**Regulatory Compliance Manager**

**AREAS OF EXPERTISE**

- **Quality System and Supplier Auditing**
- **Quality System Remediation**
- **Training (21 CFR Part 820, 803, 806, ISO 13485, MDD, CMDR)**
- **Development of Internal and Supplier Audit programs.**
- **Perform FDA mock inspections, conduct FDA audit prep activities, and training**
- **Quality System gap assessments to QSR and ISO 13485**
- **Complaint Handling/Adverse Event Reporting**
- **Corrections and removals**
- **Manufacturing transfer activities**
- **Building of Quality Systems infrastructure including SOP and Work Instruction development**
- **Development of regulatory strategies for bringing new devices to market**
- **Formulation of regulatory affairs policies and procedures.**
- **Completion of STED templates for International regulatory submissions**
- **Technical File Compilation**
- **Premarket (510k) Submissions**
- **Development of quality system remediation plans**
- **Quality System Integration**

## INTRODUCTION

Energetic, strategic, and forward-thinking Quality and Regulatory professional with more than 32 years of Medical Device industry experience. A broad range of both strategic and tactical experiences in all aspects of medical devices including: Regulatory Compliance, Quality Assurance, Regulatory Affairs, Quality Systems, and Quality System Remediation.

## WORK EXPERIENCE

**11/2013 – Present**
Industry Consultant
**Example Engagements:**

- Auditing of QMS records during remediation: CAPA's, Management Review, Receiving Inspection, Complaints, Deviations, Defect Investigations, and Correction and Removal records.
- Managed and drove the timely completion of CAPA's relating to FDA 483 observations in Production and Process Control and Purchasing Controls.
- Conducted CAPA effectiveness checks in Corrections and Removals for Third Party Certification audits.
- Conducted gap assessment and remediated client Corrections and Removal files.
- Acted as Final QC Auditor of QMS records during FDA 483 inspection and Third-Party Certification Audits.
- Revised Post Market (Corrections and Removals) standard operating procedures and work instructions.
- Lead Assessor for Quality System Audits for 21 CFR Part 820, 806, 803, ISO 13485, CMDCAS, and JPAL requirements for global clients.
- Conducted FDA prep activities and FDA Mock inspection for client's international site.

- Wrote Quality Management System procedures for a startup medical device company.

**07/1985 – 11/2013**
Zimmer Surgical, Dover. Ohio

Regulatory Compliance Manager (2003 – 2013)
**Duties:**
- Manager of Regulatory Affairs and Compliance for global divisions responsible for assuring site compliance with domestic and international standards.
- Successfully managed regulatory affairs/compliance functions, internal/supplier audit programs, and post market surveillance activities including complaint handling and adverse event reporting, and recalls.
- Additionally, successfully managed the document control and change managed systems and resources.

Quality Manager (1999 – 2003)
**Duties:**
- Responsible for the quality control department including the supervision of numerous quality inspectors.
- Responsibilities including oversight of Incoming, In- process, and finished device acceptance activities.
- Performed DHR review and final product release.
- Responsible for the administration of the calibration program.
- Acted as Quality subject matter expert during regulatory agency inspections.
- Responsible for the development and maintenance of Opex and capital budgets.

Quality Supervisor (1993 – 1999)
**Duties:**
- Responsible for the quality control department including the supervision of numerous quality inspectors on various shifts.
- Responsibilities including oversight of In-process inspections.

Calibration Specialist (1990 – 1993)
**Duties:**
- Responsible for the creation of the gauge calibration program at Zimmer Surgical.
- Successfully transferred gauge calibration program due to facility closure into the Surgical Quality System.

Quality Technician (1985 – 1990)
**Duties:**
- Responsible for the inspection of medical devices using sampling tables.

## ADDITIONAL EXPERIENCE

### Regulatory Compliance
- Acted as Front Room Lead, Facilitator and Subject Matter Expert for FDA inspections.
- Successfully led FDA Audit Preparation activities including front room/back room preparation, audit preparedness planning and employee/regulator interface training.
- Successfully managed numerous notified body audits, UL- In metro, and FDA audits.

- Prepared or directed the preparation of additional information responses as requested by regulatory agencies including the preparation of data for FDA 483 response.
- Acted as QA/RA lead for the manufacturing transfer activities as a result of facility closures.
- Conducted Proactive Post market review including the review of warning letters, 510ks, recalls, and adverse events.
- Project leader of successful site implementation of revised medical device Directive 2207/47/EC.
- Skilled at performing MDD, CMDR, QSR Training for employees.
- Managed device recalls and formulated Part 806, FSCA, FSN reports.
- Experienced in building internal audit and supplier audit programs. Also, in conducting internal, supplier, and due diligence audits.
- Expertise in developing regulatory strategies and in Quality System remediation for remediating quality systems including containment activities, remediation planning, risk assessments, and managing overall remediation projects.
- Expertise in CAPA remediation and in FDA expectations of CAPA programs.
- Led QMS and Regulatory activities in transferring manufacturing operations across sites and to contract manufacturers.
- Maintain documentation of compliance activities, such as complaints received or investigation outcomes.
- Successfully filed appropriate compliance reports with regulatory agencies including adverse event follow up reports to the FDA or competent authorities.
- Investigated product complaints and prepare documentation and submissions to appropriate regulatory agencies as necessary.
- Maintained and interpreted existing and emerging regulations, standards, or guidance documents.
- Managed the complaint investigation unit, reviewed complaint records, and filed adverse event reports with appropriate regulatory agencies.
- Responsible for identifying budget needs and maintaining Opex and capital expenses to budget.

**Quality Systems**

- Expertise in performing Quality System gap assessments to regulatory standards and building a QMS.
- Responsible for the management of the Document control, Change Management, and calibrations systems.
- Experienced in the creation of a document control infrastructure and in the creation, writing, and maintenance of SOP's.
- Managed the assessment, acquisition, and deployment of new electronic complaint and CAPA data management systems.

**Regulatory Affairs**

- Experienced at assessing and building systems for assessing changes to domestic and international submissions.
- Established system for creating and maintaining MDD technical files
- Developed STED templates for international regulatory submissions
- Provided regulatory strategies to departments or development project teams regarding design, development, evaluation, or marketing of products.
- Formulated or implement regulatory affairs policies and procedures to ensure that regulatory compliance is maintained or enhanced.
- Coordinated, prepared, or reviewed data for regulatory submissions for domestic (510k) or international medical device markets.
- Reviewed device promotional materials, labeling, device history records, specification sheets, or test methods for compliance with applicable regulations and policies.

## EDUCATION

Malone College
Bachelor of Arts Degree: Business Management

Stark State College
Associate's Degree: Medical Laboratory Technology

## CERTIFICATIONS/TRAINING

- Certified ISO 13485 Lead Auditor
- Internal Auditor, ASQ
- ISO 13485 Lead Assessor Stat-a-Matrix
- Lean/Six Sigma Black Belt Training, Kent State University
- Quality System Regulation Training, AAMI