Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

# Applied Statistics for FDA Process Validation

Boston, MA

April 25th & 26th, 2019

9:00 AM to 6:00 PM

## Price

Price: **$2,000.00**

*(Seminar for One Delegate)*

Register for 5 attendees

Price: **$10,000.00**

Register for 10 attendees

Price: **$20,000.00**

Register now and save $200. (Early Bird)

ENROLL

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

### 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.

## Overview :

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.

# Agenda:

## Day One

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

### 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.

## Day Two

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

### 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)

## 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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**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

**GlobalCompliancePanel**