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SUMMARY

- Over 20 years in the medical device industry (surgical equipment and in-vitro diagnostics)
- Authorized as a “Notified Body” auditor (2001 by TUVPS, 2003 by KEMA)
- ASQ Certified Quality Engineer (since 1996), re-certified 1999, 2002, 2005, 2008
- Specializing in development and implementation of minimalist approaches to US/European/Canadian-compliant Quality Systems
- Many years of hands-on experience in R&D, Manufacturing, Product Support, & QA/QC/Regulatory in the medical device industry
- Trainer and consultant in QSR/GMP, ISO13485, and Statistics
- Expertise in applied statistics, including spreadsheet development
- On statistics workshop faculty at SV Tech Institute, ASQ, & Ohlone College, & UCSC (ext)

PROFESSIONAL SKILLS

Quality Systems

- Designing & implementing quality systems in medical device companies in order to meet requirements for CE marking, Canadian licensing, ISO9001/ISO13485 registration, QSR (i.e., FDA GMP / 21CFR820) compliance, and California State FDB Medical Manufacturer Licensing. Specializing in creating systems that focus on minimizing the amount of paperwork, training, and disruption to R&D and Manufacturing while still meeting regulatory requirements.

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, 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 (e.g. Reliability Plotting), gage analysis statistics (e.g., Gage R&R), and power calculations
- Extensive experience developing spreadsheets for those statistical applications

Trainer / Instructor

- Extensive experience as a trainer in quality systems and statistics
- Statistics workshops given at SV Tech Institute, Ohlone College, ASQ, & UCSC(ext)

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)
- **Adiana**, Redwood City CA, catheters (GMP, MDD)
- **Avantec Vascular**, Sunnyvale CA, catheters (GMP/MDD auditing)
- **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)
- **Idaho Technology**, Salt Lake City UT, anthrax detection systems (QSystems & Statistics)
- **Juva Medical**, Foster City CA, cosmetic surgical devices (Quality Systems)
- **KEMA**, Lafayette 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)
- **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 manufacturing (Quality)
- **Specialized Bicycles**, Morgan Hill CA (performance bicycles and helmets)

WORKING EXPERIENCE as a "REGULAR" EMPLOYEE

Summary: 20 years "employee" experience in the medical products industry

- 4 years in Manufacturing / Process Engineering
- 6 years in R&D
- 10 years in Quality / Regulatory

1997-1999

Intuitive Surgical (Mtn. View CA)

Development and manufacture of robotic surgical instruments

Quality Systems Manager; Safety Officer

- develop and implement quality system
- internal audits, interface with external regulatory agencies
- develop, implement, and manage safety program
- wrote and obtained clearance on 510(k) for stereoscope

- 1996-1997 FemRx (Sunnyvale CA)
Development and manufacture of gynecological surgical instruments
Quality Assurance Manager; Safety Officer
- develop and implement quality system
 - internal audits, interface with external regulatory agencies
 - develop, implement, and manage safety program
 - manage all QC functions, from raw material testing to finished product
 - manage all QA functions, including review and release of finished product, MRB, and customer complaints investigations
 - wrote and obtained clearance on 510(k) for resectoscope
- 1992-1996 SmithKline Diagnostics (San Jose CA) (a division of Beckman/Coulter)
Development and manufacture of in-vitro diagnostics
QC Supervisor; Quality & Regulatory Specialist; Safety Coordinator
- develop and implement quality system applicable to new business unit
 - internal audits, interface with external regulatory agencies
 - manage safety program
 - manage all QC functions, from raw material testing to finished product
 - Involved in all QA functions, including review and release of finished product, MRB, and customer complaint investigations
- 1990-1992 Biotrack (Mtn. View CA)
Development and manufacture of in vitro diagnostic reagents and instruments
Process Engineer; Safety Committee Chair
- develop/document manufacturable processes for R&D projects
 - manufacture of reagents
 - manage safety committee
 - member of product transfer group
- 1989-1990 Collagen Corporation (Palo Alto CA)
Development and manufacture of injectable biologics
QC Lab Supervisor
- manage the testing and release of raw materials, in process components, and final product.
 - member of document review board
- 1983-1989 Monoclonal Antibodies, Inc. (Mtn. View CA)
Development and manufacture of in-vitro diagnostics
QC Supervisor; R&D Associate Scientist
- manage the chemical testing and release of raw materials, in process components, and final product.
 - lead scientist on development of new products
 - responsible for transfer of products to manufacturing department
 - responsible for product support and complaint handling
- 1981-1983 Helena Laboratories (Beaumont TX)
Development and manufacture of in-vitro diagnostics and laboratory instruments
Research Development Chemist
- development of antibodies for radio-immunoassays
 - development of new RIA products

1979-1981

Antibodies, Inc. (Davis CA)

Development and manufacture of in-vitro diagnostics

Manufacturing/QC/R&D Chemist

- manufacture, QC, and packaging of RIA kits
- development of new RIA products

EDUCATION, CERTIFICATIONS, MEMBERSHIPS, PUBLICATIONS

- Authorized (2001-2002) as a Notified Body Auditor to MDD/IVDD/CMDR for TÜV Product Service
- Notified Body Quality Systems Auditor for KEMA, 2003 to present, to ISO 9001, ISO 13485 & CMDR
- ASQ Certified Quality Engineer (since 1996), re-certified 1999, 2002, 2005, 2008
- Canadian CMDCAS & ISO13485 certified, March 2000; certification still current (via KEMA)
- BS and MS from the University of California (Botany, with emphasis in chemistry & math)
- Author of:
 - ✓ Several commercial statistical-application spreadsheets
 - ✓ *How to Give Prop65 Warnings to Employees* (May 2002, in *Prop65 News*)
 - ✓ HazMat65 (chemical-safety-related database computer program)
 - ✓ Complete set of quality system procedures suitable for a medical-device start-up