




2-day In-person Seminar:

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

-  Houston, TX
-  May 4th & 5th, 2017
-  9:00 AM to 6:00 PM



### 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

### 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 : 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 : Statistical Significance: ANOVA calculations
- Lecture 5 : Metrology (Gage R&R, Correlation, Linearity, Bias , and Uncertainty Budgets)
- Lecture 6 : QC Sampling Plans (C=0 and Z1.4 attribute AQL plans, and alternatives to such plans)
- Lecture 7 : Statistically valid statements for use in reports
- Lecture 8 : 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)

### 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
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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**