PharmaED RESOURCES, Inc.

CSV, Data Integrity & Process Validation Virtual Summit, 2021

January 20–21, Online, EST

Featuring Lessons Learned and Case Studies From Industry Experts

Katherine Giacoletti
Partner
Synolo Stats, LLC

Humberto Vega
Sr. Director
Bristol Myers Squibb

Raul Soto
Sr. Principal Engineer
Johnson & Johnson

Mariza Jafary
Consumer Safety Officer
FDA

Mayank Bansal
Dir. of Product Development
AbbVie

Tara Scherder
Partner
Synolo Stats, LLC

Dushyant Varshney
Global Head of Manufacturing Sciences & Technology
Kite Pharma-Gilead

Joe Cagnassola
Sr. Validation Specialist
MMR Consulting

Jeff Karbin
VP Sales & Engineering Compliance Team LLC

Chris Wubbolt
Principal
QACV Consulting

Mark Mitchell
Principal Engineer
Pharmatech Associates

Mike Fitch
QA CSV Consultant
Takeda

Gyorgy Vas
Quality Control
Intertek Pharmaceutical Services

And Comprehensive Coverage On:

- Artificial Intelligence (AI) in Process Validation
- Meeting FDA Regulatory Requirements for Process Validation
- Examining FDA's Data Integrity Guideline
- Rethinking Computer System Validation—Implementing Lean CSV Without Jeopardizing Data Integrity
- FDA Inspection of CSVs—Key Takeaways & Lessons Learned
- Applying Process Validation Process Design Principles to a Human Tissue Derived Biologic: A Case Study
- Technology Transfer and Process Validation for CAR T Products
- Software Validation Case Study: Validation Of Mes System
- How to Achieve Data Integrity for Complex Analytical Systems, and Deal Effectively with Vendor Provided COTS Solutions?
- Statistical Methods for Process Validation—How to Avoid Common Mistakes
- Right-Sized Sampling & Statistics for the PV Lifecycle
- And Much More!

Featuring Representation From:

Kite, A GILEAD Company · Takeda · Bristol-Myers Squibb · FDA · abbvie · Johnson & Johnson

pharmatech associates · Compliance Team, A Guideline Medical Company · intertek, Total Quality. Assured. · QACV Consulting · SynoloStats, Integrating Total Solutions · MMR Consulting, Pharma Validation Engineering, Project Management, GMP Compliance

Contact: Kim Hubbard
khubbard@pharmaedresources.com or call (217) 721-5774

Wednesday, January 20, 2021

9:00 *Chairperson Tara Scherder's Welcome and Opening Remarks*

9:15 **Danger: Statistics Ahead! Learn How to Avoid Common Mistakes**

Tara Scherder, Partner, Synolo Stats

The use of statistics across the product lifecycle has increased dramatically since the adoption of the 2011 FDA Guidance for Process Validation. This paradigm shift has certainly improved understanding of processes, increased robustness and managed risk. but with this increase comes the risk of inappropriate methods, unnecessary analysis, and incorrect interpretation. The consequences can vary from minor, such as a small waste of resources, to an increase in patient risk resulting from a flawed analysis. In this talk, several common mistakes that are made in typical application of statistical methods for process validation are shown by example.

Spotlight on Regulatory Expectations

10:00 **Examining FDA's Data Integrity Guidance**

Raul Soto, Senior Principal Software Engineer, Johnson & Johnson Vision Care

FDA's 2018 Guidance on Data Integrity and Compliance with Drug CGMPs, written in a Questions-and-Answers format, shows the Agency's thinking on the subject of Data Integrity. This talk will summarize key areas of Agency concern, including:

I. What is "Data Integrity"?
II. The meaning of ALCOA
III. Static vs Dynamic Data
IV. Audit Trails
    a. The various types
    b. Who should review them and how often?
V. When does electronic data become an Electronic Record?
VI. System security: FDA's view on group accounts

10:45 *Morning break. Visit the networking chatroom.*

Emerging Technology Spotlight—Artificial Intelligence in Process Validation

11:00 **AI in Process Validation**

Mayank Bansal, Director of Product Development, AbbVie

Artificial intelligence (AI) is an emerging field. It allows a machine to make decision based on data, environment or inputs. AI can be of particular use in efficient process validations. It can learn complex interdependencies among numerous inputs. And use this learning in validating the outcome of a process with very high efficiency and precision. In this talk Mayank will discuss the examples of process validation using AI.

11:45 **Meeting FDA Regulatory Requirements for Process Validation**

Mariza Jafary, Consumer Safety Officer (Compliance Officer), Office of Regulatory Affairs, US FDA

Process validation of manufacturing processes is a requirement of the Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals (21 CFR 211.100 and 211.110) and is considered enforceable under section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 351(a)(2)(B). An effective process validation contributes significantly to assuring drug quality. The basic principle of quality assurance is that a drug product should be produced for its intended use. Process validation is the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product. Process validation involves three stage of activities which takes place over the lifecycle of the product and process: process design, process qualification and continued process verification. The integration of process design, process qualification, and continued process verification provides assurance the product/process will consistently remain in control throughout the entire product lifetime.

12:30 *Lunch Hour. Visit the networking chatroom.*

1:30 **Technology Transfer and Process Validation for CAR T Products**

Humberto Vega, Sr. Director/Lead CTCC-MS&T at Bristol Myers Squibb

Chimeric antigen receptor (CAR) T cell therapies are being investigated to provide patients with cancer and other serious diseases treatment using the immune system. These products are unique in that they are produced by adding chimeric antigen receptors (CARs) to a patient's T cells; the CAR can recognize and attack cells that display a target protein (antigen), including cancer cells.

The manufacturing process for CAR T products can be summarized in the following general steps: (a) optional isolation of T Cells; (b) activation and transduction; (c) cell expansion; (d) harvest of CAR T cells and formulation; (e) cryopreservation and shipping; (f) release testing. Technology transfer activities will focus on the capability of a new facility to conduct those manufacturing steps as designed during process and product development while the process performance qualification activities will provide documented evidence that the process is executed as designed (e.g., pre-defined

process parameters) resulting in a product satisfying all pre-defined quality attributes.

The presentation will provide a summary of key considerations and learnings during technology transfer and process validation activities for CAR T products. Among the considerations and learnings are: equipment design, facility fit assessment, material sourcing, risk assessments, control strategy, validation master plans, and process performance qualification design and execution.

Critical Issues—CSV & Data Integrity

2:15

Rethinking Computer System Validation—Implementing Lean CSV Without Jeopardizing Data Integrity

Jeff Karbin, Vice President of Sales & Engineering, for Compliance Team LLC

This presentation will cover the most common obstacles companies have encountered and strategies for how to overcome those obstacles to successfully implement the lean computer system validation (CSV) methodology. When done properly, they will significantly improve their ability to minimize overall validation costs while still achieving compliance and without sacrificing data integrity.

Attendees will gain:

- An historical perspective of the evolution of the regulatory landscape
- Mastery of the principles needed to comply with 21 CFR 11/Annex 11 regulations and a better understanding of how to achieve data integrity by applying GAMP 5 validation of computerized systems practices to computerized systems
- Knowledge of what Lean Computer System Validation means, and how to successfully implement it in their organizations
- Where cost savings can be realized by using the Lean CSV methodology
- An understanding of how to reduce the burden of validation documentation by using Lean Documentation & Risk Assessment Best Practices while still fully complying with regulations and achieving data integrity
- Clarity on how to select automated testing vendors to ensure that use of vendor tools allows for the flexibility to use Cloud/SaaS/IaaS/PaaS related technologies while maintaining data integrity

3:00 *Afternoon break. Visit the networking chatroom.*

3:15

A Case Study in FDA Inspection of CSVs—Key Takeaways & Lessons Learned

Mike Fitch, Independent QA CSV Consultant at Takeda

This presentation will cover lessons learned relating primarily to CSV but applicable to Data Integrity, from the point of view of CSV and CSV QA Team members. I will summarize our experience of beginning remediation of CSV-inspection resulting in consent decree, 3rd party certification, and finally a successful FDA Re-Inspection.

Our team quickly went from a mostly insignificant player to being very critical to the success of the entire organization—if we did not get IT right, the division would never ship products. We had the option to go back to paper processes, which we did in some cases. For our first inspection by the 3rd party, we were feeling ready. We had all the basic elements of validation covered. At least we thought we did. We failed miserably. We licked our wounds and tried to figure out what went wrong. Second Inspection also failed, although not quite as miserably. Our third try started seeing some systems that were considered validated! Facing the FDA was new for most of the IT folks, but we had the chance for a new experience. We learned a lot from the entire effort and at the end were confident that our systems were sufficiently validated to pass a rigorous inspection. There were a lot of constraints due to the consent decree that were outside normal experiences—you effectively put yourself on parole and have an ankle monitor that makes everything you do subject to extreme scrutiny.

Ask the Experts

4:00

Roundtable Discussion: Managing the Inherent Risks in PV Across Product Life-cycles



Panelists:

Raul Soto, J&J
Tara Scherder, Synolo Stats
Humberto Vega, BMS

Participants:

The Audience

4:45 *End of Day 1*

Thursday, January 21, 2021

9:00 *Chairperson's Welcome & Opening Remarks*

9:05 **Right-Sized Sampling & Statistics for the PV Lifecycle**

Katherine Giacoletti, Partner, Synolo Stats, LLC

The expectation that sponsors will employ enhanced sampling during PPQ and Stage 3a is broadly recognized in the industry. But to find the optimal level of sampling requires understanding the underlying reasons for taking additional samples. Further, understanding how sample size relates to statistical uncertainty and how this knowledge can be used to choose sampling plans and interpret results is critical to making PPQ and CPV decisions that protect that patient and the business. This talk will discuss the role of statistical uncertainty in making inferences based on samples and the implications for designing sampling plans, in the context of the goals of lifecycle PV. The focus will primarily be on PPQ and the transition from PPQ to routine manufacturing, but will also touch on the opportunities to gain enhanced process understanding and more efficiently use development resources with DOE in Stage 1 – and how the benefits of the optimal use of statistics in Stage 1 can be reaped through the rest of the lifecycle.

9:50 **Software Validation Case Study: Validation of Mes System**

Raul Soto, Senior Principal Software Engineer, Johnson & Johnson Vision Care

In 2015, Johnson & Johnson Vision Care's MES upgrade project was awarded the Siemens Manufacturing Star Award. Mr. Soto was the Quality & Validation Lead for this project. This presentation will summarize the team's approach and deliverables.

I. A Systems Development Lifecycle Approach to MES validation
   a. What are the benefits of an MES?
   b. ANSI/ISA-95 Control Hierarchy Levels
   c. Medical Devices: how MES can help you maintain your Device History Record
   d. Defining your project scope: Hardware and Software components of an MES
   e. What is an SLDC? Phases
II. Validation and Project Deliverables
   a. Which assessments do you need before validation?
   b. Software Validation Deliverables
   c. Hardware & Infrastructure Validation Deliverables
   d. Interfaces
   e. Electronic Records & Signatures
   f. From Workflows to Use Cases, to Test Scripts
   g. Testing: a risk-based approach
III. Going Live
   a. System governance: procedures and processes
   b. Change control
   c. What is "Hypercare"?

10:35 *Morning break. Visit the networking chatroom.*

Critical Issues—Software Validation for Manufacturing Execution Systems

10:50 **Applying Process Validation Process Design Principles to a Human Tissue Derived Biologic: A Case Study**

Mark Mitchell, Principal Engineer, Pharmatech Associates, Inc.

Several pharmaceutical companies are beginning to investigate biologics derived from harvested human tissue. Historically, when human tissue is used for transplant or grafting, the product is regulated under Good Tissue Practices (GTP). However, when the tissue is no longer "minimally manipulated" the product becomes a biologic and is regulated under GMPs and the principles of Process Validation apply, such as Stage 1: Process Design. In this case study, we will examine the transfer of a human tissue derived biologic from development to process design in order to produce material for human clinical trials. Key topics include:

- Using the principles of risk assessment to evaluate existing process knowledge and development data
- Developing a plan for a series of process design experiments to reduce risks
- Employing Design of Experiment (DOE) principles
- Analyzing and interpreting data to determine criticality of process parameters
- Adding and improving unit operations to reduce risk and increase product quality
- Applying a revised risk assessment to justify the final process and control strategy

11:35 **Statistical Process Control (SPC) and Process Validation**

Joe Cagnassola, Senior Validation Specialist, MMR Consulting

Statistical Process Control (SPC) is a powerful tool to help analyze process validation data. SPC is one element to show process understanding and to monitor trends, for all the three stages of the process validation life cycle.

SPC is an effective and efficient operational technique available to simultaneously improve both Quality and Cost. SPC is useful in reduction of variation, centering a process, early warning of quality problems and predictive maintenance.

Understanding the variation in the process is important when developing risk assessment for process validation. Participants learn approaches to gain process understanding and optimize.

The discussion will detail the theory of control charts how to calculate, read and how to apply Control Charts, e.g. implementing control charts in production or QC and setting up a good review process. Examine the use of Control Charts in validation and process improvement.

12:20 *Lunch break. Visit the networking chatroom.*

1:20 **How to Achieve Data Integrity for Complex Analytical Systems, and Deal Effectively with Vendor Provided COTS Solutions?**

Gyorgy Vas, Ph.D., Intertek Pharmaceutical Services

Data Integrity is a "hot topic" in the Pharmaceutical Industry. Besides the importance of the data integrity FDA has not yet published a final guidance to clearly indicate the expectations for data integrity. The complexity of the industry would require complex oversight for the problem, as different solutions are needed for a QC environment where less complex instrumentation is used for release of finished pharmaceutical products, and for R&D where more complex instrumentation is used, however data integrity and compliance is important than for both environments.

The instrument and the related software qualification and cGMP validation is an essential part of the data integrity package. If the vendor provided software solution is not in compliance with the current regulations, the qualification will be very difficult or not even possible. It is important to highlight that establishing a fully compliant data integrity solution is a complex workflow, involving the vendor, the user, and the quality control unit. Every step in the complex workflow must be in compliance with current regulations, guidances or industry best practices.

This presentation will use case studies to focus on the following major areas:

- What to do before the instrument/software is purchased, what steps need to be completed?
- Roles of the vendor, the user and the quality unit
- Lessons learned during multiple computer software validations
- Common roadblocks for complex system validations; higher compliance with limited system performance, or lower compliance with maximum system performance?

2:05 **Critical Data—What Is It and What Do You Do With It?**

Chris Wubbolt, Principal, QACV Consulting

Abstract Coming Soon

2:50 *Close of Conference*

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In the Age of COVID, the Show Must Go Online

In response to overwhelming audience and speaker feedback, and in view of the current health and safety concerns involving the novel coronavirus COVID-19, we're taking our events online (at least for the foreseeable future; we do hope to see you again soon in person when all this is over!) **CSV, Data Integrity & Process Validation Virtual Summit, 2021** is an entirely online event, complete with insightful presentations from leading researchers, 1:1 networking opportunities, live question & answer sessions, and sponsored informational presentations that highlight how vendors are tackling some of the key issues facing the Microneedle market today. Just sit back and enjoy this online learning experience from the safety and comfort of your home or office. Missed a session or two? No worries—the full program will be archived and available for post-conference viewing and download.

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