Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Quality by Design using Design of Experiments (QbD)

Baltimore, MD

April 6th & 7th, 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~~

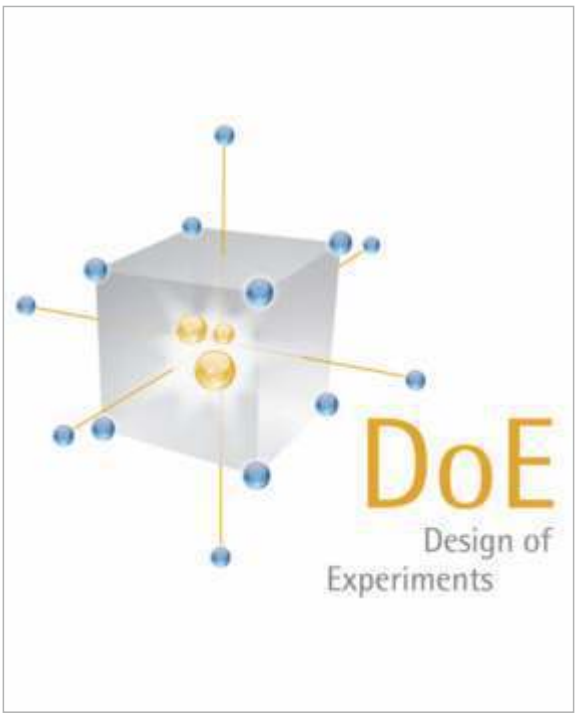
ENROLL

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

Heath Rushing

Co-founder and Principal, Adsurgo

Heath Rushing 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. 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.



Overview :

This seminar focuses on how to establish a systematic approach to pharmaceutical development that is defined by Quality-by-Design (QbD) principles using design of experiments (DOE). In addition, this course teaches the application of statistics for setting specifications, assessing measurement systems (assays), developing a control plan as part of a risk management strategy, and ensuring process control/capability. All concepts are taught within the product quality system framework defined by requirements in regulatory guidance documents.

Using a QbD approach for pharmaceutical development studies should include a systematic understanding of the process and using this understanding to establish a control strategy as part of a comprehensive quality risk management program.

Agenda:

Day One

Lecture 1: Introduction to Quality by Design (QbD)

- •Quality by Design (QbD) principles
- •Product Quality System framework

Primer on Statistical Analysis

- •basic statistics

Lecture 2: Primer on Statistical Analysis (cont.)

- •hypothesis testing

Lecture 3: Primer on Statistical Analysis (cont.)

- •ANOVA

Lecture 4: Primer on Statistical Analysis (cont.)

- •regression

Why should you attend:

As stated in Q8, the ICH guidance document on pharmaceutical development, drug product should meet its intended product performance as well as meet the needs of patients. Although the strategy for pharmaceutical development may vary from company-to-company and/or from product-to-product, a systematic approach defined by quality by design (QbD) principles is encouraged.

Further guidance and policies have been provided to explain how the QbD approach should be integrated into the pharmaceutical quality system including process design, qualification, continued process verification, risk management, and validation.

Day Two

Lecture 1: Foundational Requirements for QbD Studies

- • setting specifications
- • Measurement Systems Analysis (MSA) for assays

Introduction to Design of Experiments (DOE)

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

Screening Designs - Identifying Critical Process Parameters

- • factorial designs

Lecture 2: Screening Designs - Identifying Critical Process Parameters (cont.)

- •fractional factorial designs
- •D optimal

Lecture 3: Response Surface Designs - Develop Functional Relationships and Establish Design Space

- •Addition of center points
- •Central Composite Designs (CCD)
- •I optimal designs

Lecture 4: Utilizing Systematic Understanding from QbD Studies

- •presenting results
- •developing a control plan as part of a risk management strategy
- •process control and capability

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

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