

# John N. Zorich, Jr.

## Zorich Technical Consulting & Publishing

Sunnyvale, California (cell) 408-203-8811 <http://www.johnzorich.com> johnzorich@yahoo.com

### SUMMARY

- Over 20 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 KEMA)
- ASQ Certified Quality Engineer (since 1996), re-certified 1999, 2002, 2005, 2008
- 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, to ISO 9001, ISO 13485, 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 CONSULANT (1999 -- present), and as a "REGULAR" EMPLOYEE (1979-1999)

- **50+ 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 Quality Systems Auditor to ISO 13485 & CMDR for KEMA, 2003 to present
- Canadian CMDCAS & ISO13485 certified 2000 (via TUVPS); certification current (via KEMA)
- ASQ Certified Quality Engineer (since 1996), re-certified 1999, 2002, 2005, 2008
- Statistics workshop faculty member 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: "How to Give Prop65 Warnings to Employees" (May 2002, in *Prop65 News*), HazMat65 (a chemical-safety-related commercial computer database), and several commercial statistical-application computer spreadsheets.