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

Houston, TX

March 26th & 27th, 2019

9:00 AM to 6:00 PM

Price

Price: **$2,000.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees

Price: **$10,000.00**

Register for 10 attendees

Price: **$20,000.00**

ENROLL

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

John Zorich

Statistical Consultant & Trainer,

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

Overview :

The 2-day seminar explains how to apply statistics to manage risks and verify/validate processes 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, including distributions such as binomial, hypergeometric, and Normal, and transformations into Normality.
- Statistical Process Control
- Statistical methods for Design Verification
- Statistical methods for Product/Process Qualification
- Metrology: QC Sampling Plans the statistical analysis of measurement uncertainty, and how it is used to establish QC specifications

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)

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)

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 you should attend:

Almost all design and/or manufacturing companies evaluate product and processes either to manage risks, to validate processes, 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, new products not being launched that, if analyzed correctly, would have met all requirements.

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Applied Statistics, with Emphasis on Verification, Validation, & 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
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1. Learning Objectives
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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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