANGENE CORPORATION

11:20 PANEL DISCUSSION: PERSPECTIVES ON PROPER IMPLEMENTATION OF QUALITY SYSTEMS

This panel will allow for an in-depth question and answer between speakers and attendees to further discuss the implementation of quality systems allowing for a better understanding of successful steps taken.

Jeffrey Hartry
Director, Quality Systems & Information
CANGENE CORPORATION

Penny E. Hylton, PhD, MBA
Executive Director, Quality
NOVAVAX

12:10 DOING MORE WITH LESS: ENSURING QUALITY ASSURANCE WHILE BEING EFFECTIVE

Quality Assurance executives within manufacturing organizations continually face the challenge of evolving compliance requirements, dynamic business needs (e.g. complexity of supply chains, multiple markets/regulatory jurisdictions, and increasing product complexity & quality requirements) and pressures of resource optimization. While Risk Management techniques can provide guidance on where to focus resources to have maximum impact, an integrated approach of Quality Processes & Systems, Risk Management, Organizational Design, and Colleague Development can meet these challenges in a global, scalable, and sustainable manner.

- Understanding how to save money while still remaining compliant
- Internationally sourcing components for a lower cost
- Validating cost-effective techniques

Kenneth Ray
Director, Global Quality Systems & Continuous Improvement
CELGENE CORPORATION

2:30 BREAKOUT SESSION: AN EXCHANGE OF IDEAS

Breakout sessions will be conducted in an unconference format. Conference participants will identify topics they wish to discuss further in smaller groups. From there, conference facilitators will take volunteer moderators from the audience to lead each discussion. Through the unconference format, all attendees, speakers and sponsors are encouraged to become active participants allowing for better exchange of ideas, peer-to-peer learning, and open discussion.

3:20 COFFEE & NETWORKING BREAK

3:40 CREATING LINES OF COMMUNICATION BETWEEN QUALITY & MANUFACTURING

Traditionally the departments of quality and manufacturing do not see eye to eye on how a product should be manufactured and this is often where companies run into trouble. The two need to work hand in hand for a business to be successful while guaranteeing the quality and compliance of a product. Open lines of communication will ensure that quality is involved in every decision manufacturing makes.

- Forming communication lines between quality & manufacturing
- Importance of quality and manufacturing working together
- Successful lines of communication between quality & manufacturing

Sandra Roque
Director, Manufacturing QA
NOVEN PHARMACEUTICALS

4:30 CORRECTING DISCREPANCIES FOUND BY INTERNAL AUDITS

Internal audits provide assurance that quality systems are in place, preventing discrepancies from occurring and allowing for any necessary changes in the standard operating procedures to be solidified before FDA visits. Instilling good manufacturing practices through frequent internal audits reassures corporations that employees are not becoming complacent with quality procedures. Running in-house inspections and fixing deviations helps in establishing an optimal compliance cycle with the FDA ensuring less frequent audits.

- Creating internal auditing capabilities, routines and SOPs
- Effective root cause analysis to successfully fix discrepancies
- Setting internal quality systems to maintain quality control

Michael G. Beatrice, PhD
VP Quality & Regulatory
ABBOTT

5:20 DAY ONE CONFERENCE CONCLUSION
DAY TWO / TUESDAY, OCTOBER 4 / QUALITY ASSURANCE IN PHARMA MANUFACTURING

8:00 REGISTRATION & CONTINENTAL BREAKFAST

9:00 OPENING REMARKS

9:10 PANEL DISCUSSION: MEETING REGULATORY EXPECTATIONS OF THE FDA
Escalating regulatory expectations require pharma companies to stay current on guidelines for proper GMPs and quality systems. Reviewing golden sheets and GMP trends of companies who have received negative marks from regulatory bodies will help strategize plans of preventative action. Manufacturing plants need to understand what is expected in the beginning stages of starting a manufacturing process and how to maintain quality assurance.

- Meeting regulatory body requirements & discussing recent changes
- How to prepare for regulatory audits through extensive internal audits
- Impact FDA regulations has on the QA of manufacturing facilities

Sandra Roque NOVEN PHARMACEUTICALS
Colleen Juliano NEPHRON PHARMACEUTICALS
Kenneth Ray CELGENE CORPORATION

10:00 OVERVIEW OF INTERNATIONAL REGULATIONS & GUIDELINES ON QUALITY
Understanding regulations and regulatory trends on a global level will ensure manufacturing facilities stay ahead of the curve when it comes to maintaining quality and regulatory compliance. Manufacturing plants answer to numerous regulators and environmental agencies along with routine audits from customer companies visiting the plant to ensure compliance and quality standards are being met. Creating a template listing expectations of each regulatory body confirms compliance on a daily basis.

- Staying current on standards and expectations of each regulator
- Standardizing environment within the plant to best meet all regulations

Colleen Juliano
VP, Quality Assurance & Regulatory Affairs
NEPHRON PHARMACEUTICALS

10:50 COFFEE AND NETWORKING BREAK

11:20 ASSURING ELECTRONIC DATA INTEGRITY IN THE MANUFACTURING PROCESS
FDA announced July 2010 that they will begin conducting inspections focused on 21 CFR Part 11 to ensure the compliance of computerized systems used in the manufacturing process. On June 30, 2011 the revision to Annex 11 became effective. Demonstrating data integrity has become paramount in a successful inspection.

- Expectations and requirements for data integrity
- Implementing controls to ensure data
- Electronic signature and records requirements
- Training and procedural requirements

Stephen Shields
WWQA Director of Computer System Compliance & Quality
ALLERGAN, INC

12:10 LUNCHEON FOR ALL ATTENDEES, SPEAKERS, & SPONSORS

1:30 QUALITY SYSTEMS RELATED TO COMBINATION PRODUCTS
The potential benefit of combination products is significant for companies looking to provide cutting edge healthcare solutions and maintain a competitive edge. Breaking into the combination product sector can provide numerous opportunities while at the same time posing several challenges. It is imperative to have proper quality systems in place from the beginning of development through product commercialization to market quickly and efficiently.

- Quality System (QSR) vs GMP preparedness
- Properly training employees for challenges with quality systems
- Regulations and guidance documents

James A. Boiani
Associate
EPSTEIN BECKER GREEN

2:20 DISCUSSION OF LAWSUITS BROUGHT AGAINST PHARMACEUTICAL COMPANIES NOT MEETING QUALITY STANDARDS
Even when proper GMPs are in place, a pharmaceutical company is still at risk for a lawsuit from the consumer. This discussion will give an overview of what went wrong in the manufacturing process and the steps taken by the companies to amend their pharmaceutical practices. Cutting corners in the manufacturing process to save time and money does not ensure quality and could result in additional money and time spent rectifying problems discovered once a product is on the shelf.

- Case study: share holder suits against pharmaceutical companies
- Steps taken by companies to amend manufacturing practices
- Risks seen through cost-reduction strategies
- Impact on pharmaceutical earning

Jason Koral
Partner
COOLEY LLP

3:10 DAY TWO CONFERENCE CONCLUSION

Q1 Productions designs and develops webinars, training courses, conference programs and forums aimed at specifically targeted audiences in order to provide strategic and timely information. Through a rigid production process focused on end-user research and design, our team is able to understand the immediate business concerns of today’s leading executives. Whether focusing on new or pending legislative issues, enhanced business processes or technologies that will drive efficiency and customer service, our programs provide solutions to the urgent needs of our attendees.