




2-day In-person Seminar:

# Applied Statistics for FDA Process Validation

-  San Diego, CA
-  April 20th & 21st, 2017
-  9:00 AM to 6:00 PM



## Richard (Rick) K. Burdick

Richard (Rick) K. Burdick is an Emeritus Professor of Statistics, Arizona State University (ASU) and former Quality Engineering Director for Amgen, Inc. for 10 years. He taught at ASU for 29 years at all levels including undergraduate business students, MBAs, Master of Statistics students, and doctoral candidates in both business and engineering. He received numerous teaching awards and taught a variety of courses for adult learners.

### 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.

## 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.*



## 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

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

- statistical intervals and hypothesis testing

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

- statistical intervals and hypothesis testing
- ANOVA

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

- regression
- run charts

### Day Two

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

- setting specifications
- analytical methodology

#### Stage 1 - Process Design

- steps to DOE
- screening designs

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

- response surface designs
- establishing a strategy for process qualification

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

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

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

- statistical process control
- process capability

#### Who Will Benefit:

- 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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### 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**