Senior Manager of Quality Systems

AREAS OF EXPERTISE

- **Total QMS management including: Design, Supplier, Document, and Engineering Controls; Corrective and Preventative Action (CAPA); Nonconforming product and Inspection/ Acceptance activities; Complaint Handling and MDR reporting; Auditing programs**
- **Strategic and holistic Risk Management Programs**
- **Process Validations Assessing, Planning, and Execution**
- **Effective Quality Planning and Process Mapping**
- **Strategic Suppliers Controls program**
- **Maintaining compliant Quality Management Systems**
- **Supplier and Internal Auditing**
- **QMS documentation**
- **Supplier evaluations**
- **Control Plan Generation**
- **Integration teams for mergers and acquisitions**
- **Data entry for quality system software programs**
- **New Quality System Assessment Creation and Implementation**
- **FDA Remediation**
- **ISO 13485 certification preparation**

INTRODUCTION

Consultant has proven leadership in implementing & managing quality & operations systems. Understands quality systems and assessing compliance with FDA 21 CFR Part 820, Parts 210 & 211, Part 58, ISO 13485 and ISO 9000. Experienced with implementing complete quality systems to comply with these regulations and standards, and specifically excels in developing and implementing supplier control, design control and risk management systems.

Strong skills in team building, interpersonal communication, collaborating with international cultures. (Native English speaker, functionally conversational in German, understand some technical French and Spanish.) Experienced in project management, and manufacturing in the medical device and pharmaceutical industries. A resourceful and determined leader, who achieves company objectives, motivates team members and adapts well to changing environments.

WORK EXPERIENCE

2010 – Present
Industry Consultant
Duties:

- Wrote project plan for and led a cross-functional team of client personnel to implement a Strategic Supplier program, targeting Dock-to-Stock arrangements for 80% of the client's purchased product. (Also assisted with 2- audits in Germany, as the only German speaking auditor, to assess the Strategic Suppliers.)
- Negotiated Quality Agreements with 12-Strategic Suppliers for the client.

- Remediated a Warning Letter for a small start-up company, acted as the liaison with the U.S. FDA and achieved receipt of a Close-Out Letter for the Warning Letter.
- Put team of 3-consultants in place for CiNQ Systems to integrate inspection requirement documents from two acquired companies. Worked with attorneys and the client to negotiate subcontractor contracts, General Service Agreements and Statements of Work (SOWs.)
- Mapped business processes and wrote procedures for the instrument Loaner Services Department at a large orthopedic OEM, operating at their Global Distribution Center. This included operations for receiving, cleaning, RFID handling, inspection, nonconforming material handling, rework, shipping and shipping of customized instrument trays.
- Facilitated Kaizen events to implement a Dock to Stock program.
- Guided a Defect Review Board toward closing over 200 defects under remediation at a large Advanced Molecular Imaging, capital equipment company.
- Assessed and prepared a client for an FDA inspection, and subsequently handled the inspection for the client. Highlights include
    - Implemented Purchasing and Supplier Selection and Approval system & procedures resulting in zero 483 Observations against 21 CFR Part 820.50 Purchasing Controls.
    - Implemented Final Release procedures, forms and retrospective evaluation of distributed product and prevented a probable injunction.
    - Implemented MDR Reporting procedure and performed assessments on existing complaints resulting in zero 483 Observations against 21 CFR Part 803 Medical Device Reporting.
    - Prepared complete response to FDA Form 483 Observations for the client.
- Wrote complete Quality System for start-up orthopedic client.
- Guided 6-project teams through the Design Control Process, for contact lens and lens care products, at a global contact lens and lens care solution manufacturer. Project types include:
- 2-Fashion wear contact lens designs
- 2-H2O2 lens care systems (a medical device in some countries & pharmaceutical in others)
- 2-Contact lens designs for prophylactic myopia treatments, in Asian specific optic anatomies
- Acted as interim member of a Global Change Review Board for Lens Care Products and manufacturing operations in Canada.
- Performed supplier and internal audits for two OEM Medical Device companies and assessed gaps in ISO 13485 compliance with 2-contract manufacturers of orthopedic and spinal implant devices.
- Managed subcontract regulatory consulting work to write and submit the 510(k) for a Health Assessment Kiosk.
- Mapped and re-wrote the Design Control & Risk Management processes for the start-up producing and manufacturing the Health Assessment Kiosk.
- Performed weeklong assessment for a client with a contract manufacturer in Austria and recommended actions & strategies for handling FDA inspections (required German speaking auditor.)
- Planned Phase-2 development of the software driven Health and Wellness Kiosk. Accomplishments include:
    - Drove complete re-write of the Health Assessment Kiosk Risk Analysis, considering potential
        - Product component failure modes
        - Software functional failure modes
        - User Requirements
        - Design Requirements
        - User Interface malfunctions
        - ISO 14971 Annex-C considerations
    - Clarified documentation of requirements for User Interface/Touchscreen facilitating the following:
        - Visual acuity testing
        - Body Mass Index measurement/calculation

        - Blood pressure measurement
        - Storage/retrieval of historical data in user created account
        - Selection of, and appointment set-up with, local doctors, based on assessment
- Project Leader for a Medical Safety Department, TrackWise system upgrade implementation project.
    - Drove the establishment of the Medical Safety Team Software User Requirements Specifications (URS) for the TrackWise upgrade.
    - Prioritized requirements in the URS, with Sparta Systems & independent TrackWise programmers.
    - Drafted approximately 1/3 of the OQs & PQs for software validation of the TrackWise system.
    - Participated in "Dry Runs" of the upgraded software in the prototype environment.
    - Executed OQs & PQs authored by other software validation team members.
- Project Leader and Account Manager for a third party consulting company, leading and managing 9-consultants in pharmaceutical quality systems, with responsibilities in both the U.S. and Canada.
    - Advisor during hiring process for subcontract consultants to work, including writing contract letters to obtain Canadian Work Permits for each member of the consulting team.
        - Wrote multiple project plans to qualify Third Party Organizations (TPOs) to produce 30+ SKUs for OTC pharmaceuticals; and for contract renewal remediating APQRs, Complaints, Stability Testing and Quality Agreements, according to 21 CFR Parts 210 & 211.
        - Assigned delegate quality consultants and worked directly with:
            - Contract Manufacturers overseeing quality systems remediation prior to manufacturing operations.
            - Backlog remediation on Complaints, APQRs, CAPAs, Change Controls and Quality Agreements.
            - Organizing and coordinating initiation of Follow-up Stability Testing.
        - Worked with "Dietary Supplement" manufacture remediating quality system issues in manufacturing, according to 21 CFR Part 111.
        - Wrote Quality Agreements for a Canadian pharmaceutical manufacturer covering Health Canada and U.S. FDA requirements with their contract manufacturers and packagers.
        - Established a Manufacturing Transfer Checklist template for transferring processes into multiple TPOs.
- Established insurance at $1MM for Errors & Omissions, and $2MM aggregate for General Liability.
- Achieved ASQ Certified Biomedical Auditor.
- Mapped business processes and re-wrote procedures for contract manufacturer.
    - Implemented completely re-designed Risk Management process, tying customer requirements with all quality system and manufacturing processes into 1-Risk Management File. As a contract manufacturer, the system was challenged through lack of design information from customers, to provide product related risks. The new system tracks risks through all processes, for all product lines, regardless of customer served. Built-in feedback systems automatically drive continual updates of the Risk Management File.
    - Completed Installation Qualifications (IQs) on 14-machines on the manufacturing floor.
    - Characterized the process for 4-vertical milling centers.
    - Designed Experimental Test strategy for Operational Qualification (OQs) of the 4-vertical milling centers, establishing worst-case factors and extreme operating parameters.

2009 – 2010
Novalign Orthopaedics, Inc., Memphis, TN
Senior Manager of Quality Systems
Duties:
- Drove implementation of entire quality system & operations.
- ISO 13485 Registration with BSi
- Management Representative for the quality system audits and the Technical File audit with BSi.

- Implemented processes and procedures for complying with Health Canada.
- Implemented procedures for creating and managing Technical Files and applied for CE Mark.
- Fielded questions and assisted negotiation of regulatory pathway with BSi and the MHRA, in the U.K.
- Directed structure of Design Review, Risk Assessment & investigation of clinical trial adverse events
- Design & employment of:
  - Production & assembly facility
  - Warehouses for finished goods, components, instruments & accessories
  - Inventory management procedures
  - Procurement systems and initial materials ordering systems
  - Shipping and distribution models and systems
- Drove an alternative plan to avert an 8-week production delay in getting implant inventory in time for surgeries in the clinical trial. Result: no missed surgeries in the clinical trial

2005 – 2009

Medtronic Spinal and Biologics, Memphis, TN

Supplier Quality Manager, (2006 – 2009)

Duties:

- Implemented division-wide, centralized Supplier Quality Program, using a Risk Burn Down process for categorizing and prioritizing suppliers. Also staffed the new Division Level Supplier Quality department.
- Managed a Supplier Quality team that established, maintained and monitored quality requirements for a foreign and domestic supply base of 500+ suppliers for 5-Spinal and Biologics facilities; in the U.S., Puerto Rico and Germany. Scope included medical device, tissue, biologics and pharmaceuticals. Responsibilities included:
  - Audit management
  - Initial approvals of suppliers
  - Control of Approved Supplier List
  - Auditing foreign suppliers (performed audits in Germany, Switzerland, France, England, and Puerto Rico, -managed audits done in China, Taiwan & Japan)
- Developed a process for managing outsourced OEM products, linked with Design Controls. Included special requirements for OEM components, requiring evaluation of interfaces with "own branded" products.
- Completed a 10-month management course (BAMM – Becoming a Medtronic Manager) modeled after the IBM Blue program. Course included:
  - Ethics & compliance
  - Talent management & retention
  - Team building
  - Stakeholder analyses
  - Effective communication
  - Problem solving techniques
  - Conflict management
  - Methods of giving effective feedback
  - Decision making
  - Lean & Six Sigma principles
  - Talent development
  - Case studies
- Planned & negotiated supplier quality integration between Medtronic & the acquired Kyphon business.
- Green Belt Trained in Six Sigma & Lean Sigma techniques.

Lead Quality Engineer, (2005 – 2006)

Duties:

- Managed 6-direct reports and led design quality engineers through the product development process with division- wide projects.
- Hired 4-new Design Quality Engineers (DQEs.)
- Directed DQEs working on teams for over 60-active product development projects.
  - Mentored associate level engineers into team contributors achieving CQE status.
- Substituted for the Senior Manager of Design Quality Engineering while sequestered for 3-months, implementing a major Design Control System overhaul.
- Achieved division-wide agreement on a centrally controlled Supplier Quality System, answering FDA questions on PMA & HDE submissions, and eliminating 15-plant specific work instructions.
- Drove compliance for the Waste Electronic Equipment in Europe (WEEE) Directive.

2003 – 2005

Synthes USA, Horseheads, NY

Sr. Quality Engineer, (2004 – 2005)

Duties:

- Plant wide responsibility for leading quality projects, product line extensions and driving corporate quality objectives in a Lean Manufacturing environment.
- Project Leader for corporate wide improvements:
- Coordinated all gages procured for new products and delegated amongst 4-Quality Engineers
- Corporate Quality Engineering team representative for the Horseheads plant:
- Evaluated and piloted Inspection Reduction Software. Took lead evaluating CAQ inspection software as sole German speaking team member. Evaluated CAQ software demo available only in German.
- Global Harmonization of Gages, evaluating techniques in Switzerland to incorporate at US sites (Harmonization needed after Synthes merger and acquisition of two European companies.)

Quality Engineer, (2003 – 2004)

Duties:

- Led quality improvements in 3-JIT Manufacturing Cells.
- Project Leader for plant wide improvements:
- Pushed AQL/Cost reductions with team savings at approximately $111,000 in 2004 (additional, personal savings beyond AQL reductions at $38,388 and $61,811 in 2003 & 2004 respectively,)
- Employed Cosmetic Standards contributing to 10% reduction in cosmetic nonconformances

1998 – 2003

Novoste Corporation, Norcross, GA

Project Engineer, (2000 – 2003)

Duties:

- Launched 4-products & implemented production work stations by leading 6-crossfunctional teams.
- Commercialized 2-Novoste Beta-CathTM System 5F XL Catheter products, increased revenue by $90,000 per month. Launched on schedule, within 11-months, including 6-month FDA review.
- Led design, development and implementation of cutting and skiving fixtures; and re-launched the 3.5F Beta-Rail™ Catheter, after a voluntary recall. Done in 52-calendar days halting a $1,000,000/wk loss

Senior Engineer, (1998 – 2000)

Duties:

- Reorganized the design control system resulting in 0-nonconformances in 2-ISO 9001 surveillance audits and the first FDA PMA audit of Novoste.
- Implemented department metrics: number of changes "before vs. after" design transfer, intellectual property disclosures, number of patent applications and design phases completed vs. time

1996 – 1998
Genzyme Surgical Products, Tucker, GA
Quality Engineer
Duties:
- Supervised 2-direct reports for complaint investigation and repair of insufflators, cameras & scopes.
- Led several teams implementing systems that gained ISO 9001 & EN 46001 certification.
- Point of contact for FDA inspections and successfully defended FDA allegations for numerous Medical Device Reports (MDRs) not submitted. Result of the successful defense, prevented regulatory action from FDA and future need for an additional 120-MDR reports annually.
- Created MS Access database managing & trending complaint investigations and the Material Review Board.
- Achieved Certified Quality Auditor (CQA) certification with the American Society for Quality (ASQ.)

1993 – 1996
C.R. Bard, Bard Urological Division, Covington, GA
Plant Quality Engineer
Duties:
- Investigated and closed all complaints submitted against all products produced in the Covington Plant for C. R. Bard's Urological, Gynecology/Radiology, Patient Care and Medical divisions
- Supervised 2-direct reports responsible for roving plant floor inspections, complaint investigation and release of serviced & repaired Urotrack Monitors™ and Biopty™ Guns.
- Developed repair trending system for the electronic Urotrack Monitor™ and Biopty™ Gun equipment

1990 – 1993
Brasseler USA & Komet Medical, Savannah, GA
Technical Director
Duties:
- Supervised 7-direct reports, 1-technician and 6-QC inspectors.
- Led senior management through implementing their first FDA 21 CFR Part 820 compliant quality system.
- Point of contact for, and handled one audit each, for FDA, EPA & OSHA investigations.
  - Three 483 observations were issued by the FDA and cleared all three within 1-month.
- Handled first EPA investigation, with no observations issued.
- Handled first OSHA investigation and resolved a citation for lack of a Blood Bourne Pathogens program.
- Audited suppliers and internal quality systems.
- Named on patent for new surgical saw blade tooth geometry.

1989 – 1990
Rochester Optical Manufacturing Company, Rochester, NY
Manufacturing Engineer
Duties:
- Supervisor of 1-direct report responsible for production equipment maintenance and repair.
- Implemented several production lines for the standard military eyeglass frames.

- Implemented a new lens edging production line for the new product line of designer sunglasses.
- Trained employees and production supervisors on use of the new lens edging equipment.

1984 – 1989
Caldwell Manufacturing Company, Rochester, NY
Design Engineer
Duties:
- Named on 3-patents, one resulting in a $750,000 out-of-court settlement with a competitor.
- Re-engineered 2-year old product with negative revenue and turned it into a $5,000,000/year product.

EDUCATION

1982 – 1986
Rochester Institute of Technology, Rochester, NY
Bachelor of Technology: Mechanical Engineering

1980 – 1982
State University of New York (SUNY) at Morrisville, Morrisville, NY
Associates in Applied Science: Mechanical Engineering
Dean's List in 1st and 4th semesters

1976 – 1980
Palmyra Macedon High School, Palmyra, NY