SHURIG SOLUTIONS INC.

INTEGRA LIMIT UNCERTAINTY

Quality Engineering Manager
Job Location: Boston, MA (onsite)

Responsibilities

The Quality Engineering Manager will manage the Product Quality Engineering team focused on product compliance in support of Product Design and Manufacturing, including the critical quality system elements of CAPA, Complaint Investigations, Risk Management (pFMEA), Process/Test Method/Equipment Validations, Deviations, Control of Nonconforming Product, Product Holds, and Equipment management. Works closely with Operations, Manufacturing Engineering, Design Engineering and Post-Market Surveillance groups to ensure a high level of product quality and effective and efficient investigations when needed.

Directly supervises Quality Engineering and Microbiology.

Responsible for management of site Quality Engineering activities (including process and equipment validations, test method validations, deviations, non-conformance and CAPA investigations, product hold management, design/manufacturing change support, test method validations, pFMEAs, microbiology and equipment management). Management of key Quality Management System elements including Control of Nonconforming Product, Deviations, Microbiology and Calibration. Management and mentoring of Quality Engineering personnel.

Qualifications

- Bachelor's degree required, preferably in Quality Assurance, Biological Sciences or Engineering, or related discipline.
- Five to ten (5-7) years' of experience in Quality Engineering in the Medical Device Industry. Minimum 1-3 years in supervisory role.
- Experience in personnel management and mentoring.
- Demonstrated experience in successfully leading a team.
- Experience in project management.
- Experience with statistical techniques.
- Working knowledge of QA Engineering related QMS elements including Design Controls, Production and Process Controls (including Process Validation), Control of Nonconforming Product, Facilities/Environmental Controls, Labeling and Packaging Controls, Handling, Storage, Packaging and Distribution of Product, Inspection and Test, Test Method Validations.
- Experience with CAPA processes including investigational techniques.
- Experience with Risk Management regulations and application (ISO14971).
- Working knowledge of medical device regulations (including FDA QSRs, ISO13485).

- Strong technical aptitude (i.e., able to read and comprehend technical documentation, ability to comprehend and execute procedures, demonstrated understanding of system documentation).
- Ability to interface with top organizational leadership and internal and external customers, responding in a professional manner.
- Ability to communicate effectively (both written and oral) using English (or local language).
- Ability to influence positive change effectively.
- Exceptional conflict-resolution skills.
- Experience with development and implementation of quality system procedures.
- Experience with Cleanroom environment and requirements preferred.
- Experience with tissue products preferred, but not required.
- Certified Quality Engineer (e.g., ASQ CQE) preferred, but not required.

While undertaking the essential duties and responsibilities of the position, the employee must repeatedly sit, listen, speak, stand and move throughout the facility. The employee is required to be on the ground in all areas of the building. The employee must be able to lift items of up to 25-30 lbs. Periodic travel may be required.

In an effort to minimize the spread of the coronavirus and to protect our employees, all new hires in the US and Puerto Rico will need to be fully vaccinated for COVID-19 in order to be considered for employment with Integra LifeSciences, unless eligible for an accommodation as provided by law.