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EVENTS LIST

Design of Experiments (DOE) for Process Development and Validation

Date : Aug 02, 2018 - 09:00 AM - Aug 03, 06:00 PM

Event URL : http://www.sfbayeventslist.com/events/design-of-experiments-doe-for-process-development-and-validation-aug-2018

Organizer : GlobalCompliancePanel

Venue : WILL BE ANNOUNCED SOON

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

Prior to developing a process control plan as part of an overall risk management strategy, process development studies must be completed. The objective of these process development studies is to gain knowledge and understanding about how variation in process parameters explains variation in the product quality characteristics of the product.

The use of DOE methodology provides a means to identify process parameters which impact product quality (critical process parameters) and determine the functional relationship that links the process parameters to those critical quality attributes. Screening designs, such as 2k factorial and D-optimal designs, are used to determine critical process parameters. Response surface designs, such as Central Composite Designs (CCDs) and I-optimal designs, are used to model the functional relationship between those critical process parameters and the critical quality attributes.

This course will begin by presenting a primer on statistical analysis, focusing on the methods required for analysis of designed experiments. It will then present the steps to DOE, while demonstrating valuable risk management tools (Ishikawa and FMEA) which can be use pre and post DOE studies. Next, participants will learn to generate and analyze multiple screening and response surface designs; the participants will leave with an understanding of why and how each are used. Then, the participants will learn how results of the studies can be presented. Lastly, using the results of the studies, the risk management tools will then be updated.

Why you should attend:

The Global Harmonization Task Force (GHTF) Process Validation Guidance for Medical Device Manufacturers provides guidance on where design of experiments should be applied during process validation; it suggests the use of both screening and response surface designs during Operational Qualification. In addition, DOE should be used during multiple phases of design controls: design and development planning, design verification, design validation, design transfer, and design changes.

In *Guidance for Industry Q8 Pharamaceutical Development* (as well as the annex to Q8), suggests applying experimental design to demonstrate "...an enhanced knowledge of product performance over a range of...process parameters." Using this "...enhanced, quality by design approach..." leads to greater system understanding. That greater system understanding has two elements: identifying critical process parameters and developing a functional relationship that link those critical process parameters to your critical quality attributes (CQAs). This suggests the use of both screening and response surface designs during pharmaceutical development studies.

The need for DOE in product and process development is not only suggested, but imperative for both medical device and drug manufactures.

Areas Covered in the Session:

Learn how to effectively use JMP to:

- identify critical quality attributes (CQAs) that will be used as responses in your designs
- utilize risk management tools to identify and prioritize potential critical process parameters
- identify critical process parameters and develop a functional relationship between those process parameters and your critical-to-quality attributes (CQAs) using both screening and response surface designs
- be able to design and analyze screening designs including a factorial, fractional factorial, and D-optimal design
- understand the need for adding center points to a design
- be able to design and analyze response surface designs including central composite designs (CCDs), Box-Behnken designs, and I-optimal designs
- present results of DOE studies
- use systematic understanding from DOE studies to update the control plan that is part of the overall risk management plan

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Who Will Benefit:

This webinar is designed for pharmaceutical, biopharmaceutical, and medical device professionals who are involved with product and/or process design:

- 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:

Primer on Statistical Analysis

- basic statistics
- two-sample t-test
- ANOVA
- regression

Lecture 2:

Introduction to Design of Experiments (DOE)

- steps to DOE
- defining critical quality attributes (CQAs)/responses
- identifying and prioritizing potential process parameters

Lecture 3:

Screening Designs

- full factorial designs
- 2^k factorial designs

Day 2 Schedule

Lecture 1:

Screening Designs (continued)

- fractional factorial designs
- D-optimal designs

Lecture 2:

Response Surface Designs

- 2^k factorial designs with center points
- Central Composite Designs (CCDs)
- Box-Behnken designs
- I-optimal designs

Lecture 3:

Utilizing Systematic Understanding from DOE Studies

- presenting results
- control plan/risk management strategy

Jim Wisnowski

Jim Wisnowski is the cofounder of Adsurgo LLC and co-author of the book Design and Analysis of Experiments by Douglas Montgomery: A Supplement for using JMP. He has over 25 years of experience and currently provides training and consulting services to industry and government in Design of Experiments (DOE), Reliability Engineering, Data Visualization, Predictive Analytics, and Text Mining. Dr. Wisnowski has been an invited speaker on applicability of statistics for national and international conferences. Prior to his current position, he was a senior program manager for URS, Chief of the Statistics Division in the Mathematics Department at the Air Force Academy, and a retired military officer. He is currently a member of the editorial board of Quality Engineering and has published numerous international refereed journal articles on statistics. Jim has a PhD in Industrial Engineering from Arizona State University.

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