**Operations / Product Development / Regulatory / Quality Assurance Executive**

**Executive Experience:** Strategic Leadership, Competitive Intelligence, Resource Planning, Project Management, Employee Training and Development

**Operations Experience:** P/L, sales forecast, and production planning and scheduling experience. Experienced in continuous improvement for both manufacturing and transactional processes. Experienced in implementing Lean Six Sigma initiatives into high speed automated assembly, manual assembly, and batch processes in the medical device, consumer and automotive industries.

**Product Development and Implementation:** Cradle to grave experience in bringing new products from inception to full production implementation. Have lead cross functional teams on multi-million dollar product development programs meeting both time and budgetary constraints. Designed and put into full production over 16 products. Handled all stages of production implementation including inception, prototype development, tooling and plant equipment design and installation, production ramp-up and final full-scale implementation using DFSS, DOE, VSM and FMEA tools.

**Project Management:** Experience in managing development and improvement programs on both products and processes. Experienced in stage gate methodologies. Have developed and implemented a project prioritization methodology to identify both viable and non-viable product and projects.

**Regulatory Experience:** Knowledgeable in FDA / EU MDD and other international regulations, experienced in FDA and EU MDD audits, submissions, registrations and responses. Experienced in 510k, PMA, IDE and CE Mark submission and approval processes. Experienced in FDA 483 responses and corrective actions. Experienced in the selection of Authorized representatives and translation services

**Quality Systems:** Leader in developing and deploying ISO 9001 and ISO 13485 certified quality systems from ground zero. Experienced in the transitioning quality systems from a quality control to a quality assurance mentality focusing efforts on improving design and process controls using six sigma methodologies.

**Certifications:** Certified Six Sigma Black Belt (CSSBB), Manager of Quality/Organizational Excellence – (CMQ/OE) (formerly CQM), Certified Quality Auditor (CQA), Certified Quality Engineer (CQE), Certified Reliability Engineer (CRE), Certified Software Quality Engineer (CSQE).

**Education**

BS/MS Chemical Engineering, Case Western Reserve University, Cleveland, Ohio 44106

**Career Advancement:**

**2013-Present – Director of Quality - Delta Systems - Streetsboro, Ohio - High Tech Electronics and Complete Service Medical Device Contract Manufacturer. Reports to VP Operations.**

Quality Assurance - Quality Management System development, implementation and awareness training, regulatory compliance, supplier selection and qualification, incoming, in-process and finished product inspection, customer complaint processing and resolution, product return, recall and containment processes.

**2005-2013 – Director of Operations and Quality - NDI Medical - Cleveland, Ohio - Neuro-stimulation medical device manufacturer. Reports to CFO.**

Operations – Interface between sales, manufacturing, quality, engineering and regulatory. Full responsibility for P/L, strategic planning, process and transactional improvement initiatives, production ramp-up, production planning and scheduling, warehousing, distribution, shipping and delivery of Class II and III medical devices.

Quality Assurance - Quality Management System development, implementation and awareness training, regulatory compliance, supplier selection and qualification, incoming, in-process and finished product inspection, customer complaint processing and resolution, product return, recall and containment processes.

Regulatory – Lead Management Representative for FDA Regulatory audits. Quality team leader for PMA and 510k submissions.

Information Technology - server and client hardware and software planning, acquisition, maintenance and data integrity, backup and disaster recovery.

Successfully managed new product commercialization and production

Identified, qualified and implemented key contract manufacturing, warehousing and distribution partners.

Established a supplier qualification development program to ensure that suppliers are qualified and capable of meeting product quality and delivery metrics.

Leading cost reduction effort through Design for Manufacturability improvements in initial product design specifications.

Led company successfully through multiple FDA audits with no systematic issues identified.

Led successful project to obtain ISO 13485:2003 certification. Authored and deployed entire quality management system from the quality policy through to the SOP’s, work instructions and forms

Developed and implemented a stage gate approach to the new product development process

Developed and significantly improved risk management process to allow for more rapid and timely risk management activities

Established formalized controlled build procedures to ensure that all builds for design verification and validation purposes met the necessary regulatory requirements for build control, identification and traceability.

Implemented an electronic document management system, which both made approved documents available company wide but also reduced resource needs by 90%.

Developed and deployed a robust customer complaint process, including where necessary MDR filings, which has repeatedly passed both registrar and FDA audits.

**2003 to 2005 – Quality Assurance Manager – Gyrus/ACMI - Norwalk, Ohio – Medical Device Manufacturer of Urology and Gynecology surgical instruments. Reported to VP Quality. 12 reports - 3 Engineers, 1 Supervisor, 8 indirect inspectors**

Implemented DFSS techniques into the New Product Development Process, including the development of definable and measurable customer specifications, reliability requirements and statistical confidence levels for performance testing and decision making.

Designed and implemented an electronic data management system to allow for rapid tracking of supplier performance.

Developed and implemented incoming inspection, MRB and stocking system improvements which resulted in a 50% improvement in throughput by improving transactional information flow between production planning, quality assurance and receiving departments.

**2003 to 2003 – Regulatory Affairs Manager – AMRESCO - Solon, Ohio – Medical Diagnostic/Fine Chemical Manufacturer. Reported to Owner/President. 7 reports - 4 direct 3 indirect (1 Compliance Supervisor, 2 Compliance Technicians, 1 Disposal Specialist, 1 QA Auditor, 1 Complaint Investigator, 1 QA Clerk)**

Initiated a rewrite of entire quality system to eliminate unnecessary complexity and redundancy. Projected to reduce overall documentation by 50%.

**2002 to 2003 - Manager of Quality Assurance – Sunrise Medical Products - Avon, Ohio – Medical Device manufacturer. Reports to VP North American Quality. 4 direct reports (1 QA Engineer, 2 QA Technicians, 1 Inspector)**

Plant Quality Representative of Corporate Team performing Lean implementation throughout the corporation.

**2002 to 2002– Manager of Quality Assurance – Pechiney Plastic Packaging, Bellevue, Ohio – Plastic bottle manufacturer for food industry. Reports to Plant Manager. 28 direct reports (3 QA Technicians, 16 QA Inspectors and 9 Rework personnel)**

Executive Continuous Improvement Team Member.

**1998 to 2001 – COO/Director of Quality Assurance - UV Coatings, Limited, Berea, Ohio – Specialty chemical formulator of custom engineered UV cured coatings for wood, metals and plastics. Reported to CEO. 8 direct reports in Product Research and Development, Production, Quality, and Technical Service.**

Developed and deployed ISO9001 certified quality system from ground zero. Selected and implemented a QS9000 compliant Quality Management System software package which allowed for a paperless system

Managed production planning, scheduling, materials management, manufacturing, maintenance, logistics and technical service.

Designed and implemented a production management system to meet the needs of a batch formulation manufacturing system. System includes production scheduling, inventory, lot tracking, quality assurance, MSDS generation, etc.

Set up production control and quality system for a blow molded HDPE and PP film plant in Honduras.

**1979 to 1998 - Staff Product Engineer - Eveready Battery Co., Inc, Westlake, Ohio. – Battery Manufacturer - Ultimately responsible for implementation of large-scale business critical product/process development and implementation programs spanning multiple plant locations.**

Managed Worldwide Competitive Product Surveillance and Intelligence Group

Managed and lead cross functional product development teams on a wide variety of programs