




2-day In-person Seminar:

## Design of Experiments and Statistical Process Control for Process Development and Validation

-  Philadelphia, PA
-  November 17th & 18th, 2016
-  9:00 AM to 6:00 PM



### Dr. Steven Kuwahara

*Founder & Principal, GXP Biotechnology, LLC*

Dr. Steven Kuwahara, Ph.D. is the founder and Principal of GXP BioTechnology LLC, a consulting firm that works in the areas covered by the GLP and GMP of drugs, biologics, and nutraceuticals. Steve has over 30 years of experience in supervising quality control laboratories, including an animal testing facility, and in performing GLP and GMP audits of internal and external testing laboratories. Steve has participated in the development of drugs and biologics through all phases of clinical research and final product production.

### Overview :

This course will present the procedures that must be used in the application of DOE and SPC to the development, design and monitoring of manufacturing and testing processes. A practical approach with case studies and examples will be used, with theoretical information introduced only when necessary to understand an experiment. Examples from real processes and testing procedures will be used to present the student with examples that will be directly applicable to their work.

### Who will benefit:

- Directors
- Managers
- Supervisors
- Lead workers in Process Development
- Manufacturing
- Regulatory Affairs

### Price

(Without Stay) Price: **\$1,495.00**

*(Seminar for One Delegate)*

(With Stay) Price: **\$1,895.00**

*(Seminar for One Delegate)*

Register for 5 attendees (With stay)







**Price: \$4,833.00** You Save: \$4,642.0 (49%)\*

~~\$9,475.00~~

**ENROLL**

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

### Seminar Pricing Includes (With Stay)

-  Samsung Galaxy Tab 4
-  2 Days Stay
-  Pick-up and Drop Facility (Nearest Airport)
-  Break-Fast and Lunch
-  High Tea
-  Pack of 3 Webinars will be provided which has been done in the past on similar subject

## Agenda:

### Day One

#### Dietary Design of Experiments

##### Lecture 1 : Introduction

- Input/Output, CPP and CQA, what are they?
  - Defining the CPP and CQA for a process
  - Defining the design space
- Snedecor's F-test and ANOVA

##### Lecture 2 : One Level, One Factor Designs. Simple Comparisons.

- The simplest form of the full F-test.
- A one factor ANOVA with multiple treatments
  - The least significant difference (LSD)
- The use of blocking in a one factor experiment.

##### Lecture 3 : Two-Level Multi-factorial Design

- Description of the experiment
  - Conversion to the standard form with results of testing
- Definition of an Orthogonal Array
- Interactions in the array
- Effects (Contrasts) in the array.

##### Lecture 4 : Extracting Information from the Experiment

- Use of a Half-normal Plot.
- What about the second set of test data?
- Using the effects for a Pareto Chart
- Interpreting the interactions for process design

#### Why should you attend:

Any pharmaceutical worker who performs, supervises or reviews manufacturing or testing processes needs to understand the relationships among the process parameters and be able to monitor the performance of processes and test methods. This is particularly true for the worker in Quality Control and Quality Assurance as the recent FDA guidance document on Process Validation has assigned the responsibility for reviewing and interpreting DOE and SPC studies to the Quality Unit.

### Day Two

#### Statistical Process Control

##### Lecture 1 : Shewhart Charts for Variable Data

- Classical X-bar and R-bar charts
- Estimating control limits for early studies
- Significance of events using the "Western Electric Rules."

##### Lecture 2 : Shewhart Charts for Attribute Data Especially Counts.

- p and np charts for attributes.
  - Handling binomially distributed data.
- c charts and u charts for non-conformities
  - Handling binomially distributed data.

##### Lecture 3 : Considerations from Shewhart Charts

- Rational subgroups.
- Setting the process capability indices.
- Coupling as a problem

##### Lecture 4 : Other Types of Charts Related to Shewhart Charts

- Moving average chart
- Exponentially weighted chart
- CUSUM chart



### 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
- 2 Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
- 3 PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
- 4 Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

### What You will get

- 1 Learning Objectives
- 2 Participation certificates
- 3 Interactive sessions with the US expert
- 4 Post event email assistance to your queries.
- 5 Special price on future purchase of web based trainings.
- 6 Special price on future consulting or expertise services.
- 7 Special price on future seminars by GlobalCompliancePanel.
- 8 Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
- 9 Networking with industry's top notch professionals

### 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**