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EVENTS LIST

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

Date : Feb 14, 2018 - 09:00 AM - Feb 15, 06:00 PM

Event URL : http://www.sfbayeventslist.com/events/applied-statistics-with-emphasis-on-verification-validation-sample-size-and-in-1516036328

Organizer : GlobalCompliancePanel

Venue : DoubleTree by Hilton Houston Intercontinental Airport

Location : 15747, JFK Blvd
Houston, TX, USA, ZIP: 77032

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: 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 recommendations

Why should you 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. In QC, mistakenly chosen sample sizes and inappropriate statistical methods may result in purchased product being rejected that should have passed, and vice-versa.

This seminar provides a practical approach to understanding how to interpret and use more than just a standard tool-box of statistical methods; topics include: Confidence intervals, t-tests, Normal K-tables, Normality tests, Confidence/reliability calculations, Reliability plotting (for extremely non-normal data), AQL sampling plans, Metrology (i.e., statistical analysis of measurement uncertainty), and Statistical Process Control. Without a clear understanding and correct implementation of such methods, a company risks not only significantly increasing its complaint rates, scrap rates, and time-to-market, but also risks significantly reducing its product and service quality, its customer satisfaction levels, and its profit margins.

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)

Who will benefit:

- QA/QC Supervisor
- Process Engineer
- Manufacturing Engineer
- QC/QC Technician
- Manufacturing Technician
- R&D Engineer

Day 1 Schedule

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 2 Schedule

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

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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

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. He creates and sells formally-validated statistical application spreadsheets that have been purchased by more than 75 companies, world-wide.

Please contact Marilyn Turner: Phone: +1 929 900 1853 Email: marilyn.turner [a] nyeventslist.com for registrations

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