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PharmaED's

PROCESS VALIDATION

Managing Process Validation Activities to Efficiently Meet Compliance Expectations

JUNE 23-24, 2011, RADISSON-PLAZA WARWICK, PHILADELPHIA, PA

Featuring Case Studies and Lessons Learned from Industry Experts!

- Implementing a Science and Risk-Based Approach to Commissioning and Qualification in Line with the FDA's Recent Process Validation Guidance
- Risk-Based Validation and Re-qualification of Processes & Equipment
- Stability Considerations in Process Validation
- Developing and Executing Validation Master Plans and Validation Protocols
- A Roadmap for Implementing the New Process Validation Guidance
- Best Practices for Defining and Executing a Cleaning Validation Program
- Defining the Design Space for Cleaning Validation, Cleaning Process Qualification, and the Continued Verification of a Validated Cleaning Process
- Implementing A System for Continued Process Verification

In-Depth Conference Workshop:

Understanding FDA's New Process Validation Guidance: Assess Challenges Associated With the Interpretation and Implementation of the Guidance

Led by: Jeff Boatman, CQA, Quality Systems Subject Matter Expert, QPharma

Featuring Representation From:

Abbott Laboratories
QPharma
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Thursday, June 23, 2011

8:30 *Registration and Coffee*

8:45 *Chairperson's Welcome and Opening Remarks*

9:00 *Workshop Begins*

Understanding FDA's New Process Validation Guidance: Assess Challenges Associated With the Interpretation and Implementation of the Guidance

In 1987, the US Food and Drug Administration (FDA) released General Principles of Process Validation, the first-ever guidance standard on process validation in the life sciences field. That document spawned many other more specific standards published by governments and industries, each reflecting the latest state of the art, until the 1987 guidance was considered by many to be hopelessly outdated. Modern standards and even competing guidances put out by individual FDA divisions such as General Principles of Software Validation (CDRH) and Validation of Cleaning Practices (CDER) all incorporate modern techniques and risk-based methodologies that simply did not exist in 1987.

As part of its 21st Century Initiative, FDA has recently finalized its Process Validation: General Principles and Practices, which throws the 1987 guidance out the window and moves directly to the forefront of modern validation theory. While it is technically a guidance and therefore "optional," FDA has already stated that nothing in the new standard is not already expected under 21 CFR 211, and the agency fully anticipates issuing 483s and Warning Letters for noncompliance.

To anyone with experience in the medical device industry, this is likely old news; CDRH has been requiring these practices for more than 10 years. But the CDER guidance is rocking the pharmaceutical industry with new requirements, expectations, enforcement—and benefits.
This presentation will explain the new guidance, what is completely different from the old standard (nearly everything!), and discuss some of the principles underlying the new CDER thinking. It is essential for validation engineers, and quality and compliance staff. Quality engineers, manufacturing engineers, quality management, and facilities planners will also find it informative.

About your workshop leader:

This course is presented by Jeff Boatman, CQA. Mr. Boatman is a Quality Systems Subject Matter Expert at QPharma, a regulatory and validation compliance consulting firm in Morristown, N.J. With 23 years in the medical device and pharmaceutical industries, Mr. Boatman has worked in virtually every aspect of life science engineering, from laboratory supervisor, manufacturing engineer, R&D, and quality and compliance management. He is a frequent speaker at industry conferences and was selected by PharmaVoice Magazine as one of 2010's "100 most influential people" in the drug industry.

12:00 *Luncheon*

INDUSTRY CASE STUDY!

1:30 **Managing Process Validation Activities to Efficiently Meet Compliance Expectations**
Belinda Briscoe, Process Validation and Process Management, Genentech, Inc.

Genentech has created a system to efficiently manage process validation activities and mitigate compliance risks. This system ensures alignment to internal quality standards and industry guidance. Process work flows and service level agreements are used to define roles, responsibilities, and timelines. Study templates are produced to ensure consistency across projects and sites. A final audit of the report package is performed and the data is captured in databases that facilitate knowledge sharing and retrieval. Lastly, the system employs tracking and reporting metrics to facilitate improvements in the process validation program.

2:15 **Q&A**

2:30 **Implementing a Risk-based Approach to Process Validation**
Ashweni Sahni, President, Ash & Associates

To conduct an efficient and effective process validation, a risk-based approach is a must. Major activities/methods which are used are Process FMEA, regulatory compliance, a sound manufacturing quality plan and some important pre-validation activities. This presentation will cover all these activities/methods as they are applied to validate a process and reduce the risks before large scale production is started.
The attendees will benefit with learning:

- How to develop a compliant validated process

- How to effectively use Process FMEA before validating a process and
- How to develop a good Manufacturing Quality Plan

3:15 *Refreshment break*

3:30 **Risk-Based Validation and Re-qualification of Processes & Equipment**

Nancy Tomoney, Associate Manager Validation, QPharma

This session will review the regulations and industry standards a user must be familiar with to completely execute a risk based validation. The applicability of these documents to the validation process will be addressed:

- Guidance documents from Regulators what those documents say
- What are the applicable US Predicate laws and FDA guidance documents
- What other non US regulatory standards are accepted by FDA
- What Industry Standards are recognized by regulators follow behind?
- What other standards that can be put in place and used for the process with regulatory permission.

This session will address in detail the risk based process itself, how to successfully approach it and be able to:

- Establishing the difference between Qualification / Verification / Commissioning / Validation
- When Change Control should be implemented, and cur
- Evaluation of systems changes in assigning risk; what really is a like for like change.
- How to categories of GXP Systems/Processes for computerized system and non computerized equipment
- How to handle risk with defined processes such as, batch workflows, cleaning, sterilization &/or sanitization
- How really are the key players and need to be approvers
- What are the required deliverables in the process, how deliverables can be combined.
- How to deal with the re-qualification process: what triggers, assessments, and pre and post approvals can be used and when.

4:30 **Stability Considerations in Process Validation**

Walter A. Routh, III, Stability Manager, Abbott Laboratories

Stability studies are a vital part of many process validations and often require three lots to be evaluated through shelf-life, but the requirements are often overlooked at the early stages of planning until a critical gate is reached. This presentation will highlight considerations that need to be made well in advance to ensure stability factors do not delay the project. In addition to meeting deadlines, strategies will be presented for cost savings that can be realized when stability factors are carefully considered.

These will be supported with anecdotal experiences about how seemingly insignificant process changes have had drastic impact on a product's ability to meet expiration dating.

The attendees will benefit with learning:

- Regulatory stability requirements for process validations
- How and why to incorporate stability factors into the early planning stages of a validation project
- Cost saving strategies to incorporate into the stability program
- Various process changes that might be overlooked that could impact product stability

5:15 *End of Day one*

Friday, June 24, 2011

8:15 *Chairperson's Welcome and Opening Remarks*

8:30 **Implementing a Science and Risk-Based Approach to Commissioning and Qualification in Line with the FDA's Recent Process Validation Guidance**

Aaron D. Weinstein, Integrated Project Services - IPS

The FDA's new Guidance for Industry "Process Validation: General Principles and Practices", includes an outline of the expectations around facility and equipment qualification. Throughout the new Guidance there is an emphasis on using a science and risk-based

approach for all aspects of Process Validation, and facility and equipment qualification are no exception. For the past decade, the Pharmaceutical industry has been implementing approaches to validation that focus on impact to the process and apply verification and testing to those areas of the greatest impact. With the rise in the application of risk-based and science-based approaches and the industry-wide focus on Quality by Design, it is imperative that a good understanding of the Commissioning & Qualification (C&Q) effort be realized from the outset and the activities planned accordingly. Science and Risk-Based approaches require early involvement of the Commissioning & Qualification representatives and a continued presence throughout the product lifecycle. When project teams are quantifying Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs), the Commissioning & Qualification representatives can add their experience and knowledge to the overall effort and begin preparation for facility and equipment qualification during all phases of the product lifecycle.

This level of integration and planning is one of the overall themes of the Guidance and is the cornerstone for a focused Commissioning and Qualification effort. The actual execution of the Commissioning and Qualification effort is then an extension of the overall project and is a value-added activity, versus a major hurdle, on the road to manufacturing.

Drawing on project experience, the speaker will begin with an overview of the Commissioning and Qualification effort, including a brief history. The presentation will then focus on integration of CQAs and CPPs into early stage planning, formal Risk-Assessment techniques to identify and mitigate risks. The speaker will then present the C&Q activities that take place during design (including forma Design Review) and construction. Finally, the presentation will address execution of the facility and equipment qualification effort and ongoing qualification activities. The speaker will examine issues relative to implementation of the Science and Risk-Based approach and methods for navigating through the issues to a successful and overall value-added Commissioning & Qualification effort.

CASE STUDY

9:15 **Developing and Executing Validation Master Plans and Validation Protocols**

Purna Thakker, Audit Manager, Pfizer Inc.

Implementation of Validation Master Plans, Validation Protocols, and execute them in compliance with regulatory requirements. Identify appropriate information from the regulatory guidance documents and industry Guidance Documents that best fits your organization. Examine different validation master plan structures and validation protocol templates.

Identify the required components of Validation Master Plans and Validation Protocols to avoid regulatory pitfalls.

- Understand the regulatory requirements for Validation Master Plan and protocols
- Examine different structures of Validation Plans and Protocol Templates
- Use of vendor supplied protocols

10:00 **A Roadmap for Implementing the New Process Validation Guidance**

Wai Wong, General Manager & Vice President and Bikash Chatterjee, President & Chief Technology Officer, Pharmatech Associates

The presentation will review the key elements of the process validation guidance and describe an approach for practically implementing the new guidance along with a discussion of the tools necessary to be successful. The presentation will include an application of the roadmap along with a discussion of the roles and responsibilities for product and process development functions, engineering, technical services, and QA/QC as pertains to demonstrating process validation.

10:45 ***Mid-Morning Break***

11:00 **A Contract Packager's Continuous Monitoring Journey**

Diane Konopa, VP Quality Assurance at Anderson Packaging

This session will contain an overview of our journey from a highly manual method of Deviation/Exception reporting to an automated Deviation/Exception software system, attribute data driven Pareto charts, trending

methodology, CAPA tracking/completion, and effectiveness checks. It will also cover the importance of Value streams, escalation to Validation Department, and Management Review Meetings to identify improvement opportunities, assign actions, and ownership. In addition, the session will cover future improvements to reporting and utilization of the Deviation/Exception software.

12:00 *Luncheon*

1:30 **Defining the Design Space for Cleaning Validation, Cleaning Process Qualification, and the Continued Verification of a Validated Cleaning Process**

Mike Gietl, Technical Service Specialist, STERIS Life Sciences Group

The release of the FDA Guidance Document, "Process Validation: General Principles and Practices" in early 2011 marks another point in the evolvement of validation in the pharmaceutical and biopharmaceutical industries. This presentation will examine this guidance document and associated documents (ICH Q8,Q9, Q10) and assess their respective impact on the approach to cleaning validation. The presentation will look at defining the design space for cleaning validation, cleaning process qualification, and the continued verification of a validated cleaning process.

I. What is Cleaning Validation? Why clean?
II. Traditional vs. Current Approaches to Cleaning Validation
III. Implementing Principles of FDA Guidance into Cleaning Validation
    a. Design Space for Cleaning Validation
i. Differences between DS for Cleaning and Process Validation
ii. Defining the Design Space for Cleaning Validation
    b. Cleaning Process Qualification
    c. Continued Process Verification
i. Use of At-line or On-line Analytical Methods
ii. Use of Statistical Process Control (SPC)
iii. Setting alert/action levels
iv. Revalidation/requalification

2:45 **Q&A**

2:45 *Afternoon Break*

3:00 **Best Practices for Defining and Executing a Cleaning Validation Program**

Matt Wiencek PE, CAP Project Manager, Commissioning Agents, Inc

The regulatory guidance and best practices for biotechnology cleaning validation activities continues to evolve. PDA technical report No. 49, Points to Consider for Biotechnology Cleaning Validation, summarizes recommended best practices for defining and executing a cleaning validation program. The focus of the presentation will be to first cover in a general way what is contained within the new "Points to Consider" and focus on aspects related to validation master plans and protocols. Finally, some case study examples will be presented from recent projects related to biotechnology cleaning validation applications.

3:45 **Implementing A System for Continued Process Verification**

Ronald D. Snee, PhD, Snee Associates, LLC

"Continued Process Verification" is the focus of Stage 3 of the FDA Process Validation Guidance. A system that addresses this need is presented. The system utilizes systems thinking and statistical engineering principles to integrate the tools needed to implement and operate such a system. Central to the approach are state-of-the-art Process Control, Quality by Design and Design of Experiments concepts, methods and tools that are used to create the needed process understanding. The system integrates process control with process improvement and process design. These elements are described and the decision mechanisms for deciding how to move from one element to another are discussed. Pharma and biotech case studies are used throughout the presentation to illustrate how the various parts of the approach work together.

- How to design and implement continued process verification systems
- How to integrate process control, process and process design
- Awareness of QbD and its role in creating robust manufacturing processes
- How to sequence and link the QbD building blocks to create process understanding
- Guiding principles, tips and traps for the effective process verification systems

4:30 *Close of Conference*

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