Director of Quality Assurance

AREAS OF EXPERTISE

- **Quality Assurance**
- **ISO 13485**
- **Design Control**
- **Quality System**
- **Medical Devices**
- **Change Control**
- **CAPA**
- **Continuous Improvement**
- **Validation**
- **Root Cause Analysis**
- **Lean Manufacturing**
- **Process Engineering**
- **V&V**
- **GMP**

INTRODUCTION

Consultant is a proven Quality Assurance leader with extensive, broad based experience and a successful record of introducing and implementing quality systems across various global locations. Demonstrated ability to simplify, harmonize and improve bottom-line compliance to applicable regulations with technology driven quality systems. Strong background in Medical Device design, manufacturing and daily Quality System Management with excellent communication and leadership skills. In-depth knowledge of supplier management and developing related processes in accordance with ISO 13485.

WORK EXPERIENCE

11/2007 – Present
Industry Consultant
Duties:

- Provide Quality Assurance and Regulatory assessment consulting services to Medical Device design and manufacturing companies.
- Ensure regulatory compliance to clients by supporting and guiding existing organizations in the management of supplier partnership, design assurance, internal auditing, and CAPA remediation.
- Establish and support company goals and objectives by identifying improvement opportunities and upgrading the quality systems throughout the organization.
- Conduct risk based supplier audits and establish measurement systems.

07/2007 – 10/2007
Hologic Corporation (formally Cytyc), Marlborough, MA
Director of Quality Assurance, Surgical Products Division
Duties:

- Responsible for post market surveillance, document control, design assurance, supplier management, training, and quality control functions.
- Responsible for the overall CAPA process and operating practices for the business.
- Supported new product introduction teams for design review and risk management activities to ISO 14971.

- Managed the review and approval process for Engineering Change Orders and supportive validation documentation.
- Focused on staffing the QA organization to support the relocation of the surgical products division from west coast to east coast.
- Developed an overall strategy to harmonize surgical and diagnostic divisional business processes for purchasing, warehouse management and customer returns. Increased system efficiency by eliminating redundant processes and procedures that supported these services.
- Created a supplier QA management function to service multiple divisions and foreign manufacturing sites realizing an efficient and common method for placing component and end item purchase orders.

2006 – 2007
Medtronic, Inc., Taunton, MA
Director of Quality Assurance, Cardio/Vascular Closure Division
Duties:

- Hosted 3rd party audits and presented Business and QA Metrics to the organization on a regular basis. Supported the development of local procedures from divisional requirements to better serve business objectives. Provided input to PMA product registrations for FDA filings and inquires.
- Provided leadership to an Early Stage Business Unit. Created and developed a fully functional QA organization which maintained ISO registration with zero observation during surveillance audits.
- Established a Supplier Management function that was crucial in identifying and correcting process/design deficiencies at suppliers. Worked with critical suppliers to increase their production yields.
- Set up a Field Assurance department to manage customer complaints and product evaluations. Data analysis was used to assist in setting failure investigation priorities.

1995 – 2006
Conmed Endoscopic Technologies (formally Bard Endoscopic Technologies), Billerica, MA
Director of Quality Assurance (2002 – 2006)
Duties:

- Responsible for all aspects of Quality across the Division and product manufacturing locations including Design Assurance, Field Assurance, Risk Analysis, Quality Control, CAPA program, Failure Investigations, and remedial actions.
- Supervised the daily activities of three managers and five direct reports. Handled divisional field reporting, communications, and audits with FDA and ISO Registrar.
- Conducted quarterly Management Reviews to ensure adequacy of the Quality System.
- Implemented an Electronic Document Control management system (QUMAS) resulting in simultaneous review and approval of change documentation across multiple sites in US and Mexico.
- Sponsored the implementation of a multi-phased design control system allowing for a systematic approach to new product launches. Utilized ISO 14971 risk assessment methodology for new designs and changes.
- Managed the divisional implementation of the TrackWise complaint handling system. Corporate office and manufacturing sites spent less time faxing, resending lost documentation, and realized a quicker time to closure.
- Chaired the corporation's harmonization effort to identify and implement best practices at multiple divisions for common systems and platforms for auditing, CAPA system, and sharing of 3rd party audit findings which improved overall regulatory compliance.
- Oversaw foreign (Asia, Europe, Mexico) and domestic product transfer activities and performed the quality aspect of divisional related due diligence process. Several products that were slated for market removal were salvaged from eroding ASPs.

Manager of Design Assurance (1995 – 2002)

Duties:

- Managed a group of 5 Design Assurance Engineers and 2 Senior Technicians. Responsible for the development of new OEM products and related specifications. Provided laboratory services for validation and verification of new product design. Interfaced with Regulatory Affairs for regulatory submissions. Oversaw product changes in manufacturing at international and domestic locations. Interfaced with customers and sales reps to gain first hand product performance feedback and utilize information for product changes.
- Reorganized the Quality Engineering group into a value-added Design Assurance Engineering organization eliminating post market product redesign.
- Streamlined the Product Development cycle thereby commercializing products quicker.
- Provided project leadership for the redesign of BETs flagship product line, resulting in a renewed quality reputation and increased sales growth.
- Created a fully functional auditing system to meet the requirement of ISO 9000 and QSRs in less than four months.

1994 – 1995

Steinbrecher Corporation, Burlington, MA

Senior Project Engineer / Lead Auditor

Duties:

- Developed and trained personnel to quality policies and procedures that were vital in establishing a functional manufacturing organization. Conducted training classes for new and existing personnel in Workmanship Standards and ISO 9000 Quality system requirements.
- Created an internal audit function meeting the requirements of ISO 9000. Trained a team of eight auditors in the performance of audits meeting the corporations ISO 9000 implementation objective.
- Developed systems for monitoring the reliability of Steinbrecher manufactured telecommunication equipment performance at customer installation sites that proved invaluable in improving design and system requirements.
- Managed a commodity team for the selection of suppliers of Printed Circuit Boards to the IPC standards that met the established Quality goals. Wrote and implemented quality systems procedures for product test, corrective action and material review to ISO 9000 Standards that greatly reduced manufacturing waste, thereby increasing product through put.

1987 – 1994

GTE Government Systems, Taunton, MA

Manager of Quality Assurance, (1989 – 1994)

Duties:

- Directed the Quality Engineering function of a $4.2 billion contract to deliver high-reliability electronic mobile military communications systems. Responsible for a department of 26, analysts, vendor and quality engineers utilizing quality system standards MIL-Q-9858A, MIL-I-45208, ISO 9000 and Commercial Off-the-Shelf (COTS) requirements.
- Reduced the number of backlogged discrepant material reports by 95% by introducing major changes to the non-conforming material control system.
- Refocused the supplier quality engineering function to prevention of defects rather than detection, thereby reducing the amount of in-house rejects and rework.
- Provided leadership for major TQM initiatives including Statistical Process Control (SPC), Assembly Process Enhancement (APE) and Ship-to-Stock programs.

Supervisor of Final Quality Assurance, (1987 – 1989)
Duties:

- Managed analysts and supervisors in performing in-process and final inspection of complex electronic assemblies.
- Scheduled workload for 25 employees, set standards, resolved quality problems, and promoted a safe work environment.
- Supported the sell-off and retrofit of equipment at various army fielding sites and maintained a 100% on-time delivery status throughout the life of the contract.

EDUCATION

Wentworth Institute of Technology, Boston MA
Bachelor of Science: Mechanical Engineering Technology

ADDITIONAL TRAINING

- Risk Management for Medical Device Manufacturers ISO 14971:2007, ISO 13485:2003 Documentation / Implementation Process, FDA Regulations, Environmental and Regulatory Management, Statistical Process Control, Management Development, Finance for Non-Financial Managers, Biocompatibility Testing & Management ISO 10993, Sterilization Workshops, IEC 60601-1 3rd addition.
- Certified Quality Auditor (CQA).
- Computer skills: Microsoft Office Suite; MS Project

PROFESSIONAL AFFILIATIONS

- The American Society for Quality
- Regulatory Affairs Professionals Society