Senior Regulatory Compliance Analyst

AREAS OF EXPERTISE

- **Audits/Gap Assessments to meet 21 CFR 820, 210/211 and Health Canada Medical Device Directive**
- **ISO 13485, 14971 and 9001**
- **Design Controls**
- **Product/Process Verification & Validation**
- **Management Controls**
- **Complaints**
- **Recalls**
- **MDR's and ADE Reporting (310.305/514.80)**
- **Supplier Controls**
- **Servicing**
- **3rd Party Audit Prep**
- **Quality Systems Development or Remediation**
- **Records/Documentation/Change Controls**
- **Personnel Training**
- **CAPA**
- **Production and Process Controls / Lab Controls / Aseptic Processing / Clean Rooms**
- **Business Process Re-engineering**
- **cGXP**
- **Non Conformances / Deviation Management**
- **PCR Technology**
- **Risk Management**

INTRODUCTION

A results-driven senior executive with strong leadership who provides clear direction, development of people and who can motivate them to action. A proven analytical evaluator, solutions-finder with 25+ years' strong technical skills and experience in Medical Devices, In-vitro Diagnostics and Biopharmaceuticals Quality Management Systems and Regulatory Compliance. Promote continuous improvement and risk mitigation. Meet critical deadlines for FDA 483 observations, Warning Letters, FDA Consent Decrees and Import Detentions.

WORK EXPERIENCE

EMPLOYMENT AND/OR CONSULTING REPRESENTATIVE COMPANIES INCLUDE:

Pharmaceuticals and Medical Devices Organizations:
Baxter Healthcare: Chicago, IL; Medina, NY
Beckham – Coulter: Miami, FL; Bristol TN
Cardinal Health: Tempe, AZ
ConvaTec: Skillman, NJ
DuPont Medical Products (now Siemens): Wilmington, DE
Hill Rom: Phoenix, AZ
Immucor: Atlanta, GA
Isotypes: Newark, DE
J&J Advanced Sterilization Products (ASP): Irvine, CA
J&J Ortho Clinical Diagnostics (OCD): Rochester, NY
J&J DePuy-Synthes: West Chester, PA

Maquet: Antalya, Turkey, Rastatt, Germany, NH USA
Novartis Chiron: Emeryville, CA
Philips Healthcare: Andover MA, Cleveland OH.
Stryker Corporation: Kalamazoo, MI
Terumo: Ann Arbor, MI
XZeal, Kissimmee, FL

Clinical Laboratory Employment:
Alexandria Hospital: Alexandria, VA
Kaiser Permanente: San Diego, CA
River Parish Medical Center, LaPlace, LA

Medical Device Field Service Clinical Customers:
Laughlin Memorial: Greenville, TN
Holston Valley Hospital: Kingsport, TN
Bristol Regional Med Center: Bristol, TN
Johnson City Medical Center: Johnson City, TN
Dickenson Community Hospital: Clintwood, VA
Abingdon Hospital: Abingdon, VA
Indian Path Medical Center: Kingsport, TN
Unicoi County Memorial Hospital: Erwin, TN
Whitesburg ARH Hospital: Whitesburg, WV

CONSULTING PROJECTS

04/2016 – Present
The FDA Group, Boston, MA
Senior Consultant
Duties:
Computer Tomography (CT Scanners) and Advances Molecular Imaging (AMI)
- CAPA Facilitator – Coach/Mentor.

11/2015 – 04/2016
The FDA Group, Boston, MA
Senior Consultant
Duties:
Defibrillators
- Complaint Files Remediation Project, FDA Readiness

06/2015 – 11/2015
Black Diamond
Senior Consultant
Duties:
Reprocessing & Sterilization of Surgical Equipment.
- Corporate Audit Remediation, CAPA, Complaints, Design Controls, Production and Process Controls.

05/2015 – 05/2015
The FDA Group
Senior Consultant
Duties:
Dental X-ray
- Wrote 483 Letter Responses and advised on QMS development.

03/2014 – 12/2014
Randstat Engineering, Atlanta, GA
Industry Consultant
Duties:
Infusion pumps, Biologics
- CAPA Remediation. Part 820 and ISO 13485. CAPA Coaching, training and investigations.

11/2013 – 05/2014
Quintiles, Durham, NC
Principle Consultant
Duties:
Dialysis and Cardiopulmonary Devices, ETO Sterilization
- QMS Remediation Parts 801, 803, 806 & 820 and ISO 13485
- FDA Audit Readiness and Guidance: Front Room Preparation and Back Room Management

08/2013 – 10/2013
Becker & Associates, Washington, DC
Senior Consultant
Duties:
Single-use consumables-fecal management, wound care, catheters, etc. – 483 letter(s)
- Complaint Files (Complaint Handling) Remediation Part (820, 198)
- MDR Remediation (Part 803)
- Performed complaint retrospective reviews for US and Outside US (OUS) to determine reportability
- Identified gaps in MDR Reporting, Recall (Part 806) Escalation, SCARs, & complaint documentation

06/2013 – 08/2013
Black Diamond, Boston, MA
Senior Consultant
Duties:
Spinal Implants – 483 Letter(s)
- Management Responsibility Gap Analysis and Remediation
- Statistical Trending Development and Training Materials; Management Control SOP writing

09/2012 – 04/2013
Becker & Associates, Washington, DC
Senior Consultant
Duties:
Sterilization – 483 Letter(s)
- CAPA Remediation and FDA Audit Preparation through Storyboarding, Coaching and Role Playing.
- Performed Assessments, Identified and filled compliance gaps, aligned CAPA with Corporate SOPs and Work Instructions.
- Developed and Provided CAPA Training Tools. Facilitated CAPA Review Board, CAPA Risk Assessments and Monthly Metric Reviews for investigations and CAPA inputs and triggers.

04/2012 – 11/2012
Avarent, LLC, Libertyville, Illinois
Senior Consultant
Duties:
Infusion Pumps – 483 Letter(s)

- QMS Remediation and Re-engineering for CAPA, Management Review and Quality Data Management. FDA Inspection Preparation. TUV Audit Readiness.
- Performed Assessments, as is-to be Mapping, SIPOC, Planning, RACI, Wrote SOP&WI and Implementation activities to identify and fill compliance gaps in addition to aligning CAPA, Management Review and Quality Data Development (Statistics and Trend Reporting) with Baxter Corporate CAPA and Mgt. Review Processes.
- Developed and provided CAPA Training Tools. Initiated CAPA Review Board, CAPA Risk Assessments and Monthly Metric Reviews for CAPA inputs and triggers.

01/2011 – 02/2011
Valident, San Francisco, CA
Senior Consultant
Duties:
Cardio-Pulmonary – Consent Decree

- Re-designed Quality Complaint Handling Compliance Stream to meet ISO 13485 and FDA QS Regulations 820.198 and 820.200. Validated all complaint handling touch points to all other compliance steams within the FDA QS Regulation and ISO including: Servicing, Personnel, Change Control, MDRs, Risk Management, Management Controls, CAPA and GXP.

01/2010 – 01/2011
Synergetics, Boston, MA
Consultant
Duties:
Biopharmaceuticals – VERDE Report: Unsatisfactory Customer Service/Support

- Re-designed Customer Support, Technical Support, Technical/QA Laboratory and Field Technical Support to enhance customer satisfaction using QMS standards. Used "AS IS" and "TO BE" re-engineering techniques to identify gaps and establish a highly customer focused team. Developed process flow mapping for all tasks assigned to the Technical Support/Complaint Handling function. Performed time allocation studies to statistically optimize staffing for Technical Support phone coverage. Completed organizational redesign. Completed software "User Requirements" and "Functional Requirements" Wrote SOPs, Work Instructions, and Technical Documents. Validated all complaint handling touch points to the other compliance steams within the FDA QS Regulation and ISO including: Servicing, Personnel, Change Control, MDRs, Risk Management, Management Controls, CAPA and GXP.

02/2010 – 06/2010
Maetrics, Indianapolis, IN
Consultant
Duties:
Ambulance Cots – 483 Letter(s)

- Responsibilities - Performed Quality Engineering Complaint Investigations in Manufacturing on ambulance cots for Root Cause and then assigned Risk Assessments based on the findings for FDA readiness. Filed MDRs for injuries and deaths associated with the nature of the event.

03/2009 – 01/2010
Kelly Scientific, Rochester, NY
Consultant
Duties:
In-Vitro Diagnostics – Clinical Chemistry

- Responsibilities - Performed all activities associated with Technical Troubleshooting within a Technical Support Call Center for Clinical Chemistry Analyzers using In-vitro Diagnostics. Performed instrument troubleshooting using remote diagnostic techniques. Acted as subject matter expert on quality and regulatory issues to identify gaps within the Quality Management System.

10/2006 – 02/2009
Adecco Technical, Phoenix, AZ
Consultant
Duties:
Infusion Pumps – 483 Letter(s)

- Performed Validation (IQ/OQ) on Infusion devices at local area hospitals. In addition, loaded software upgrades as needed. Completed validation and verification procedures to qualify all units prior to PQ.
- Performed infusion device refurbishment (QS Regulation 820.200) on all returned infusion devices. Identified root cause defects using electrical and mechanical techniques and then corrected all defects. Performed verification and validation on devices prior for qualification.

11/2004 – 12/2005
Worldwide Competition Consultants, Maryville, TN
Senior Consultant
Duties:
Carrier Corporation – Tyler Refrigeration, Waxahachie, TX

- Built entire Quality Management System to meet ISO 9001 equivalency.

MEDICAL DEVICE PERMANENT POSITIONS

06/2011 – 06/2012
Invacare, Elyria, OH
Senior Regulatory Compliance Analyst – Permanent Position
Duties:
Home Health Care – Consent Decree

- Worked under pending Consent Decree.
- Primary duties included Part 803 MDR, MDD, CMDR submissions and Part 806 Recall Co-ordination
- Responsibilities – Manage Adverse Event Complaint Investigations
- Review Complaint File data as received for timeliness and correct data collection for FDA and Health Canada reporting. Facilitate reporting in the US from Europe, South America and Asia Pacific.
- Provide opinion for root cause determinations using documented engineering rationale, inspection reports, test results and other data.
- Work with engineering staff as part of complaint investigation to identify product malfunctions or defects.
- Document Risk Analysis including DFEMA when appropriate applying ISO 14971
- Initiate CAPAs as needed. Trend and report key metrics including complaint investigation activity and MDR reporting.

- CAPA and Complaint Handling/MDR/Recall Compliance Streams Redesign Committee Member [483 Letter]. Team Lead and subject matter expert in CAPA Remediation and Re-engineering on a global level for Class I and II devices. Due to a recent FDA consent decree the CAPA process required a complete overhaul and process redesign. The following areas were improved upon: Event Reviews, Cause Analysis, CAPA Initiation, Root Cause Investigation, 5Y's, Risk Assessments, Action Plans, Implementation, Effectiveness Checks, and Closures. In addition, focus was placed on touch points with other compliance streams such as, but not limited to: Complaint handling, MDRs, Risk Assessment, Design Controls, Change/Document Control, Management Review, etc. Also, the team was tasked with identifying and training investigators, defining CAPA owners, writing the SOPs/Work Instructions, implementing a CAPA Review Board and hiring a CAPA Manager.
- Weinberg Group Webinar Attendee 15JUN2011; "Ensuring Successful FDA Meetings".
- Trackwise Webinar Attendee 22OCT2011: "Medical Device Regulatory Reporting - eMDR"
- Pathwise 18OCT2011 – FDA QS Regulation Training
- Pathwise 03DEC2011 – CAPA Training

01/2006 – 05/2006
Chiron – Novartis, Emeryville, CA
Quality Manager
Duties:
HVAC – Quality Management
- Resolved FDA 483 Letter for Complaint Handling avoiding FDA penalties and fines.
- Re-engineered entire Technical Support - Complaint Handling operations meeting all benchmarks, milestones and deliverables.
- Wrote SOP's for effective operation of Technical Support operations.
- Enforced policies, procedures and Quality standards to ensure continuous compliance.
- Identified training gaps and accountability.
- Interacted with FDA, ISO and Internal auditors on a frequent basis during audits and aided with all FDA 483 responses.
- Directly responsible for all of the FDA's MDR submissions.
- Managed Technical Support for all field complaints from end users of Nucleic Acid Testing (HIV-1, West Nile Virus, Hepatitis B, and Hepatitis C).
- Developed statistical trending to review the Complaint Handling Team performance
- Managed a department of 12 Technical Support Representatives and a department budget of over $2 million.

QUALITY MANAGER EXPERIENCE

06/1999 – 11/2004
Duties:
Bristol Compressors, Inc., Bristol, VA
- Drove continuous improvement by TQM principles in a manufacturing plant running 24/7 & 2,500 employees building 2.5 million compressors per year with $3 billion in sales.
- Managed CAPA System: Root Cause Investigations, Validations, and Verifications.
- Wrote SOP's, Engineering Specs and Work Instructions. Approved all Engineering Drawings.
- Reported Statistical Trending for the entire manufacturing facility on a monthly basis.
- Managed SPC Trending, Metrology Lab, Metallurgical Lab and Final Test Laboratory.
- Managed New Operation Start Studies and Change Control.
- Managed multiple on-going projects simultaneously.

- Identified training gaps and accountability
- Interacted with ISO 9000 Auditors every 6 months during audits.
- Planned and performed Internal, External and Supplier Audits to meet ISO and ASQ standards.
- Technical Support for all field complaints from end users of compressors.
- Co-ordinate recalls
- Managed a department of over 30 direct reports of **Supplier Quality Engineers, Quality Engineers**, CQTs, Lab Technicians, Metrology Technicians, Machine Shop Inspectors, Process and Assembly Inspectors, In-Coming [Supplier] Inspectors, Final Test inspectors.

MEDICAL DEVICE TECHNICAL SUPPORT EXPERIENCE

03/1993 – 05/1998
Beckman-Coulter, Miami, FL
Technical Support – Clinical Hematology & Hemostasis

12/1988 – 03/1993
E.I. DuPont de Nemours, Inc., Wilmington, DE
Technical Support – Clinical Chemistry
Duties:
- Technical Support for all field complaints from end users of IVD Medical Devices.
- Supported Recalls Part 806 and MDR reporting Part 803.
- Negotiated Customer Service Contract purchases at Beckman – Coulter and DuPont.
- Managed Field Territory in East Tennessee and Southwest Virginia for Beckman - Coulter.
- Met and exceeded statistical trending in Tech Support for ACD and incoming call closures.
- Wrote, edited, and published a Technical Chemistry-based newsletter entitled Analyst News.
- CLIA 88 Subject Matter Expert at DuPont- Medical Products.
- Technical Trade Show Representative for Clinical Chemistry Medical Devices at DuPont.

START UP EXPERIENCE

1991 – 1992
Isotypes, Inc., Wilmington, DE
IgG Subclass Immunoassay Kits – ELISA methodology
Duties:
Start Up – In-Vitro Diagnostics (Part Time while at DuPont)
- Purchased and prepared reagents established testing protocol and performed validation experiments.
- Performed manufacturing, packaging design, managed labeling for kits.
- Performed 510(k) testing and assisted with 510(k) submission – gained FDA approval.

LABORATORY SCIENCE

1980 – 1988
Medical Laboratory Technician
Duties:

- Preformed hospital lab testing in Hematology, Chemistry, Microbiology, and Histology.
- Assisted Pathologist with autopsies, made frozen section slides.
- Met all National, State and Local Regulatory Requirements and Hospital Standards
- Wrote and edited Technical Manuals in preparation for 3rd party audits and inspections

EDUCATION

- Virginia Intermont College, Bristol, VA – **B.S. Organizational Management** Graduated Summa Cum Laude 3.96 GPA
- Louisiana State University, Baton Rouge, LA – **Major: International Trade and Finance; Minor: Spanish**
- George Mason University, Fairfax, VA – **Major: Chemistry/Biology/Medical Technology**