

John N. Zorich, Jr.

Zorich Consulting & Training

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SUMMARY

- Over 30 years in the medical device industry (surgical equipment and in-vitro diagnostics)
- Notified Body Auditor (2001-2002 for TUV Product Service, 2003 to present for (now called DEKRA)
- ASQ Certified Quality Engineer (since 1996), re-certified 1999, 2002, 2005, 2008, 2011
- Specializing in development and implementation of minimalist approaches to Quality Systems compliant with FDA, FDB, Canadian, & EU requirements
- Hands-on experience in R&D, Mfg., Product Support, & QA/QC/RA in medical device industry
- Expertise in Statistics (R&D and Manufacturing)

PROFESSIONAL SKILLS

Quality Systems

- Designing & implementing quality systems in medical device companies

Auditing

- Notified Body Auditor (2001-2002 for TUV Product Service to the MDD, IVDD, Canadian MDR, and related standards; 2003 to present for KEMA/DEKRA, to ISO 9001, ISO 13485, the MDD and the Canadian MDR)
- Over 10 years auditing to FDA/FDB & ISO9001 requirements

Statistics

- Extensive knowledge of basic statistics, such as SPC (statistical process control), sampling plans, reliability statistics (e.g., Reliability Plotting), gage analysis statistics (e.g., Gage R&R), and power calculations
- Extensive experience developing spreadsheets for those statistical applications

Training

- Extensive experience as a trainer in quality systems and statistics

EXPERIENCE as CONSULTANT (1999 -- present), and as a "REGULAR" EMPLOYEE (1979-1999)

- **60+ medical device startups and established firms**, including designers/manufacturers of catheters, robotics, sterile surgical equipment, in-vitro diagnostics, biologics and reagents.
- **Several non-medical firms**, for quality and statistics.

EDUCATION, CERTIFICATIONS, MEMBERSHIPS, PUBLICATIONS

- Authorized (2001-2002) as a "Notified Body" auditor to MDD & IVDD for TÜV Product Service
- Notified Body Auditor to ISO 13485, ISO 9001, MDD & CMDR for KEMA/DEKRA, 2003 to present
- Canadian CMDCAS & ISO13485 certified 2000 (via TUVPS); cert current (via KEMA/DEKRA)
- ASQ Certified Quality Engineer (since 1996), re-certified 1999, 2002, 2005, 2008, 2011
- Taught statistics workshops at SV Tech Institute, ASQ, Ohlone College, & UCSC (ext)
- BS and MS from the University of California (in Botany, with emphasis in chemistry and math)
- Author of: *Reasonable Confidence Limits for Binomial Proportions* (Aug 2010, in MD&DI), and several commercial statistical-application computer spreadsheets.

A much more detailed resume is available on the "about us" page of my website: www.johnzorich.com