Jay Quality Engineer
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EDUCATION BS – Electrical Engineering, 1978: Rutgers University, New Brunswick, NJ

SUMMARY Over 20 years experience in engineering, including:

- Extensive ***medical device quality assurance*** engineering and management.
- Experience ***with reliability, failure analysis, corrective actions, training, supplier audits, and software auditing and validation.***
- Experienced with ***GMP*** and ***ISO 9000*** regulations, assuring ***FDA*** compliance.
- ***ISO-9000 Certified Lead Auditor, GMP Certification***

EXPERIENCE

ABC Corp., Somewhere, NJ 3/02 – Present

QC Supervisor/QA Engineer

- Responsible for maintaining the quality program, including investigation and resolution of performance issues related to instrumentation.
- Integrate QC/QA Functions to provide product investigation as a result of customer complaints, high non conforming activity and/or internal quality issues.
- Authorize the release of finished products and raw materials. Analyze product performance trends and initiate corrective action for quality defects and quality system discrepancies.
- Chair non conforming materials for products and raw materials.
- Responsible for closure of NCMR issues.
- Perform Internal and External Audits. Provide reports to Senior Managers.
- Review customer complaints and responsible for closure of all product performance and repair customer complaints.
- Provide technical assistance to QC/QA, Mfg, purchasing and vendors.
- Review and approve test plans, verifications, and validation reports.
- Attend product design review, product reliability and QIP meetings.
- Assist in training QC group on GMP's and ISO 9000 regulations, assuring compliance with FDA.GMP (QSR) regulations. EN 46001 and EN 13485 standards.
- Responsible for the review and approval of engineering drawings, ECO's and raw materials specifications, responsible for the timely calibration of test equipment and updating of the calibration database.
- Work with Manufacturing, R&D, Technical Service and Sales/Marketing to track, monitor and resolve customer complaints and product performance issues.

DEF Co., Inc., Somewhere, NJ 3/00 – 10/01

Quality Assurance Engineer

- Conducted analysis that identified the cause of defects and suggested methods for avoiding them through Continuous Process Improvement.
- Assisted in efforts to meet ISO-9001 and QSR compliance requirements for software validation, calibration, documentation, internal audits and reliability.
- Provided reliability, maintainability and quality engineering supported to R&D, Manufacturing Engineering, production and marketing.
- Team member of suppliers management. Performed external supplier quality audits.
- Provided Technical and Quality Assurance guidelines to purchasing and SHI suppliers.
- Evaluated customer complaints' and recommended solutions.
- Investigated minimum training requirements for production and quality personnel and developed training matrixes.

GHI, Inc., Somewhere, NJ **1986 – 2000**

5/97 – 3/00: MRI/CT Safety Modification Specialist/ Lead Auditor

- Responsible for the evaluation of modifications made to MRI/CT units database and generating the batch file via SAP for sites impacted by modifications.
- Provided technical assistance to the service engineers and managers.
- Set priorities to implement modifications and also provided status reports, in conjunction with department managers and directors.
- Performed quality audits at supplier facilities, assessing their QA systems based on GMP and ISO-9000 standards. Provided recommendations to follow up on action plans agreed to by suppliers, based on audit results.
- Acted as a liaison between international and US suppliers to minimize costs and turn-around time when purchasing, repairing or refurbishing electronic components.

1/86 – 5/97: Quality Assurance Manager/ Project Manager

- Coordinated Manufacturing and Quality Assurance operations for high technology, new product introduction, MR Diagnostic Imaging Systems.
- Established quality control and quality assurance testing and procedures including Image quality acceptance for mobile MRI medical units.
- Planned and scheduled testing of mechanical and electrical components of MRI units.
- Reviewed failure analysis and proposed corrective action and procedure recommendations.
- Team leader for incoming inspection and testing of RF components for MRI units.
- Conceived and established quality audit procedures of suppliers quality system to ensure compliance with GMP and ISO-9000 standards.
- Supervised pre-staging for inspection, final testing and on time delivery schedule of MRI units to customers.
- Consulted with overseas office and received approval for the MRI parts Re-certification project, by following GMP compliance I developed procedures and managed the Re-certification project from field to finish goods.
- Saved company $70,000,000 overall.

JKL Corp., Somewhere, NJ **1984 – 1985**

Production Engineer

- Supervised technical and procedural support team for production and technical service departments.
- Reviewed product design and performance functions and made effective recommendations.
- Implemented procedures of designed analytical instruments from R&D to production.

MNO Co., Somewhere, NJ **1981 – 1984**

Manufacturing / Production Engineer

- Supervised technical and procedural support for production/manufacturing and technical service departments.
- Developed accurate, workable bills of material and product structure, method and routing sheets for Production Group.
- Provided technical assistance to Inspection, QA, Purchasing and sales departments.
- Consulted with various department managers on product design and performance.

PQR Company, Inc., Somewhere, NJ **1980 – 1981**

Quality Assurance Engineer

- Responsible for technical assistance to inspection and testing personnel.
- Provided procedural and technical support for quality assurance function, and developed accurate, workable quality standards and controls.