Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Statistical Methods for Design Verification, Process Validation, and Process Control

Houston, TX

December 8th & 9th, 2016

9:00 AM to 6:00 PM

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: $4,642.00 (49%)*

~~$9,475.00~~

ENROLL

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

John N. Zorich

Statistical Consultant & Trainer,
Ohlone College & SV Polytechnic

John N. Zorich, has spent 35 years in the medical device manufacturing industry; the first 20 years were as a "regular" employee in the areas of R&D, Manufacturing, QA/QC, and Regulatory; the last 15 years were as consultant in the areas of QA/QC and Statistics. His consulting clients in the area of statistics have included numerous start-ups as well as large corporations such as Boston Scientific, Novellus, and Siemens Medical. His experience as an instructor in statistics includes having given 3-day workshop/seminars for the past several years at Ohlone College (San Jose CA), 1-day training workshops in SPC for Silicon Valley Polytechnic Institute (San Jose CA) for several years, several 3-day courses for ASQ Biomedical, numerous seminars at ASQ meetings and conferences, and half-day seminars for numerous private clients.

Overview :

This 2-day seminar provides a 1-day introduction to the statistical tools used to analyze Design Verification data and Process Validation results. The entire 2nd day is spent on Statistical Process Control and Process Capability Indices. The goal of the 1st day is to help the student understand how to choose statistical methods and sample sizes, and to correctly interpret the results. The goal of the 2nd say is to explain how to monitor a validated production process, using tools that can also help improve product quality.

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

STATISTICAL ANALYSIS OF DESIGN VERIFICATION DATA AND PROCESS VALIDATION RESULTS

Lecture 1 : Regulatory Requirements

Lecture 2 : Basic vocabulary and concepts

Lecture 3 : How to interpret Linear Regression Correlation coefficients

Lecture 4 : How to calculate Confidence Intervals (for proportions & for measurements)

Lecture 5 : How to perform and interpret simple t-Tests of Statistical Significance, including consideration of "p-values" and sample-size, and the concepts of "superiority" and "non-inferiority".

Lecture 6 : Calculation of confidence and reliability (= % in-specification) for Normally distributed data (K-tables)

- attribute data
- normally-distributed variables data (including Tests of Normality)
- non-normal data (including Transformations to Normality)
- non-normal data that cannot be transformed to normality

Day Two

STATISTICAL PROCESS CONTROL (SPC) AND PROCESS CAPABILITY INDICES

Lecture 1 : What is Quality?

Lecture 2 : Process Variation

Lecture 3 : What is Statistical Process Control?

Lecture 4 : Basic Types of Control Charts and how to construct them: XbarR, XbarS, XmR, P, and U.

Lecture 5 : Control Limits: Calculation & Re-calculation

Lecture 6 : Out of Control: How to Detect It, & What to Do if Detect It?

Lecture 7 : Sample Issues: Random, Sub-grouping, & Sample Size

Lecture 8 : Capability Indices and how to calculation them

Lecture 9 : Non-normal Data, and its impact on SPC.

Lecture10: How to Initiate & Implement a Successful SPC Program

Why should you attend:

All design and/or manufacturing companies perform design verification and/or process validation studies. A clear understanding of relevant statistical principles and statistical methods ensures that such studies are efficient and accurate. In addition, all validated processes must be monitored to ensure their continued suitability (per the FDA).

The statistical methods used for such activities are easily misused when their fundamental principles are not well understood. Mistakes in usage can lead to new products being launched that should have been kept in R&D; or, conversely, can lead to erroneously deciding to not launch a new product.

Areas Covered in the Session:

- FDA, ISO 9001/13485, and MDD requirements
- Statistically valid rationales for sample sizes
- The interpretation of statistical significance and statistical non-significance
- The impact of normality and non-normality
- Tests of Normality
- Transformations to Normality
- Concepts of "Confidence" and "Reliability" (a.k.a., %-in-specification)
- Concepts of "Quality" and "Variability" and "Process"
- Risk management

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
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What You will get

1. Learning Objectives
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7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
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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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