

John N. Zorich, Jr.

Zorich Technical Consulting & Publishing

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CORE COMPETENCIES related to statistics in R&D and Manufacturing

- Extensive professional experience in Statistics
- Well-versed in use of MSEXcel for statistical applications
- 20+ years hands-on experience in R&D, Manufacturing, Product Support, and QA/QC

KEY ACCOMPLISHMENTS related to statistics in R&D and Manufacturing

- Re-developed an R&D IVD product for efficient commercial production, in part by using statistic analysis to redesign raw-material, in-process, and final testing protocols.
- Designed a custom alternative IQC Sampling Plan to replace MilStd105E, resulting in net savings of 7% in QC inspector time for one client, but with no increased risk to customers
- Helped implement an SPC program that resulted in raising CpK's from 0.6 to 1.8 within a year, which allowed going from 100% inspection to sample-monitoring only.

STATISTICAL CONSULTING CLIENTS (and product)

- Caliper Technologies (Mountain View, CA) (IVD lab test equipment and reagents)
- D&D Consulting (Orinda, CA) (510(k) preparation)
- Paracor (Sunnyvale, CA) (sterile, implantable cardiac devices)
- Evera Medical (ex Juva Medical) (Redwood City, CA) (soft-tissue implants)
- IntraBiotics (Mountain View CA) (pharmaceuticals)
- KEMA (Chalfont, PA) (Notified Body, tech-file reviews, for the MDD, IVDD, and AIMD)
- Over 2 dozen other companies, mostly medical, mostly in the SF Bay Area

FORMAL STATISTICAL SEMINARS AND/OR CLASSES (partial list) GIVEN AT

- Abbott Vascular Solutions (ex-Guidant) (thru UC Santa Cruz Extension)
- ASQ Statistics Group, and ASQ Biomedical Group (Santa Clara Valley chapters)
- BC Technology (Santa Cruz, CA)
- Boston Scientific/EPI (Santa Clara, CA)
- Circle Medical (Los Gatos, CA)
- KEMA (the Dutch "notified body")(Lafayette, CA) (for their MDD auditors)
- Novellus (San Jose, CA)
- Ohlone College (San Jose, CA) (off-site training workshops)
- Siemens Medical Solutions (Concord, CA)
- Silicon Valley Technical Institute (San Jose)
- Smith-Kline Diagnostics (San Jose, CA)
- TUV Product Service, USA (for all of their quality systems & medical auditors)

EDUCATION and TRAINING

- BS and MS from the University of California (Botany, with emphasis in chemistry and math)
- ASQ Certified Quality Engineer (since 1996), re-certified 1999, 2002, 2005, 2008
- "Notified Body" auditor for TÜV Product Service (2001-2002) and KEMA (2003 to present)

STATISTICAL APPLICATION SPREADSHEETS designed, developed, and sold by ZTC

- *VARIABLES DATA SPC, and COUNT DATA SPC* -- for corporate-wide SPC efforts
- *C = 0, LQL, ATTRIBUTE SAMPLING PLAN* -- a custom sampling plan
- *RELIABILITY STATISTICS BASICS* -- simplifies standard component reliability calculations
- *RELIABILITY PLOTTING* -- calculates reliability with small samples & non-normal distributions
- *POWER CURVES FOR T-TESTS* -- simplifies calculation of the statistical power of t-tests.
- *GAGE STATISTICS* -- simplifies calculation of bias, correlation, R&R, linearity, guard-banding.