

Process Validation Summit 2017

Racquet Club of Philadelphia, PA

May 18–19, 2017

Featured Speakers Include:



Dushyant Varshney
Pfizer



Alan Golden
Abbott



Tara Scherder
SynoloStats



Kashappa Desai
GSK



Anita R. Michael
FDA



Dave Kahlenberg
Takeda

With Comprehensive Coverage On:

- FDA Process Validation and Risk Management Approaches
- Lifecycle Approach to Process Validation
- Global Technology Transfer and Process Validation
- Achieving the Business and Compliance Benefits of Quality by Design (QbD) and Continued Process Verification (CPV)
- Biologics & Vaccines Process Validation and Technology Transfer
- Validation Sampling Plans and Statistical Process Control
- Cost-effective Process Validation Lifecycle Management
- Implementing a Comprehensive Strategy for Process Validation: Stage 3, Continued Process Verification
- Process Control Strategy and Process Performance Qualification of a Drug/Device Combination Product
- The Drug Supply Chain Security Act—How Does it Relate to Validation?
- And Much More!

Are you compliant with FDA requirements for process validation? Today's regulators are applying more fine-grained specifications and demanding more sophisticated procedures for planning, executing, and documenting your processes throughout a drug product's lifecycle. This two-day intensive summit brings together industry leaders to help you exceed regulatory thresholds and avoid costly FDA inspection findings.

With Representation From:



Thursday, May 18, 2017

8:15 *Complimentary Breakfast & Chairperson's Welcome and Opening Remarks*

Regulatory Considerations

8:30 **FDA Process Validation and Risk Management Approaches**

**Anita R. Michael, FDA ORA
Pharmaceutical Specialist, FDA**

The presentation on "FDA Process Validation, Data Integrity and Risk Management" will address Validation General Principles, Data Integrity and Risk. We will review cGMP regulatory requirements for validation, data integrity and risk management. We will discuss the importance of maintaining a State of Control for your process and facility. We will discuss the Quality System requirements and why data integrity is so important. The presentation will address key Life Cycle approaches. In addition, we will review FDA cGMPs 21CFR parts 210, 211 including pertinent FDA 483 Inspectional Observations and deficiencies.

9:30 **The Drug Supply Chain Security Act—
How does it relate to Validation?**

**Regina Fullin, Senior Compliance Consultant,
Compliance Team, Inc.**

This presentation will review the state of implementation of the Drug Supply Chain Security Act (DSCSA), and how it will impact Process Validation professionals. The seminar will discuss a history of the DSCSA, and what the FDA expects to see in a company when they begin auditing to the DSCSA. This seminar will teach the participant how to prepare for a supply chain audit. Most importantly, this seminar will teach you how you can leverage the DSCSA to build a stronger business and a stronger organization.

Attendees will learn:

- A history of how the Drug Supply Chain Security Act came to be.
- How this history affects the letter of the law, and its intent.
- The current state of the DSCSA implementation.
- The validation actions impacted by the DSCSA
- How to prepare for a DSCSA-centric audit.

10:30 *Networking Break*

10:50 **Process Validation: General Principles and Practices**

**Jeff Boatman, Sr. Subject Matter Expert,
Medical Devices and Quality Systems,
QPharma, Inc.**

In 1987, FDA released General Principles of Process Validation (PV), the first-ever guidance standard on pro-

cess validation in the life sciences field. That document spawned many other more specific standards published by governments and industries. 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.

In 2011, FDA finalized its Process Validation: General Principles and Practices, which obviated the 1987 guidance and moved directly to the forefront of modern validation theory. Meanwhile, the FDA's Medical Device division needed a more modern standard to support the PV requirement built into the Quality System regulations, and had adopted the European SG3 Process Validation standard.

This course, which is appropriate for both pharmaceutical and device industry participants—since the standards apply to both industries—will give you the information you must have to comply with domestic and international Process Validation requirements. By attending this interactive session, you will:

- Understand what the various guidances call for, and get help "filtering through the noise" so you can focus on critical aspects rather than wasting time and money
- Be able to develop a Process Validation plan that will ensure compliance
- Ensure that root cause analysis, corrective and preventative actions, and continuous improvement become part of your compliance culture

Finally, this presentation will explain the new guidance, highlight what is different from the old standard (nearly everything!), and discuss the principles underlying the new CDER thinking.

12:30 *Complimentary Lunch*

1:45

Implementation Strategies for Continued Process Verification: Examining FDA's new PV Guidance

**Pritish Patel, AH Ops Process Technology,
Bayer Healthcare**

This presentation will give an high-level idea of FDA's new Process Validation guidance. The presentation focuses on Stage 3 of Process Validation :Continued Process Verification and its implementation strategy. Further, the presentation will detail out the documentation requirements and strategy for the selection of various parameters or attributes for the Continued Process Verification. The Stage-3 process verification implementation of already manufactured products as well as for the future products is also included in presentation. Looking at the future, presentation speaks about the upcoming approaches to make the Continued Process Verification more robust.



Spotlight on the Drug Supply Chain Security Act

2:30

Stage 2 Process Validation in Manufacturing of Biopharmaceuticals: Approaches to Determine and Justify the Number of PPQ Batches

Kashappa Goud Desai, Investigator, Biopharmaceutical Product Sciences, GlaxoSmithKline

Prior to the release of an updated Food and Drug Administration guideline in 2011, a one-time activity of three consecutive successful process validation batches was considered to be sufficient to demonstrate reproducibility of biopharmaceutical manufacturing process. The updated guideline includes a 3-stage validation approach (stage 1: process design, stage 2: process performance qualification/PPQ, and stage 3: continued process verification) over the lifecycle of process and product. In stage 2, the manufacturing process as designed and developed in stage 1 is evaluated for reproducibility by manufacturing of conformance lots. However, the updated guideline does not recommend the number of PPQ batches required nor specific methods to determine it. It does state that the approach to PPQ should be based on sound science and the manufacturer's overall level of product and process understanding and demonstrable control. Biopharmaceutical manufacturers are expected to determine the number of PPQ batches based on a reasonable approach. This presentation includes an overview of current regulatory expectations with regard to the number of PPQ batches and reasonable approaches to establish the number of batches based on a science and risk-based approach, and use of statistical methods when applicable.

3:15

Afternoon Networking Break

3:30

Process Validation Case Study: Process Control Strategy and Process Performance Qualification of a Drug/Device Combination Product

Mark Mitchell, Principal Engineer, Pharmatech Associates, Inc.

CASE STUDY

The number of new Drug/Device Combination products is increasing in the pharmaceutical industry and this provides unique challenges in the area of process validation. The FDA Process Validation guidance covers the process validation of drug products, but explicitly excludes medical devices. The design control methodology applied to medical devices uses Verification and Validation (V&V) to qualify device designs. However, application of the principles of drug process validation to combination products has advantages. This presentation provides a case study of an auto-injector combination product. In this example, development challenges leading to the creation of a Process Control Strategy covering both drug and device elements are presented. Confirmation of this control strategy is then completed

4:10

Process Monitoring Tips and Traps

Ronald D. Snee, PhD, President, Snee Associates, LLC

CASE STUDY

Stage 3 of FDA's Process Validation Guidance calls for "ongoing assurance is gained through routine production that the process remains in a state of control." Two critical considerations in assessing process behavior are process stability and capability. Tools commonly used to demonstrate that a process is in a state of control include: control charts, process capability indices, analysis of variance and graphics. Unexpected problems are often encountered when using these tools. In this session "tips and traps" are discussed that enable pharmaceutical scientists and engineers to develop effective process monitoring systems and avoid commonly encountered problems and pitfalls. The issues discussed include: how to reduce false out of control signals, measures of process stability, how to identify causes of out of control signals, how to select the appropriate sampling procedures. The approaches and tools discussed are illustrated with pharmaceutical and biotech case studies and examples.

4:50

Validation Master Plan-Developing a Plan for Success

Scott Collins, Director of Laboratory Operations and Compliance, QPharma, Inc

Validation Master Plans (VMP) are a company's way to communicate a clear strategy for performing validation within the company. These documents are useful to external parties such as inspectors and auditors, but also to new personnel just joining the company. There may be one VMP with many sections, or multiple VMPs addressing different topics or areas of concern. This talk will provide logical rationale why a VMP should be developed, then point to several regulatory requirements for a VMP. We will define what a VMP is; review the contents of a typical VMP; demonstrate the difference between a VMP and a Validation Project Plan, and discuss the benefits of a VMP. Finally the presenter will share his experience working with the Agile Development Methodology and provide some direction on how this can be included in a VMP. This will be an interactive discussion, so please feel free to participate!

I. What is a Validation Master Plan?

- Definition and purpose of a VMP
- Regulatory and other rationale for having a VMP
- Scope and Types of VMPs
- VMP vs. VP

II. VMP Documentation Design

- General format recommendations
- Content and template

III. VMP Do's and Don'ts

- Pitfalls of poor designs
- Supplements and Attachments vs. direct content
- Improvements and Gap Analysis
- Maintaining a Validated State
- Document Maintenance

IV. Benefits and Strategies

V. Working Within the Agile Development Process

- Designing an Agile VMP
- Documentation List

VI. Examples and TOCs

5:30 *End of Day One*

Friday, May 19, 2017

7:45 *Complimentary Breakfast*

8:00 **Unveiling the Myth of Combination Product Design & Process Validations under 21 CFR Part 4**

Leonel Vanegas, President, ResMedica Consulting LLC

The Food and Drug Administration (FDA) released in January 2015 a guideline to supplement the final rule of “current Good Manufacturing Practices” (cGMPs) requirements of combination products after years of review from regulators and industry experts. 21 CFR part 4 integrates drug cGMPs with medical device Quality System Regulations (QSRs). A commercially viable combination product requires years of collaborative efforts from scientists and engineers to design a combination of drug/biologic or device healthcare product which can symbiotically fulfill patients’ unmet needs. Such product synergy will likely achieve higher levels of patient safety, efficacy, and compliance; not to mention higher customer loyalty and business profitability. The design and validation of these products are non-exempt from technical and organizational challenges. For instance, while drug product development timelines are longer than devices, process validations in drugs occur only after filing an ANDA or NDA. In devices (class II-III), general & design controls are required to file and demonstrate acceptable product validation. A drug company’s quality system is built around GMP (21CFR part 210/211) and may need revision to enhance or to accommodate device QSRs or vice versa. As FDA pilots in 2016 (1) a new inter-center review process through the Office of Combination Products (OCP) and the lead centers (CDER/CDRH/CBER), cross-functional collaboration, redefinition, and execution at combination product companies are required to succeed. Firms that are able to build and/or integrate well a high performing teams and drive sound product and process validation strategies early in development will likely gain market approvals, avoid costly recalls, and reduce risk of FDA-483s and warning letters. This presentation will focus on why is important to

8:45

Cost-Effective Validation

Scott Collins, Director of Laboratory Operations and Compliance, QPharma, Inc

Validation teams have been developing, executing and documenting validation protocols for decades—but even today many systems are validated in a less efficient, less compliant and less cost-effective manner than achievable. In many cases, this inefficiency is based on a lack of understanding of the core fundamentals of validation best practices and regulatory obligations, as well as how to shorten cycle times. In this session, a validation and compliance expert takes attendees back to the basics, helping participants understand the differences between guidance and best practice. In addition, they’ll learn how to develop protocols that result in streamlined and cost-efficient execution, while also learning to simplify protocol problems with full compliance.

I. Validation 101

- Regulatory obligation for protocols
- Typical use of protocols in industry to address requirements
- FDA guidance vs. industry best practices

II. Types of Protocols and Their Scope

- Prospective, Concurrent, Retrospective
- The Usual Topics
- Plans vs. scripts
- Separate report or combined?
- Not-so-New Process Validation Guidance

III. Templating Your Success

- Recycle, recycle, recycle
- Starting Over
- Reuse, reuse, reuse
- Efficient documentation
 - mind your P’s & Q’s—And your GDPs
 - how to use deviations to shorten rather than increase cycle times
- Traceability

Critical Issues—Tech Transfer

Biologics & Vaccines Process Validation and Technology Transfer

Dushyant B. Varshney, Ph. D., Head of Manufacturing Science and Technology, Sterile Injectables, Pfizer Inc.

Biologicals (e.g., therapeutic proteins, mAbs, ADCs, bisimilars), oncolytic and vaccines are developed as sterile injectable dosage form by small and large biopharmaceutical companies. Development of such biologics is quite expensive and many companies lack in-house setup and capability to develop at commercial scale. On the contrary, companies engaged in core or

9:30

non-core business, have realized cost-saving by utilizing contract manufacturing organizations and improved productivity trends, as compared to investing in setting up and maintaining own facilities with required expert staff and regular updates. In such industry trends, technology transfer and validation of manufacturing process is becoming increasingly important to deliver safe and quality products. Moreover, challenges unique to each modality warrant special attention to manufacturing process and analytical method transfer during the entire product lifecycle in accordance with cGMP.

The talk will focus on the current challenges and solutions during process validation and technology transfer. Specifically, process validation roadmap for manufacturing of sterile liquid or lyophilized biologics & vaccines products will be discussed.

10:30 *Mid Morning Networking Break*

10:45 **Global Technology Transfer and Process Validation**

Abizer Harianawala, Senior Director, Product Development and Technical Operations, Taris Biomedical

Topics covered:

- Discuss key elements and stages of a successful global technology transfer and process validation approaches
- Application of QbD/PAT to enhance robustness and minimize risk
- Examine unique CMC challenges posed during technology transfer and process validation for oral solid dosage forms with breakthrough status
- Case studies

11:30 **Fostering a CMO Validation Playbook: Global Technology Transfer & Sterility Assurance**

Dave Kahlenberg, Associate Director of Validation Services, Takeda Vaccines

Today's global marketplace demands that validation professionals do more with less, to perform better and faster—and often in partnership with CMOs across the globe. This presentation will advocate practical strategies based on road tested experiences for Validation SME's to consider in crafting their plans in order to clearly and concisely satisfy the expectations associated with sterility assurance and validation of vaccines with technology transfer to CMO partners.

Creating effective strategies to meet the needs of Validation in the 21st Century requires navigating a maelstrom of different paradigms:

- Concepts like Quality by Design (QbD), Product Lifecycle Management (PLM), Quality Risk Management (QRM)
- Details like the effective integration of analytical and process control strategies, process design and single

use systems, risk assessments, technology transfer and quality agreements

- Different Operating Models: internal capabilities vs. use of contract manufacturing organizations (CMO), contract research organizations (CRO) and contract laboratories

12:15 *Complimentary Lunch*

1:05 **The Key Role of Specifications in Process Validation**

Julia O'Neill, Principal, Tunnell Consulting

In the modern Quality by Design paradigm, specifications should be established to insure the final product is acceptable for its intended purpose. Specifications are the key to which all other process controls should be linked, and play a critical role in planning for reliable supply using process capability metrics. However, knowledge of true product requirements is often difficult to obtain, and becomes even more challenging for breakthrough and orphan drugs, when the amount of data available is often extremely limited during control strategy development. This presentation will explore alternative approaches for specification setting, and recommend specific strategies for both traditional and accelerated validation.

1:50 **Overcome 5 Pitfalls in Process Validation Statistics**

Tara Scherder, President, SynoloStats

If statistical methods are applied without understanding the context of pharmaceutical and biopharmaceutical manufacturing, lifecycle process validation can be seen as a costly compliance effort, instead of an opportunity to gain business benefit. This session addresses five statistical pitfalls, and means to overcome them and avoid waste of resources are discussed. Participants learn approaches to gain process understanding and optimize:

- (1) Experiments in Process Design
- (2) Intra-batch samples in PPQ
- (3) Enhanced sampling in Stage 3A of CPV
- (4) Level of Investigation during CPV and
- (5) Focus on statistical assumptions

2:40 **Statistically Based Process Validation (PPQ)/Continuous Process Verification (CPV) Acceptance Criteria**

James Bergum, President, BergumSTATS LLC

A combination of the FDA withdrawing and not supporting the approaches given in the FDA draft guidance document for industry "Powder Blends and Finished Dosage Units—Stratified In-Process Dosage Unit Sampling and Assessment" and both the USP and FDA not supporting the use of USP <905> for batch release has resulted in a gap for manufacturers and products that rely on traditional blend and dosage unit uniformity approaches for process validation and commercial batch release.

Recommendations from the Blend Uniformity and Content Uniformity Group (BUCU) sponsored by the International Society for Pharmaceutical Engineering (ISPE) will be included in this presentation as well as several statistically based acceptance criteria: ASTM E2709/E2810 referenced in the FDA process validation guidance for process validation and two tolerance interval based methods based on the percentage of content uniformity results falling between 85%-115% Label Claim. All of these methods can be used to provide a high degree of assurance that a batch will pass the USP UDU test. Several examples will be presented to show how each method can be applied to process validation and/or continuous process verification for content uniformity data. A discussion of reducing confidence levels for routine release as compared to validation will be presented. Also, if available, provide a summary of an USP Expert Panel addressing issues around the USP UDU test and work on a possible 1000+ USP informative chapter to discuss statistical methods that could be applied for batch release.

3:20 *Afternoon Networking Break*

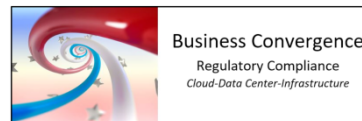
3:35 **Statistics in Bioassay Development and Validation**

Shuguang Huang, Chief Scientific Officer, Stat4ward LLC

Bioassays are generally required in the development and optimization of product manufacturing, including formulation and scale-up processes. Bioassays can be used to evaluate purification strategies, optimize product yield, and measure product stability. This talk will focus on some statistical considerations in experimental design and analysis of the bioassay data. Guidelines (including ICH, FDA, USP, and CLSI) will be cross referenced to provide insights into the understanding of an assay's 'fit-for-purpose'.

4:30 *Close of Conference*

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Dates: **May 18–19, 2017**
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