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Applied Statistics for FDA Process Validation

Date : May 17, 2018 - 09:00 AM - May 18, 06:00 PM

Event URL : http://www.sfbayeventslist.com/events/applied-statistics-for-fda-process-validation-may-2018

Organizer : GlobalCompliancePanel

Venue : WILL BE ANNOUNCED SOON

Location : 1 Main St,
Los Angeles, CA, United States, ZIP: 00000

In *Guidance for Industry Process Validation: General Principle and Practices,* process validation is defined as, ""...the collection and evaluation of data, from the process design stage through commercial production.." The guidance further delineates the 'process design stage through commercial production' into three distinct stages of the product lifecycle:

Stage 1: Process Design: The commercial manufacturing process is defined during this stage based on knowledge gained through development and scale-up activities.

Stage 2: Process Qualification: During this stage, the process design is evaluated to determine if the process is capable of reproducible commercial manufacturing.

Stage 3: Continued Process Verification: Ongoing assurance is gained during routine production that the process remains in a state of control.

The first stage of process validation is process design. The Process Validation guidance document states, "A successful validation program depends on information and knowledge from product and process development. This knowledge and understanding is the basis for establishing an approach to control of a manufacturing process that results in products with desired quality attributes:

Manufactures should:

- Understand the sources of variation
- Detect the presence and degree of variation
- Understand the impact of variation on the process and ultimately on product attributes

- Control the variation in a manner commensurate with the risk it represents to the process and product."

The second stage of process validation is process qualification. Although stage 2 has two elements, this course will focus on recommendations for the second element, PPQ. PPQ "combines the actual facility, utilities, equipment (each now qualified), and the trained personnel with the commercial manufacturing process, control procedures, and components to produce commercial batches." Additionally, the process validation guidance document that "Each manufacturer should judge whether it has gained sufficient understanding to provide a high degree of assurance in its manufacturing process to justify commercial distribution of the product. Focusing exclusively on qualification efforts without understanding the manufacturing process and associated variations may not lead to adequate assurance of quality."

The third stage of process validation is continued process verification. The process validation guidance document defines the need for this stage: "After establishing and confirming the process, manufacturers must maintain the process in a state of control over the life of the process, even as materials, equipment, production environment, personnel, and manufacturing procedures change." Manufacturers should use ongoing programs to collect and analyze product and process data to evaluate the state of control of the process. These programs may identify process or product problems or opportunities for process improvements that can be evaluated and implemented through some of the activities described in Stages 1 and 2."

This course focuses on how to establish a systematic approach to implementing statistical methodologies into a process validation program consistent with the FDA guidance. It begins with a primer on statistics, focusing on methods that will be applied in each remaining chapter. Next, it teaches the application of statistics for setting specifications and assessing measurement systems (assays), two foundational requirements for process validation. Lastly, the course applies statistic through the three stages of process validation defined by requirements in the process validation regulatory guidance documents. Methods taught through all three stages are recommended by regulatory guidance documents; references to the specific citations in the guidance documents are provided.

Why you should attend:

The Food and Drug Administration (FDA) provided a guidance for industry in 2011 that has established a framework for process validation in the pharmaceutical industry. This guidance, titled "Process Validation: General Principles and Practices" consists of a three-stage process. The three stages are 1) Process Design, 2) Process Qualification, and 3) Continued Process Verification.

This course focuses on how to establish a systematic approach to implementing statistical methodologies into a process development and validation program consistent with the FDA guidance. This course teaches the application of statistics for setting specifications, assessing measurement systems (assays), using design of experiments (DOE), developing a control plan as part of a risk management strategy, and ensuring process control/capability. All concepts are

taught within the three-stage product cycle framework defined by requirements in the process validation regulatory guidance documents.

Although established for the pharmaceutical industry, it also provides a useful framework for other industries.

Analyses in this course use the point-and-click interface of JMP software by SAS.

Areas Covered in the Session:

- apply statistics to set specifications and validate measurement systems (assays)
- develop appropriate sample plans based on confidence and power
- implement suitable statistical methods into a process validation program for each of the three stages
- Stage 1, Process Design: utilize risk management tools to identify and prioritize potential critical process parameters; and define critical process parameters and operating spaces for the commercial manufacturing process using design of experiments (DOE)
- Stage 2, Process Qualification: assess scale effects while incorporating large (pilot and/or commercial) scale data; develop process performance qualification (PPQ) acceptance criteria by characterizing intra and inter-batch variability using process design data and batch homogeneity studies; and develop an appropriate sampling plan for PPQ
- Stage 3, Continued Process Verification: develop a control plan as part of a risk management strategy; collect and analyze product and process data; and ensure your process is in (statistical) control and capable.

Who Will Benefit:

This seminar is designed for pharmaceutical and biopharmaceutical professionals who are involved with product and/or process design, validation, or manufacturing/control.

- Process Scientist/Engineer
- Design Engineer
- Product Development Engineer
- Regulatory/Compliance Professional
- Design Controls Engineer
- Six Sigma Green Belt
- Six Sigma Black Belt
- Continuous Improvement Manager

Day 1 Schedule

Lecture 1: **Introduction to Statistics for Process Validation**

- principles of process validation
- stages of process validation

Primer on Statistical Analysis

- basic statistics

Lecture 2: **Primer on Statistical Analysis (cont.)**

- statistical intervals and hypothesis testing

Lecture 3: **Primer on Statistical Analysis (cont.)**

- statistical intervals and hypothesis testing
- ANOVA

Lecture 4: **Primer on Statistical Analysis (cont.)**

- regression
- run charts

Day 2 Schedule

Lecture 1: **Foundational Requirements for Process Validation**

- setting specifications
- analytical methodology

Stage 1 - Process Design

- steps to DOE
- screening designs

Lecture 2: **Stage 1 - Process Design**

- response surface designs
- establishing a strategy for process qualification

Lecture 3: **Stage 2 - Process Qualification**

- introduction
- incorporation of large-scale data
- development of PPQ acceptance criteria

- development of sampling plans

Lecture 4: **Stage 3 - Continued Process Verification**

- statistical process control
- process capability

Heath Rushing

Co-founder and Principal, Adsurgo

Heath Rushing is the cofounder of **Adsurgo** and author of the book *Design and Analysis of Experiments by Douglas Montgomery: A Supplement for using JMP.* Previously, he was the JMP and Six Sigma training manager at SAS. He led a team of nine technical professionals designing and delivering applied statistics and quality continuing education courses. He created tailored courses, applications, and long-term training plans in quality and statistics across a variety of industries to include biotech, pharmaceutical, medical device, and chemical processing. Mr. Rushing has been an invited speaker on applicability of statistics for national and international conferences. As a Quality Engineer at Amgen, he championed statistical principles in every business unit. He designed and delivered a DOE course that immediately became the company standard required at multiple sites. Additionally, he developed and implemented numerous innovative statistical methods advancing corporate risk management, process capability, and validation acceptance criteria. He won the top teaching award out of 54 instructors in the Air Force Academy math department where he taught several semesters and sections of operations research and statistics. Additionally, he designs and delivers short courses in statistics, data mining, and simulation modeling for SAS.

Please contact Marilyn Turner: Phone: +1 929 900 1853 Email: marilyn.turner [a] nyeventslist.com for registrations

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