

Summary of Experience

- ❖ Experienced in the development, implementation, and certification of complete quality systems for both domestic and international operations, certified auditor
- ❖ Operations experience with product development, transition to production, and production continuous improvement
- ❖ Strong project management skills, work well with customers & suppliers
- ❖ Strong leadership skills that get results in both business performance and employee development
- ❖ Effective teamwork. Work well across organizational boundaries to develop buy-in and consensus
- ❖ Experienced with managing governmental regulations & building relationships with governmental agencies
- ❖ Superb understanding of medical, aerospace and other regulated industries quality requirements

Professional Experience

SWAN VALLEY MEDICAL, AURORA CO

Develop, manufacture and sell medical devices used in urology with contract manufactures worldwide. Startup Company with 5 employees

- Developed QMS system to meet ISO, CMDCAS & FDA requirements
- Oversee the regulatory submissions, manage consultants (USA, Europe, Canada, Australia)
- Manage the QMS
- Implemented new document control/ electronic records system (Arena Systems, PLM)

EMBLA SYSTEMS, BROOMFIELD CO

Develop, manufacture and service sleep anomalies recording and diagnostic equipment using contract manufactures worldwide

- Established Contract Manufacturer monitoring system to drive improvement
- Worked towards product registration in Brazil
- Lead XFT to resolve quality issues
- Improved the following Quality Systems; documentation, NCR, CAPA, Internal Auditing, Supplier Qualifications

AIRCELL, LLC, BROOMFIELD CO

Airborne telecommunications, internet provider to aircraft

- Establish new quality management system to be AS 9100 compliant, FAA approval of system to include satellite operations
- Certified AS 9100 auditor
- Worked with customers on quality issues, monitored our suppliers ratings
- Established a supplier qualifications manual, and rating system
- Hired off shore Quality Supply Chain person to help with off shore contract manufactures

CARSAN ENGINEERING, INC,

BIOVISION TECHNOLOGIES, INC, GOLDEN CO

High technology power supply development and manufacturing, with both local and offshore manufacturing facilities. Medical device manufacturer of endoscopes.

- Established a new quality system and received ISO 13485:2003 certification in seven months after being hired. Passed government certification with zero deficiencies.
- Took new product from concept to production in 12 months, including governmental approval for medical applications. Including writing the 510(k) for FDA submission.
- Worked with off-shore contract manufacturers to establish their quality systems and qualify them to import medical products. (FDA registration)

DISPLAYTECH, INC, LONGMONT, CO

Micro displays for use in digital cameras, video cameras, and TV's.

- Quality leader for transition of new product from development to production.
- Supported 12-month ramp-up to one million displays production rate, including transition to Japanese manufacturer.
- Built an independent quality organization and established quality practices for product development and manufacturing.
- Drove performance in three critical areas, supply chain management, product reliability & validation, and customer & contract manufacturing problem solving.
- Established quality specifications and test methods with Japanese and Korean customers.
- Audited and certified manufacturing line in Japan for startup of product at contract manufacturer.

- Transferred the purchasing responsibilities to our Japanese contact manufacturer, including vendor certification and incoming inspection.
- Managed cross-functional group responsible for the improvement of the overall business practices.
- Implemented an ERP system (Visual Manufacturing) for the following processes: inventory-tracking system, incoming inspection and vendor returns, customer returns and kit configurations and tracking.

MY TWINN, DENVER CO

Company that makes custom dolls that look like customer's child. Manufacturing facilities in China and the USA.

- Managed performance of offshore vendors (China and Quebec): audited facilities, drove process improvement, and monitored ongoing performance.
- Developed and implemented a rigorous supply chain management system.
- Managed compliance to government regulations and certification.
- Used Six-Sigma techniques to resolve ongoing manufacturing issue: vendor quality variability was driving final rejection rates.

SIEVERS INSTRUMENT, INC, BOULDER CO

Manufacturer of three types of precision instruments used to detect nitrous oxide, total organic carbon, and sulfur dioxide in the PPM range. Instruments were used in medical and pharmaceutical industry.

- Led integrated quality and production group. Responsible for product delivery, from detail subassembly through calibration.
- Managed cost, schedule, and technical performance for a 35-person organization.
- Led company effort to receive and maintain ISO 9001 registration.
- Led instrument approval process with government agencies.
- Created tracking system for production process.
- Reduced calibration time through continuous improvement initiative.

AAA PLATING, INC, DENVER, CO

Contract zinc, nickel, chrome and gold plating and anodizing company.

- Managed testing lab for plating/anodizing facility.
- Ensured facility availability per production schedule
- Established pro-active periodic maintenance system for plating baths.
- Monitored, tested and reported outgoing wastewater for EPA regulations.

UNION CARBIDE, ST ALBANS, VT

Manufacturer of flashlights and batteries, associated with injection molded parts, metal forming, plating, & automated assembly

- Established SPC's for all processes
- Set up new waste treatment facility for heavy metals
- Established pro-active periodic maintenance system for plating baths.
- Monitored, tested and reported outgoing wastewater for EPA regulations

Business Experience

- Owned and operated cottage industry business, sewing and knitting in Vermont
- Regulatory & Quality Systems Consultant to Aerospace, Medical Device & Environmental industries

Education

- BS Chemistry, Michigan Technological University, Houghton, Michigan
Minors in Business and Engineering
- Certified Lead Auditor
- ESD Awareness Certification