Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Design of Experiments (DOE) for Process Development and Validation

Los Angeles, CA

March 30th & 31st, 2017

9:00 AM to 6:00 PM

Price

Price: **$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees:

Price: **$4,485.00** You Save: $2,990.0 (40%)*

~~$7,475.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

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.

Overview :

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

Agenda:

Day One

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
- 2k factorial designs

Day Two

Lecture 1: Screening Designs (continued)

- fractional factorial designs
- D-optimal designs

Lecture 2: Response Surface Designs

- 2k 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

Why should you 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.

Who Will Benefit:

This seminar 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

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
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What You will get

1. Learning Objectives
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Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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