Consumer Safety Officer / Investigator

AREAS OF EXPERTISE

- **Led 250 plus regulatory inspections and 483 responses**
- **FDA, QSR, QSIT, and ISO inspections**
- **30 years experience in performing GMP, GLP, GCP, QSR audits both Domestic and International**
- **15 years of experience with facility construction, staffing and validation**
- **30+ years experience in medical device product development (Design Controls) and manufacturing operations**
- **30+ years experience of Quality and Regulatory (QSR, cGMP) leadership experience in the medical device, diagnostic, biotech and Pharmaceutical industries in the role of US FDA investigator, specialist and consultant**
- **15 years of Quality Management Experience**
- **Accomplish 100% ISO compliance restructuring and training**
- **15 years experience in preparing and managing 510(k) & PMA regulatory submissions**
- **Initiate and manage compliance activities to CRF 820.100 for CAPA regulations**
- **Initiated compliance with CFR 820 Part 11 for ERES requirements as US FDA trained consultant**
- **30+ years experience with Class I, II and III medical device products and intravenous pharmaceutical products resulted in obtaining ISO registration and ISO 9001, 9002, and 13485-2003 certification**

WORK EXPERIENCE

1997 – Present
(Nashville, TN; Lynnfield, MA; Davie, FL; King of Prussia, PA; Oviedo, FL; Livingston, NJ)
Industry Consultant
Duties:
Auditing, training and consulting for the pharmaceutical, clinical, regulatory, quality system services to medical device, biotechnology and pharmaceutical industries

- Implemented, managed with responsibilities for Quality System Regulations (QSR) and regulatory compliance for clients
- Implemented Design Controls for R&D design controls processes for clients
- Responsibilities included 510 k and PMA regulatory submissions for clients
- Successfully managed pre and post PMA inspections of Quality Systems, Clinical data bases and ISO 9001 certification for clients
- Managed the successful submission and approval of PMA for clients
- Responsible for compliance to CAPA system requirements for clients
- Coordinated supplements to the PMA
- Coordinated company-wide QSR training for clients
- Developed and presented GLP training
- Responsible for total quality and regulatory compliance at specific clients
- Prepared training and direction for compliance with CMC
- Prepared standard operating procedures for CMC, GCP and GLP compliance

- Responsible for review of documentation for PMA Regulatory Submissions – combination product
- CAPA Compliance system review
- Review and assessment of packaging system including validation documentation
- International audits

1999 – 2008
Quintiles Consulting, Rockville, MD
Senior Quality Systems Associate
Duties:
Drug and device combination products, medical device, biotechnology, in-vitro diagnostic industries domestic and international

- Responsible for the implementation of company client specific Quality System Regulations (QSR)
- Responsible for gap analysis and training for clients: large in-vitro diagnostic manufacturer; large pharmaceutical manufacturer; large and mid size medical device manufacturer and small pharmaceutical repackager both domestic and international
- Reviewed Electronic Documentation System with analysis of results for specific clients
- Reviewed validation programs for the manufacturing and Quality equipment and processes with analysis of results for specific clients
- Regulatory liaison with Customer's Regulatory Department in coordinating the preparation of responses to the U. S. Food and Drug Administration
- Managed the Design Controls Review to assure all reviews and approvals were met prior to transfer of the product to manufacturing
- Designed and participated in the environmental qualification of Class 100 clean rooms
- Participated in the largest consent decree at a client to begin the compliance process

1996 – 1997
Cord Logistics (division of Specialty Companies, Cardinal Health), LaVergne, TN
Director Quality Assurance and Regulatory Compliance
Duties:
Pharmaceutical industry

- Responsibility for FDA regulatory and QSR compliance for 2 Divisions
- Member of Senior Management Team with full P&L responsibility
- Management representative
- Restructured Quality and Regulatory organizations
- Executed the move of this third party logistics company from a distribution center to its own warehouse location
- Initiated system upgrades for complaint management, electronic documentation, audit programs, supplier identification, qualification and approval
- Validated the cold/cool room and verified the warehouse for pharmaceutical product storage
- Established, maintained and provided adherence to SOPs through training and audits; oversaw all security including cameras and video recording
- Provided cGMP, DEA and OSHA training
- Assisted an emerging biotechnology company with the successful launch of its first product
- Prepared and conducted presentations to clients for new business opportunities; provided consultations regarding regulatory compliance along with state and DEA inspections
- Provided Recall guidance to National Specialty Services, another Cardinal Specialty company and Cardinal Senior management
- FDA liaison

1995 – 1996
Pharmacia, Dublin, OH
Compliance Specialist
Duties:
Pharmaceutical industry

- Performed cGMP, GCP, GLP internal audits both domestic and international
- Management Representative
- FDA liaison – including international
- Established and maintained the State license program under the PDMA and program management
- Reviewed ANDA and NDA sections prior to submission
- Company closed the Ohio facility when merged with Upjohn

1993 – 1995
MiniMed Technologies, Sylmar, CA
Regulatory Compliance Specialist
Duties:
Medical Devices, electrosurgical products, sterile disposables, class III implants

- Member Senior Management team
- Management Representative
- Total quality and regulatory responsibilities for the company
- Directed compliance to the Medical Device Regulations
- Established Quality and regulatory organization to meet the new QSR's
- Initiated and managed documentation in support of the regulatory requirements
- Established and provided QSR training
- Revised compliant MDR procedures and reporting
- Assisted in 510(k) submissions
- Lead assessor for ISO 9000 – company received ISO certification in 6 months
- Divisional liaison in all corporate and FDA activities
- Directed and coordinated the quality and regulatory affairs activities in support of new product development, acquisitions, legal activities, facility registrations, government contracts, product complaints and FDA inspections
- Assisted in the implementation of device tracking regulations; received and proctored training on ISO 9000 issues

1972 – 1993
U. S. Food and Drug Administration, (Stoneham, MA)
Consumer Safety Officer / Investigator
Duties:
Compliance with statutes of the Federal Food, Drug and Cosmetic Act as amended

- 250 plus audit reports of observations noted during inspection of pharmaceutical, clinical laboratories, radiological product manufacturers, blood banks, IRB, clinical investigators, medical device – Class I, II and III manufacturers, biotechnology product manufacturers, LACF product manufacturers, HACCP processing as well as emerging technology
- Reviewed over 75 new, unusual intricate manufacturing processes
- Routinely trained State Investigators
- After receiving specialized year long training in computers, reviewed software programs of medical devices supplying equipment to10 blood banks.
- Wrote the triennial evaluation of the Vermont's dairy program and routinely dealt with State and local health officials

- Implemented the Interstate Milk Shipper's programming assuring 100% completion of the project
- Standardized as a Regional Milk Specialist – 1 of 20 in the country – reviewed equipment, including high temperature / short time (HTST) closed systems for compliance with the Interstate Milk Shipper's program throughout New England
- Specialized training in the HACCP (Hazard Analysis of Critical Control Points) for the pharmaceutical and food manufacturing industry.
- Negotiated with senior firm management on a routine basis to implement voluntary corrections
- Participated along with State officials in flood and disaster work in Vermont
- Assisted in the establishment of microbiological standards of raw, breaded fish
- Reviewed drug and in-vitro diagnostic firm files for the Government Wide Quality Assurance program
- Received FDA Award of Merit

EDUCATION

1972
University of Maine, Orono, ME
BS: Microbiology and Education

1991
Bunkerhill Community College, Boston, MA,
AAS: Electrical Engineering Technology

AFFILIATIONS

RAPS, (RAC certified November, 1977)
Active Member since 1975

CERTIFICATIONS

Certified Lead Auditor ISO