PharmaED RESOURCES, Inc.

2018 Pharma Analytics Summit:

Statistical Approaches for Improving Performance and Compliance

March 26–27, 2018, Racquet Club of Philadelphia, PA

Featured Speakers Include:

Ajaz Hussain
Former FDA

Ying Verdi
Upsher-Smith

J.D Williams
Lilly

Ron Snee
Snee Associates LLC

Tara Scherder
SynoloStats

Stan Alton
Janssen

Raul Soto
JnJ

With Comprehensive Coverage On:

- Solving Statistical Mysteries – What Does the FDA Want?
- Stability and Capability of Measurement System and Manufacturing Process is Fundamental to Pharmaceutical Quality Assurance in the 21st Century
- Strategies forAccelerating Process and Formulation Validation
- Measurement Systems Analysis and Some Useful Experimental Designs
- Continued Process Verification and Fit for Use Statistical Approaches
- The Need for both Fundamental and Advanced Understanding to Design Lean Statistical Approaches
- Test Method Robustness/Design Space
- And Much More!

Use of statistics has been part of the FDA's guidances and regulations for many years. Use of statistics is an integral part of the Jan 2011 FDA Process Validation Guidance. It can be argued that the FDA is looking for the pharma and biotech industries to make even greater use of statistical thinking and methods. Are you compliant with FDA requirements? 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.

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Monday, March 26, 2018

8:30 *Complimentary Breakfast & Chairperson's Welcome and Opening Remarks*

Regulatory Considerations

8:45 **Stability and Capability of Measurement System and Manufacturing Process is Fundamental to Pharmaceutical Quality Assurance in the 21st Century**

Ajaz S. Hussain, Ph.D., Former FDA, Insight, Advice and Solutions LLC

The 21st century ushered in the Experience Economy in which Assurance is a critical patient experience that links directly to safety and efficacy of pharmaceuticals. To the only state that Assurance, in and of itself, is critical to quality, safety and efficacy would fail to emphasize its importance. Reduction of errors and external failures (e.g., Product Withdrawals, Recalls, Warning Letters, and Import Alerts) is an urgent need, and it is the need to ensure effective corrective actions and preventive actions and to improve continually. Continuous Improvement means reducing variability in a process. One can only improve a (manufacturing) process that is stable, capable and in a state of (statistical) control. In the pharmaceutical sector, we often talk about continual improvement, but we cannot objectively achieve it for many reasons that span from how we set specifications, use compendial standards, and how we "validated" our measurement systems and "control" manufacturing processes. The goals and aspirations of the FDA initiatives of Process Analytical Technology and Pharmaceutical CGMP's for the 21st Century should have been realized with the accumulated guidance under ICH and the FDA Guidance on Process Validation (2011). This talk will discuss what it will take to realize these goals and to practice continuous improvement indeed.

9:45 **Measurement Systems Analysis and Some Useful Experimental Designs**

CASE STUDY

Stan Altan and Oluyemi Oyeniran, Janssen Pharmaceutical R&D LLC

Measurement systems analysis in the biopharmaceutical industry can be efficiently carried out through Gage R&R (Repeatability and Reproducibility) studies which aim to measure the total variability in a measurement system. The total variability is comprised of the measurement device, the laboratories or operators (reproducibility) carrying out the measurement and when measuring the final product of some manufacturing process, the variation in the process itself. Repeatability is defined as the basic inherent precision of the device itself. A well-designed Gage R&R study allows for the estimation of these various sources of variability so one can assess their relative importance.

In this presentation, we will discuss the application of the Gage R&R study and provide several examples to illustrate the design and its analysis. In the course of our discussion, we will point out some limitations, which can lead to misuse, as well as the utility of applying appropriate experimental designs.

10:45 *Networking Break*

11:15 **Data Integrity in the Laboratory**

Jeanne Moldenhauer, Excellent Pharma Consulting

This talk focuses on data integrity in the laboratory. It discusses concepts of data integrity and how they are applied in the laboratory setting. It will also discuss the various issues with audit trails and how they support data integrity. Lastly, we will discuss various audit observations on data integrity.

- Learn about types of data integrity issues are prevalent in the laboratory
- Identify typical FDA observations
- Prevent these observations in your facility
- Proactively identify issues in your lab
- Understand why these occurrences are an issue

12:15 *Complimentary Lunch*

Spotlight on FDA Requirements

1:45 **Solving Statistical Mysteries – What Does the FDA Want?**

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

Use of statistics has been part of the FDA's guidances and regulations for many years. Use of statistics is an integral part of the Jan 2011 FDA Process Validation Guidance. It can be argued that the FDA is looking for the pharma and biotech industries to make even greater use of statistical thinking and methods. Even with this long history, the use of statistics seems to be a source of uncertainty and anxiety for many. This presentation provides an overview of what it appears the FDA is looking for in the use statistics including examples and recommended approaches.

2:45 *Afternoon Break*

3:00 **Leveraging Analytics to Drive Commercial Decision Making in Pharma**

J.D. Williams, Ph.D., Director, Business Analytics, Eli Lilly and Company

Data analytics can play a critical role in improving business performance in the pharmaceutical industry. One key decision point is how to best reach out to health care professionals and the patients that they serve. In this talk, we will discuss some of the many data sources that exist along with the associated analytical efforts that can aid the marketing and sales organizations to make more informed data-driven decisions.

4:00 **Seven Key Principles for Applying Practical Statistics**

Jamey Crichton, Principal Statistician, Catalent Biologics

People who analyze, interpret, and present data could benefit from having a set of core principles to provide practical guidance. The purpose of this presentation is to present 7 principles that I have found helpful in my 34 year career as a practicing statistical consultant. There are times when in-depth, complicated statistical analysis is required, where an expert statistician should be consulted. However, there are a lot of analysis that practitioners can perform with available statistical software, such as control charts, capability analysis, gauge studies, even design and analysis of experiments. Accepting output from software without understanding assumptions or what is behind the black box can potentially be dangerous and caution is often needed. What can help is to have a set of principles for guidance. Two examples are the KISS and Pareto principles. These principles will help us become more statistical thinkers, not just analyzers.

4:45 *End of Day One*

Tuesday, March 27, 2018

8:15 *Complimentary Breakfast & Chairperson's Remarks*

8:30 **Continued Process Verification and Fit for Use Statistical Approaches**

Marzena Ingram, Senior Manager, Continued Process Verification, Apotex Inc.

With the implementation of ICH Q8, Q9, Q10, Q11 and draft Q12 guidelines, regulatory bodies mandate a data driven, science and risk based decision making process utilizing data from all three stages of the PV Lifecycle. Knowledge and information gained from the design stage (Stage 1) through the process qualification stage (Stage 2) and CPV Stage (Stage 3) is used in product lifecycle decision making. Stage 2 demonstrates suitability for successful commercial distribution where the data indicates that the process meets the conditions established in the protocol. Continued Process Verification (CPV) is then initiated for the subsequent commercial batches. CPV Stage 3 assures that the process remains in a state of control during commercial manufacture of the drug product.

The current industry and regulatory inspection trends clearly identify the need for a CPV program for drug product manufacturers. Stage 3A is designed to allow close monitoring of parameters and quality attributes and to detect any undesirable process variability trends observed post launch, thus providing an opportunity to update the product control strategy and finalize the routine Continued Process Verification (Stage 3B) control limits. The session will review elements within CPV Stage 3A and 3B. Novel methodologies have emerged for use in CPV Stage 3 assessments to gain product understanding and confidence for future batches to meet the required specification. The session will review the statistical methodologies that include: determining number of Stage 3A batches, acceptance probability (Pa), variability assessment, decision making indices such as PaCS, process capability & quality dashboard, and Stage 3B decision tree. The discussion will include CPV examples/case studies where automated monitoring was used in taking a proactive continuous improvement effort supporting continuous product supply.

9:30 **The Need for both Fundamental and Advanced Understanding to Design Lean Statistical Approaches**

Tara Scherder, Managing Director, SynoloStats

The use of statistical methods and statistical thinking should have significant business and patient benefit. However, if not designed properly from both a statistical and business perspective, it can result in classic wastes such as over-processing, defects, and waiting. In some cases, waste results because the fundamental statistical and lean concepts essential to translate methods to real-world pharmaceutical problems are not applied. In other situations, it results from unawareness and lack of expertise in innovative statistical methods. In this talk, several examples across the product lifecycle are used to illustrate how resources can be optimized by leveraging fundamental statistical concepts within the business context. In addition, two innovative statistical methods that can reduce experimentation, sampling, and improve modeling are presented.

10:30 *Mid-Morning Networking Break*

11:00 **Test Method Robustness/Design Space**

Ying Verdi, MS, MBA, Principal Chemist, Chemistry and Analytical Sciences, Upsher-Smith Laboratories, Inc.

For many years, robustness evaluation of an analytical procedure has not been the focus of method development and validation activities. However, with the introduction of Quality-By-Design (QbD) concepts along with the notion of the lifecycle management for analytical procedures, robustness studies and design space have been proven to be the right tools for analytical control strategy with regards to method performance. In July 2015, the Food and Drug Administration (FDA) released a guidance on Analytical Procedures and Methods Validation for Drugs and Biologics. In this guidance, robustness evaluation of an analytical procedure is listed as a requirement for NDA and ANDA submissions. This presentation will demonstrate how to systematically design an appropriate robustness study for a given analytical procedure.

Attendees will learn:

- General concepts of robustness study and design space
- Systematic approach in designing a robustness study
- Various robustness study designs
- How to evaluate method robustness and establish design space

12:00 *Complimentary Lunch*

1:00 **Strategies forAccelerating Process and Formulation Validation**
Ronald D. Snee, PhD, President, Snee Associates, LLC

Stage 1 of the FDA Jan 2011 Process Validation Guidance focuses on process design; "The commercial manufacturing process is defined during this stage based on knowledge gained through development and scale-up activities". If Stage 1 is not done properly it will likely be difficult to get the product and process validated. Considerable time may elapse resulting in lost revenues and critical market windows may be missed. A time tested strategy for accelerating process and formulation development is described and illustrated with case studies. Critical to the strategy is the use of screening experiments for both the process and formulation involved. The issues addressed include the following:

- Approaching the development process from a strategic viewpoint, with the overall end in mind.
- Using screening experiments to identify those variables that that are most important t
- Designing optimization experiments to optimize process performance
- Using graphical visualization techniques in the analysis and interpretation of both screening and optimization experiments

2:00 **Design of a Lean Continued Process Verification Program**
Tara Scherder, Managing Director, SynoloStats

Given that much of the product lifecycle falls within the third stage of lifecycle process validation, Continued Process Verification, it is critical that the context for the use of Statistical Process Control tools is understood, and the associated business process are lean. Otherwise, manufacturers can spend resources on tasks that don't benefit the patient or the business, and CPV becomes a cumbersome compliance exercise, instead of the source of substantial business opportunities. In this talk, the application of lean principles to identify ways to optimize CPV is explored. Crucial elements using a holistic approach that considers the context and true goals of CPV, the control strategy, and proper statistical interpretation are presented.

3:00 *Afternoon Networking Break*

3:25 **Analytical Design Criteria**
Jane Weitzel, Principal Consultant, Zinata

The lifecycle approach to analytical procedures provides a new way to link the performance of an analytical procedure to the intended use of the reportable value. The analytical target profile (ATP) is created and includes the target measurement uncertainty based on the intended and decisions made with the reportable value. This presentation will describe the lifecycle process and use the ATP to design the criteria for the development, qualification and continued use of the analytical procedure. Some statistical tools which are useful in this process will be presented.

4:25 **Strategies to Graph, Analyze, and Present Data**
Raul Soto, Principal Engineer, JnJ Vision Care

Charts and graphs can be used for exploratory data analysis – to uncover trends and relationships in your data – and to present your results and conclusions in a powerful, effective manner. In this session, we will discuss various types of charts and visualization techniques, and how to select the most effective for various scenarios.

I. Data Representation

How to select the most effective chart to visually represent various scenarios:

- Continuous and categorical data
- proportional data
- data as a function of time and frequency

II. Multivariable / Multidimensional data

How to use the following tools to represent multivariable data

- SPLOM
- radar / spider plots
- heat maps

5:20 *Close of Program*

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VENUE INFORMATION:

Dates:	March 26–27, 2018
Venue:	The Racquet Club of Philadelphia
Venue Address:	215 South 16th Street Philadelphia, PA 19102
Venue Phone:	(215) 735-1525
Hotel Room Block:	Club Quarters Hotel, Philadelphia
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