SHURIG SOLUTIONS INC.

INTEGRA LIMIT UNCERTAINTY

Senior Quality Engineer
Job Location: Boston, MA (onsite)

Responsibilities

The Quality Engineering team focuses on product compliance in support of Product Design and Manufacturing, including the critical quality system elements of CAPA, Complaint Investigations, Risk Management, Process/Test Method/Equipment Validations, Deviations, Control of Nonconforming Product, Product Holds, Microbiology 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.

The Sr. Quality Engineer will be responsible to serve as Subject Matter Expert in the areas of Quality Engineering, Risk Management (pFMEA), Process/Test Method/Equipment Validations, deviations, and NC and CAPA investigations. This role will be responsible for independently leading and documenting these activities to support production and manufacturing. This role will be responsible for mentoring junior Quality Engineers.

Primary responsibilities include:

- Lead CAPA investigations and action plan / VoE completion
- Lead Nonconforming product investigations
- Lead pFMEA and support all risk management activities
- Supporting equipment management activities
- Supporting process, test method and equipment validations
- Supporting changes to design or manufacturing
- Collection and reporting of metrics and data as required
- Leading and supporting site improvement initiatives

Qualifications

- Bachelor's Degree is required, preferably in Quality Assurance, Engineering or Biological Sciences.
- Minimum 5 years experience in Quality Engineering in Medical Device or similar FDA regulated industry.
- Demonstrated experience in successfully leading a team.
- Experience with measurement systems and 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.
- 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 work independently with minimal supervision.
- Ability to communicate effectively (both written and oral) at different levels of the organization.
- Experience with development and implementation of quality system procedures.
- Certified Quality Manager or Certified Quality Engineer desired but not required.

The employee must repeatedly sit, listen, speak, stand and move throughout the facility. The employee is required to be boots on the ground and spend time in all manufacturing areas. The employee must be able to lift items of up to 25-30 lbs.

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.