Director of Quality

AREAS OF EXPERTISE

- **21 CFR Parts 801 803 806 807 809 820 830**
- **Aseptic audits & Aseptic operations**
- **CAPA**
- **CE-Marking**
- **Change control programs**
- **Cleaning Validation**
- **Complaint Handling**
- **Compliance Master Plan remediation**
- **Design Control**
- **Design Dossier Reviews**
- **Deviation Handling**
- **Documentation Systems**
- **Equipment qualification**
- **Facilitating responses to FDA 483s and Warning Letters**
- **Failure Investigation and OOS**
- **FDA's cGMP**
- **GLP Laboratory**
- **Health Canada Device Regulations**
- **ISO 13485:2016, QMS**
- **ISO 14644 series, Controlled Enviroments**
- **ISO 14971:2012,**
- **ISO 60601 series, Electrical Safety**
- **ISO 9001:2015**
- **Lean Manufacturing and Six-sigma**
- **MDD/IVDD requirements**
- **MDR remediation**
- **MDSAP mock audits and implementation**
- **MHLW Ministerial Ordinance no. 169**
- **Mock FDA inspections**
- **Pharmacy Compounding Audits**
- **Post Market surveillance and Vigilance programs**
- **Pre-Approval and Readiness Assessments**
- **Process Improvement**
- **Process Validation**
- **Product Registrations**
- **QMS remediation**
- **QSIT Mock Inspections**
- **Quality Assurance, Audits, and Engineering**
- **Quality Systems and Systems-based Implementation & Auditing**
- **Regulatory Compliance**
- **Risk Management / hazard analysis**
- **Root Cause Analysis**
- **Sterility Assurance**
- **Supplier Quality**
- **Supplier Quality Assurance & Agreements**
- **Technical File Compilation**
- **Training Provided for cGMPs, GCP, GLP**

INTRODUCTION

Consultant has thirty-nine years of industry experience in the Global Quality Movement and was recognized as one of the nineteen most competent Quality Practitioners in the world in 1999. Specialized in creating, operating and assessing quality assurance and certifying systems for manufacturers and service providers. Ability to employ a variety of quality methodologies required to support international technical and regulatory requirements. A globally skilled international Quality veteran and highly effective leader. Author of classic best-selling texts of the quality field, one continuously in print since 1988. Former MBNQA US National Quality Award examiner. An expert auditor in the following areas: Certified Notified Body Medical Device Examiner and CE Marking Assessor, CMDCAS Certified, Certified, ISO 13485:2016 trainer. Certified to the following standards: QSR including 21 CFR 801, 803, 806, 807, 809, 820 and 830, ISO 13485:2016, MDD 93/42/EEC and IVD 98/79/EC, ISO 9001:2015, and CMDCAS.

REGULATORY SUMMARY

- Experience with US, Canada and EU medical device regulations, developments and trends including Pacific Rim and Latin America country product registration. International medical device product registrations for global projects from around the world, including:
  - Canada, Health Canada for CMDR / CMDCAS / CAMCAS
  - EU CE notified body marking for class II and class III products
  - Brazil ANVISA & InMetro
  - Australia TGA
  - China and South America; most countries
  - China SFDA
  - Mexico Secretaria de Salud
  - Russia device registration and Gost Mark
  - Japan MGLW. DMAH, MAH and registration of foreign manufacturers
- Internal auditor for J&J, Roche, Syncardia, Direct Flow Medical and others.
- Global exposure, having physically assessed companies and products in more than 29 countries.
- US-FDA and foreign device listing and establishment registration for US and foreign entities.
- Submission of technical files and product dossiers, pre-market notification and device licensing submissions. Canadian Licenses, amendments and Name Branding, FDA 510(k) submittals & PMA development, GMP, EU notified body submission. MDR in the EU, to the USFDA, and regulatory bodies.
- Obtaining and updating USFDA Certificates to Foreign Government (CFG) and certificates of Exportability (COE), EU notified body CE certificates, Apostilles, and foreign consularizations.
- Implemented and managed a European Authorized Representative (EC REP) and have been a US FDA US Agent and US Correspondent for foreign manufacturers.
- Brand Naming and Own Brand Labeling (OBL) for nameplating another OEM's product as our own. Have interfaced with many suppliers, Health Canada, BSI for CE OBL and with UL for Multiple Listing.
- Working and General knowledge of regulatory guidelines including cGMPs, GLPs, GCPs, EPA, UL/cUL, ETL, cGTP and others.
- Interface with project teams to assure that the goals set by the team are consistent with relevant governmental requirements, including EU, US, Canada, and Pacific Rim.
- Keep abreast of proposed regulations affecting product initiatives.
- Identify specific regulatory actions and accountabilities for product development projects.
- Provide regulatory requirements to team members
- Responsible to interpret government medical device regulations assuring that partners meet their contractually agreed to quality commitments. Often involved in contract development.

QUALITY SUMMARY

- Extensive experience in minimally invasive surgery MIS, laser surgery and compliance.
- Implementation, auditing, certification, teaching, and maintenance of ISO 13485:2012, ISO 9001:2015, 21CFR8XX cGMPs, MDD 93/42/EEC, TL, QS, TS, and several other standards.
- Enterprise Quality Management systems: Exposure with several EQM Quality modules from different enterprise systems including Mapics, SAP, Oracle, Made2Manager, MasterControl, LotusNotes, Deltek, TrackWise, Made2Manage, Metric Stream, Quickbooks, EtQ, MRP2, DataMyte, Cebos, Intelex, Syntex, TipQA, PowerWay, Dyadem, Pilgrim, EwQMS, Compuware QACenter, 2020, I3QA, IQS, Plex, AssurX, CATSWeb, Lillysoftware, CDC Factory, and others.

- Protocols and testing for Electrical IEC 60601 third edition compliance for electrocautery, cables and patient warming systems. UL, ETL, Intertek, TUV and other product safety listings. Special in-depth experience in -2-18 and -2-35.
- Coordinate Tripartite testing and certification (vivo and vitro), sterilization records, receive microbiology audits, quarterly and bioburden testing, gamma sterilization validation via AAMI/ANSI/ISO 11137, accelerated aging and shelf life studies, contact plate inoculation and incubation, particle counting, and implemented an ISO Class 8 clean room. Have worked with Toxicon, NAAMSA and BSI.
- Coordinate gamma contract sterilization (FTSI) to 10^-6 SAL. Working knowledge of steam, ethylene oxide gas (EtO), electron beam (E-beam). Experience in sterile (aseptic) filtration.
- Achieved part 11 electronic document control compliance. Established and maintained an electronic document control center for drawings, specifications, SOP's, work instructions, IFU's and external documentation. IFU development and team review.
- Created, updated FMEAs under ISO 14971 risk management, Hazard Analysis per Annex C, Mil-STD-1629, AIAG FMEA, Fault Trees and other risk methods for Hazard Based Safety Engineering.
- Supplier Audits for global Contract Manufacturing with Chinese, Canadian & US remote contract manufacturing. First article and pre-production activities including remote release. Monitored and issued report cards for vendor quality.
- Perform process and design validation. Implement process controls, SPC, Cpk, Cp, Ppk.
- Drive cost savings and efficiency improvements and meet financial goals. Contributed indices to a Balanced Scorecard.
- Key member for maximizing return on technology investments and sales strategies
- Product release - commercial, device and investigational materials. Approve DHR
- Maintain and oversee the development of departmental Standard Operating Procedures, Quality System Regulation (QSR) manual, etc.
- Implementing Validated FDA UDI Requirements, Barcode - Automatic identification data capture (AIDC) technology, BARTENDER software experience version 10.1 SR4 (Seagull Scientific), Direct Marking – laser etching of GS1 DataMatrix, GUDID Data Submission (through HL7 SPL) GS1 issuing agency, Device labels meeting 21CFR 801, 820 and 830, Labeling per EU 23/42/EEC Annex 1 essential requirement 13, Representation of UDI in AIDC Format, IFU's – statutory compliant and eIFUs, Device Identifier (DI), Production Identifiers (PI)

WORK EXPERIENCE

1987 – Present
Industry Consultant
Duties:
- Auditor for Numerous Registrars of Quality Management Systems. BSI, SGS, UL, UL/DQS, Moody, AOQC, CRS and KEMA. Designed and piloted a QMS at a single site, then expanded the program company wide.
- Reliability engineering consultation to Medical, Automotive, Military and Aerospace industries.

1986 – Present
Quality Council of Indiana
Editor-In-Chief of the Assurance Dictionary Series and Author
Duties:
- Published by the Quality Council of Indiana (QCI), formerly published by the ASQ Quality Press. Edit dictionaries and Manage editorial board representing automotive, aerospace, other industrial and medical device affiliates and organizations. Coauthored "Inside the Baldrige Award" Quality Press

1993. "RAM Dictionary" has been continuously in print for 29 years and is considered a classic text of the quality field. "Quality Dictionary" has been continuously in print for 18 years and had more than 900 printings for facility acquisition, divestiture, technology transfer, product launch and discontinuance, regulatory compliance and agency interface.

08/01/2006 – 09/29/2007
Genicon
Quality Manager
Duties:

- Designed, manufactured and distributed Minimally Invasive Surgical (MIS) USFDA Class I, II, and III. Trocars, cannulae, monopolar and bipolar electrocautery, laparoscopes, endoscopes, generators, anti-fog, irrigation, suction, pumps, medical video, carts, sterilization trays, reusable and disposable components. EO and gamma sterilization. IQ, OQ, PQ.
- Process and design validation. Risk Analysis. Performed and achieved 510(k) for class II devices. Developed PMA submittal for an endoscopic stomach band FDA class III. Supplier management. Achieved worldwide registrations.

05/01/1997 – 12/31/2003
Underwriters Laboratories Inc., Orlando, FL
Contractor, Quality Registration Department, Lead Auditor
Duties:

- Lead Auditor activities and responsibilities including defining scope of assessment, planning and managing audit, recording and reporting audit results to comply with 3rd party Registration to Quality Systems Standards, such as QS9000, ISO9000, EN46000, VDA 6.1, TL 9000 and the Chrysler Dealer Assessment Program. Lead Auditor Qualifier. Qualified Medical Device, TL and VDA assessor. QS Certification renewal planned for August 2001.

1999 – 2001
Underwriters Laboratories, S.R.L., Buenos Aires, Argentina, South America
General Manager
Duties:

- Founded and ran a foreign subsidiary. Successfully created a new company, running now for 17 years and currently flourishing, Foreign Government Certified and Nationally Recognized subsidiary despite adverse economic and social circumstances. Achieved objectives of national staffing in a shorter time, with the least confusion and least expense than any prior UL Subsidiary, as a first independent UL subsidiary on the continent.
- Opened and developed a UL subsidiary in Argentina. Achieved ISO 65 accreditation, foreign government recognition of the subsidiary as a product certifier, government approval of an MOU with UL Inc., and hired and began training a local national replacement, all in less than a year. Services developed included Product Certification Engineering Services including UL "S" Mark and UL "AR" Mark. Achieved and maintained ISO/IEC Guide 17065 CO accreditation via audits from the Organization for Argentine Accreditation, as well as official published recognition of the subsidiary with regulatory authorities in the Argentine Government "Lealtad Comercial". Issued CB Style certificates. Developed and qualified a local test lab to ISO/IEC Guide 17025, local coverage for product certification, and the third-party test data program. Qualified local client labs under the Client Test Data Program. Provided Quality Registration System services for UL Inc. Achieved ISO/IEC Guide 17020 intent with CB scheme inspections. Quality and Environmental Management System Assessments and international standards including QS, HACCP, ISO 9000 and 14000, TL and Medical Devices (EN46000). Represented UL Inc. for UL Listing Service, and Component Recognition Service. Offered Source Verification and Inspection Services (CITS) and factory inspections. Facilitated

Argentinean UL Clients Seeking International Safety Certifications from foreign testing agencies involving IEC standards and the Certification Body (CB) Scheme. While at ULA, was a CITEL Representative for the Organization of American States "OAS" for the telecommunications Industry in perhaps 10 meetings and helped negotiate the first MOU's with Brazil for recognizing the UL mark.

1995 – 1996
Schwartz Electro Optics, Orlando, FL
Director of Quality
Duties:

- Corporate officer for a dermatological and military laser designer and manufacturer.

1992 – 1995
Coleman Research, Orlando, FL
Quality Engineer
Duties:

- Classified military contract work in a Nuclear Weapon reuse program for the Ballistic Missile Defense Office Hera project at White Sands Missile Range, Huntsville-Alabama, New Mexico and Orlando, Florida.

1990 – 1992
Walt Disney World, Lake Buena Vista, FL
Staff Reliability Engineer
Duties:

- Reliability and Quality Engineer certifying vehicles and ride control systems for Gravity Kinetic Roller Coaster Vehicles, Grand Prix vehicles, Trolley Cars, Flume Ride Vehicles, River Rafts and Parasail Airplanes.

1983 – 1986
Burroughs Corporation World Headquarter, Detroit, MI
Project Manager of Reliability
Duties:

- Corporate officer in charge of reliability programs and product certification for more than 2100 product lines.

1979 – 1983
Lynch Communication Systems and Pitney Bowes Corporation
Reliability Engineer, Purchasing Department
Duties:

- Reliability programs, product certification, supplier quality controls for many telecommunications, postage meter, photocopier, mailing system, paper sorter and other related product lines.

EDUCATION

University of Nevada
Bachelor of Science: Physics, Math and Spanish

LANGUAGES

- Fluent in Spanish
- Trained in French, German, Japanese, Hebrew, and Russian

ORGANIZATIONAL AFFILIATIONS

- American Society for Quality (member since 1981), Audit, Food and Drug, Biomedical, Automotive, Aerospace and Software Divisions, Senior Member
- Quality Council of Indiana, Member, Author
- National Quality Library, Founder
- Hurricane Preparedness Certification Committee: NSFHP – 2006, Founder, Chair

PROFESSIONAL CREDENTIALS

- CMDCAS Certified by Health Canada number: M-2062
- Certified Bar Coding Professional (In Progress)
- European Certified Medical Device Examiner through Notified Bodies BSI, UL/DQS, SGS
- European Notified Body Certified to do MDD CE Marking Assessments through BSI, SGS
- Accredited Registrar Medical Device Auditor and Certified ISO assessor.
- German Certified VDA Lead Auditor
- Certified TL 9000 3rd edition Auditor
- Certified QS 9000 Auditor
- Lean Manufacturing Champion experience
- Current ASQ certificates, (1 = under renewal, 2 = perpetual) [In 2001, the world's most ASQ Certified person.]
- Certified Pharmaceutical GMP Professional, 59, CPGP, since 2009
- Certified Biomedical Auditor, 58, CBA, renewed since 2001
- Certified Quality Auditor, 434, CQA, renewed since 1988
- Certified Manager of Quality/Organizational Excellence, 265, CMQ-OE, renewed since 1992
- Certified Reliability Engineer, 1565, CRE, renewed since 1982
- Certified Quality Engineer, 11147, CQE, renewed since 1984
- Certified HACCP Auditor, 59, CHA, renewed since 2000
- Certified Software Quality Engineer, 136, CSQE, renewed since 1995
- Certificate in Quality Improvement, 43, CQIA, since 2001
- Certificate in Quality Technology, 10079, CQT, since 1995
- Certificate in Mechanical Inspection, 2033, CMI, since 1989
- Certificate in Calibration Technology, 48, CCT, renewed since 2002
- Certificate in Six Sigma, Yellow Belt, 287, CSSYB, since 2015
- Certified ISO 13485:2016 trainer
- Certified to the following standards: QSR including 21 CFR 801, 803, 806, 807, 809, 820 and 830
- Certified in ISO 13485:2016
- Certified in MDD 93/42/EEC and IVD 98/79/EC
- Certified in ISO 9001:2015
- Certified in CMDCAS

NEW PRODUCT DEVELOPMENT STANDARDS COMPLIANCE EXPERIENCE

- 21CFR's 801, 803, 806, 807, 820, and 830; ISO13485:2012 (:2003, 13486/88), European MDD 93/42/EEC, ISO 9001:2015 (:1987, :1994, :2000, :2008; :2015), Canada MDR - CMD CAS - GD211, IVDD, ISO 17025:2005, Machinery Directive, ISO 60601 series (including parts 2-18 and 2-35, others), cGLP, cGMP, TL 9000 series, QS 9000, BellCore, VDA 6.1, TS 16949, Guide 65 – ISO 16065, MIL-Q-9858, Mil-I-45208; SQA Manuals and many others.