ADMEDES
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WE ARE HIRING

Quality Engineer

Organization: ADMEDES Inc.
Department: Quality

ADMEDES INC. LIVERMORE, CA

ADMEDES is the leading global provider of finished Nitinol self-expandable components 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 provides quality engineering and manufacturing process related services that support the manufacturing, qualification, validation and post-distribution activities 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.

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RESPONSIBILITIES

- Support process validation studies, including IQ/OQ/PQ, FMEA, TMVs, Gage R&R, Equipment qualification and Software Validation as required
- Write validation protocols and reports
- Collaborate with engineering teams to support investigation, containment, and execution for quality issues (non-conformances, customer complaints, CAPA)
- Monitor quality, determine the root cause of problems and implement corrective actions and countermeasures
- Analyze and disposition component and product defects as a member of the Material Review Board
- Assist running non-conformance management (MRB) activities
- Interface with 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.
- Lead auditee for audits by external parties (customer and/or notified body)
- Perform internal audits
- Quality Engineer
- Responsible for supplier evaluation, qualification, maintenance of supplier files
- Assist in implementing, maintaining and aligning quality systems that are compliant with ISO 13485 and FDA QSR requirements.
- Comply with applicable quality system procedures.
- Flexibility for dynamic changes in day-to-day work as it pertains to daily quality priorities
- 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
- Audit experience (notified body audits, customer audits, internal audits)
- Strong knowledge in investigating of NCR, customer complaints and CAPA
- Knowledge of applying statistical analysis for tes ting, process control, and design of experiments
- Strong verbal and written communication with the ability to effectively communicate at multiple levels in the organization
- Ability to work within a team and as individual con tributor
- Organized, detail-oriented team player capable of working in a deadline dedicated environment
- Experience with Nitinol material processing is desirable

PLEASE SEND RESUMES TO
admedesincjobs@admedes.com