


ADMEDES
IDEAS. EXPERTISE. PASSION.

QUALITY ENGINEER PRODUCT & PROCESS CONTROL

ADMEDES INC. Livermore, CA

ADMEDES is the leading global provider of finished Nitinol self-expandable components for implants such as stents and heart valve frames to the medical device industry. We apply the latest micro-machining and surface finishing techniques for rapid response prototypes, pilot line and full-scale manufacturing. Together with products manufactured from tube, using advanced laser technology, we have also developed a comprehensive range of NiTi wire forming technologies. Admedes Inc. in Livermore, CA is a subsidiary of Admedes GmbH in Germany.

Job Description

The Quality Engineer Product & Process Controls provides quality engineering and manufacturing process related services that support the manufacturing, inspection, qualification and validation of components for medical devices and ensures that appropriate and/or required quality regulatory and statistical techniques are applied to manufacturing and inspection processes and equipment.

The Quality department

Develops, implements and maintains overall company quality system and procedures. Provides communication, work direction, coaching, training and guidance for employees. Participates in product, project and process development teams to provide quality support and input.
Works with customers, engineering, manufacturing and other groups to develop and conduct verification, validation and qualification activities for equipment, processes and products. Works with customers, engineering, manufacturing and other groups to develop appropriate test and inspection methods and acceptance criteria for new and existing products.
Assists the quality management of our parent company Admedes GmbH in implementing, maintaining and aligning quality systems that are compliant with ISO 13485, FDA QSR and intracompany requirements.

Responsibilities:

- Support process validation studies, including IQ/OQ/PQ, FMEA, TMVs, Gage R&R, Equipment and Software Validation as required
- Responsible for preparing, executing, and/or reviewing validation deliverables in collaboration with development engineers
- Write validation protocols and reports
- Interface to manufacturing engineers during review of process outputs and planned improvement activities
- Participate in product, project and process development teams to provide quality support and input to design specifications and manufacturing documentation
- Perform process capability analysis, determine sampling plans and appropriate process monitoring methods and criteria
- Lead auditee for audits by external parties (customer and/or notified body)
- Perform internal audits
- Responsible for supplier evaluation, qualification, maintenance of supplier files
- Oversees and coordinates incoming inspection activities
- Quality Engineer Product & Process Control
- Provide quality control support for receiving inspection, in-process and final inspection
- Assist in implementing, maintaining and aligning quality systems that are compliant with ISO 13485 and FDA QSR requirements
- Comply with applicable quality system procedures
- Performs other related duties and responsibilities as assigned by Quality Manager

Qualifications and Skills:

- Bachelor's degree or equivalent
- 2 years of experience in an ISO 13485/FDA regulated environment
- 5 years of experience in an ISO 13485/FDA regulated environment with no bachelor's degree
- Knowledge of applying statistical analysis for testing, process control, and design of experiments
- Knowledge in the areas of Validation & Verification, Risk management and manufacturing/inspection practices/principles
- Strong verbal and written communication with the ability to effectively communicate at multiple levels in the organization
- Organized, detail-oriented team player capable of working in a deadline dedicated environment
- Experience with Nitinol material processing is desirable

INTERESTED?

Please send resumes to admedesincjobs@admedes.com