

John N. Zorich, Jr.
Zorich Consulting & Training

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SUMMARY

- Over 30 years in the medical device industry (surgical equipment & in-vitro diagnostics)
- Authorized as a "Notified Body" auditor (2001 by TUVPS, 2003 by KEMA (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 FDA/MDD-compliant Quality Systems
- Hands-on experience in R&D, Mfg., Product Support, & QA/QC/RA
- 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 quality system regulations

Statistics

- Extensive knowledge of basic statistics, such as SPC (statistical process control), sampling plans, reliability statistics, 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
- Statistics workshops given at SV Tech Institute, Ohlone College, ASQ, & UCSC(ext)
- QA workshops (ISO 13485 and 21CFR820) given at Ohlone College

WORKING EXPERIENCE (partial list) as a CONSULTANT (1999 -- present)

Medical Device Companies, location, product (and areas of consultation by John Zorich):

- **Access Closure**, Palo Alto CA, implantable (MDD, Statistics)
- **Caliper Technologies**, Mtn. View CA, lab instruments/reagents (ISO9001, Statistics)
- **Caltag Laboratories**, Burlingame CA, in-vitro diagnostic reagents (Quality Systems)
- **Circle Medical Devices**, contract manufacturing, Los Gatos CA (Statistics)
- **Daniel and Daniel Consulting**, Orinda CA (Statistics, Quality Systems development)
- **Duke Empirical**, Santa Cruz CA, design & contract mfg., catheters (MDD, Statistics)
- **Boston Scientific/EPI**, Santa Clara CA, catheters (Quality System auditing; Statistics)
- **FlowCardia**, Sunnyvale CA, catheters (Statistics)
- **Fox Hollow Technologies**, Redwood City CA, catheters (Quality Systems, Statistics)
- **Genemed** South San Francisco, CA (IVD reagents and kits).
- **Hantel Technologies**, Hayward CA (internal auditing)
- **Hoya Medical**, Chino Hills CA (statistical consulting for PMA supplement)
- **Idaho Technology**, Salt Lake City UT, anthrax detection systems (QSystems & Statistics)
- **Juva Medical**, Foster City CA, cosmetic surgical devices (Quality Systems)
- **KEMA/DEKRA**, Concord CA ("Notified Body" auditing to ISO 9001, ISO 13485, MDD, & CMDR)
- **Lumend** Redwood City CA, catheters (QSystem auditing, Sterility, Statistics)
- **Marion Weinreb Associates**, Mill Valley CA (Quality Systems, Auditing, and Statistics)

- **Micrus Corporation**, Mtn. View CA, catheters (MDD, Quality Systems, Internal auditing)
- **Paracor Surgical**, Sunnyvale CA (Quality Systems and Statistics)
- **PowerVision Lens**, Belmont CA (Quality Systems and Statistics)
- **Proteus Biomedical**, Redwood City CA, cardiac devices (Quality Systems)
- **Roberts Consulting & Engineering**, Encinitas CA (Statistics)
- **Siemens Medical Solutions**, Concord CA, radiation systems (GMP, Statistics)
- **SurgRx**, Redwood City CA (active medical devices for tissue sealing)
- **TÜV Product Service**, Santa Clara CA (“Notified Body” Auditing to MDD, IVDD, & CMDR)
- **Zymed Laboratories**, South San Francisco CA, analytical reagents (Internal auditing)

Other Industries:

- **Ampro Computers**, San Jose CA, computer parts (ISO 9001 auditing)
- **Interdynamics**, Brooklyn New York, auto accessories (ISO 9001 auditing, Statistics)
- **Modulus**, San Jose CA, contract electronic component mfg. (ISO 9001/13485 consulting)
- **Specialized Bicycles**, Morgan Hill CA, bicycles and helmets (quality system consulting)

WORKING EXPERIENCE as a “REGULAR” EMPLOYEE

Summary:	<u>20 years "employee" experience in the medical industry</u> <ul style="list-style-type: none"> • 4 years in Mfg / Engineering, and 6 years in R&D • 10 years in Quality / Regulatory
1997-1999	<u>Intuitive Surgical (Mtn. View CA)</u> Robotic surgical instruments --- Quality Systems Manager; Safety Officer
1996-1997	<u>FemRx (Sunnyvale CA)</u> Gynecological surgical instruments --- Quality Assurance Manager; Safety Officer
1992-1996	<u>SmithKline Diagnostics (San Jose CA) (a division of Beckman/Coulter)</u> In-vitro diagnostics --- QC Supervisor; Quality/Reg. Specialist; Safety Coordinator
1990-1992	<u>Biotrack (Mtn. View CA)</u> In vitro diagnostic reagents/instruments --- Process Engineer; Safety Committee Chair
1989-1990	<u>Collagen Corporation (Palo Alto CA)</u> Injectable biologics --- QC Chemistry Lab Supervisor
1983-1989	<u>Monoclonal Antibodies, Inc. (Mtn. View CA)</u> In-vitro diagnostics --- QC Supervisor; R&D Associate Scientist
1981-1983	<u>Helena Laboratories (Beaumont TX)</u> In-vitro diagnostics and laboratory instruments --- Research Development Chemist
1979-1981	<u>Antibodies, Inc. (Davis CA)</u> In-vitro diagnostics --- Manufacturing/QC/R&D Chemist

EDUCATION, CERTIFICATIONS, MEMBERSHIPS, PUBLICATIONS

- Authorized (2001-2002) as a “Notified Body” auditor to MDD & IVDD, for TÜV Product Service
- Authorized (2003-present) as a “Notified Body” Auditor ISO 13485, ISO 9001, MDD, CMDR, for KEMA/DEKRA
- Canadian CMDCAS & ISO13485 certified, March 2000; cert still current (via KEMA/DEKRA)
- ASQ Certified Quality Engineer (since 1996), re-certified 1999, 2002, 2005, 2008, 2011
- (for ASQ) class instructor in statistics, and seminar presenter in quality systems
- BS and MS from the University of California (Botany, with emphasis in chemistry & math)
- Author of: --- Several commercial statistical-application spreadsheets
--- *Reasonable Confidence Limits for Binomial Proportions* (Aug 2010, in MD&DI)