Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Applied Statistics, with Emphasis on Verification, Validation, and Risk Management, in R&D, Manufacturing, and QA/QC

Chicago, IL

November 10th & 11th, 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: $4,642.0 (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.

Overview :

The 2-day seminar explains how to apply statistics to manage risk in R&D, QA/QC, and Manufacturing, with examples derived mainly from the medical device design/manufacturing industry. The flow of topics over the 2 days is as follows:

- ISO standards and FDA/MDD regulations regarding the use of statistics.
- Basic vocabulary and concepts.
- Statistical Process Control
- Statistical methods for Design Verification
- Statistical methods for Product/Process Qualification
- Metrology: the statistical analysis of measurement uncertainty, and how it is used to establish QC specifications
- How to craft "statistically valid conclusion statements" (e.g., for reports)
- Summary, from a risk management perspective

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

Lecture 1 : Regulatory Requirements

Lecture 2 : Vocabulary and Concepts

Lecture 3 : Confidence Intervals (attribute and variables data)

Lecture 4 : Normality Tests and Normality Transformations

Lecture 5 : Statistical Process Control (with focus on XbarR charts)

Lecture 6 : Confidence/Reliability calculations for Proportions

Lecture 7 : Confidence/Reliability calculations for Normally distributed data (K-tables)

Lecture 8 : Process Capability Indices calculations (Cp, Cpk, Pp, Ppk)

Day Two

Lecture 1 : Confidence/Reliability calculations using Reliability Plotting (e.g., for non-normal data and/or censored studies)

Lecture 2 : Confidence/Reliability calculations for MTTF and MTBF (this typically applies only to electronic equipment)

Lecture 3 : Statistical Significance: t-Tests and related "power" estimations

Lecture 4 : Metrology (Gage R&R, Correlation, Linearity, Bias , and Uncertainty Budgets)

Lecture 5 : QC Sampling Plans (C=0 and Z1.4 attribute AQL plans, and alternatives to such plans) including OC curves, AQL vs. LQL/LTPD, AOQL, and calculation of acceptance rates.

Lecture 6 : Statistically valid statements for use in reports

Lecture 7 : Summary and Implementation Recommendations

Why should you attend:

Almost all design and/or manufacturing companies evaluate product and processes either to manage risks, to establish product/process specifications, to QC to such specifications, and/or to monitor compliance to such specifications.

The various statistical methods used to support such activities can be intimidating. If used incorrectly or inappropriately, statistical methods can result in new products being launched that should have been kept in R&D; or, conversely, deciding to not launch a new product because of incorrectly calculated product reliability or process capability. In QC, mistakenly chosen sample sizes and inappropriate statistical methods may result in product being rejected that should have passed, and vice-versa.

Areas Covered in the Session:

- FDA, ISO 9001/13485, and MDD requirements related to statistical methods
- How to apply statistical methods to manage product-related risks to patient, doctor, and the designing/manufacturing company
- Design Control processes (verification, validation, risk management, design input)
- QA/QC processes (sampling plans, monitoring of validated processes, setting of QC specifications, evaluation of measurement equipment)
- Manufacturing processes (process validation, equipment qualification)

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Applied Statistics, with Emphasis on Verification, Validation, and Risk Management, in R&D, Manufacturing, and QA/QC

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

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