

Director, Quality Assurance and Regulatory Affairs – Pittsburgh, PA

Position Summary:

Responsible to develop, implement, and maintain the CAI Corporate Quality system to ensure compliance to the EU and FDA QS regulations, provide leadership to the organization regarding Quality concepts and initiatives, and ensure Regulatory Compliance including FDA and EU Regulatory submissions.

Working Conditions:

Office and laboratory environment; minimal travel (<15% required)

Primary Responsibilities:

- Define the quality mission and goals for Cardiac Assist and serve as the corporate Quality Management Representative.
- Manage Customer Complaint Process and perform FDA Medical Device Reporting and EU Vigilance System Reporting.
- Ensure that product verification and process validation requirements are defined, tested and updated on a periodic basis.
- Continuously upgrade and verify the testing capability of the quality laboratory.
- Translate end user needs into quality goals, and ensure that the quality organization is fully represented on new product or product improvement project teams.
- Daily supervision of the Quality Control Dept, Documentation Control Dept, Regulatory Staff, and Quality Assurance Staff.
- Maintain the Corrective and Preventive Action system including the development and implementation of corrective actions to quality, or performance issues as required.
- Provide training to the organization on the Corporate Quality System and applicable quality and regulatory requirements.
- Maintain the CAI Quality System to assure compliance to the FDA QSRs and the EU ISO 13485 and Medical Device Directive requirements.
- Manage the Quality System Internal Auditing program and represent CAI in audits of the CAI Quality System conducted by the FDA or the EU Registrars.
- Manage departmental personnel including training, coaching, mentoring, and disciplinary actions as required.
- Report to senior management on status of the Quality System.
- Implement continuous process improvements in Quality Control, Documentation Control, and Quality Assurance.
- Perform Regulatory compliance activities including regulatory review of ECOs, NCMRs, and New Product releases
- Develop EU Design Dossiers and Technical files, and prepare FDA 510(k), IDE, and PMA submissions in support of new product development.
- Develop Quality Control Inspection processes, fixtures, acceptance criteria, and inspection plans.
- Assist Customer Service with Maintaining Customer Complaint System.
- Coordinate evaluations of supplier quality systems and periodically assess supplier quality.
- Assist other departments as required to meet or exceed corporate objectives.

Position Requirements:

- Strong familiarity with FDA and EU requirements for Medical Device Quality Systems and Regulatory submissions
- Experience as a Quality System auditor including Supplier Selection and Auditing
- Strong experience in project management and planning, including Risk Management planning
- BS degree in electrical engineering. Masters degree preferred.
- Minimum of 7 years Quality Assurance and/or Regulatory experience in the Medical Device field
- Minimum of 5 years of supervisory experience
- Strong communication and presentation skills
- Sound judgment ability and attention to detail