SHURIG SOLUTIONS INC.

INTEGRA LIMIT UNCERTAINTY

Sr Quality Engineer - Design & Reliability
Job Location – Princeton, NJ

Duties and Responsibilities:

- Lead and support the design and development of new or improved products in close collaboration with Product Development, Project Management, RA, Marketing and Medical Affairs. Support Design Reviews, Technical Reviews, and Gate Reviews.
- Lead and support the execution of all Risk Management and Usability Engineering process activities, including design, process and application FMEAs.
- Support external partners in the development of products, including review and approval of development documentation such as product requirements, schematics, verification and validation strategy/execution
- Coordinate, review and approve development documentation created by external partners, including product requirements, schematics, code, verification and validation test strategy, protocols and reports.
- Develop Reliability models for predicting product performance over time.
- Lead implementation SPC programs with Manufacturing and Quality Control as a part of Process Validation and Design Transfer.
- Maintains knowledge of and applies statistical analysis to support data-driven decision making.
- Work with project teams to develop DOEs and statistically sound tests for appropriate support of results.
- Develop statistically based sampling plans for Design Verification and Validation, Process Validation, or other studies as deemed necessary.
- Participate in FDA inspections, ISO Certification and surveillance audits and customer audits as an NPD subject matter expert.
- Writing & coordinating efforts for the development and implementation of new and updated Quality System procedures for ISO/QSR, such as validation protocols, manufacturing procedures, product & material specifications, design & development documentation, SOPs, development and task force projects.
- Ensure that all projects are in compliance with GMP, QSR, ISO or other applicable requirements.
- Identify and implement opportunities for continuous improvement in the quality system.
- Interact and coordinate activities with other departments, external vendors and customers.

- Perform other Quality Systems related duties as required.

Qualifications:

- Bachelors Degree in Engineering (Biomedical, Mechanical, or Electrical) or Science (Biology).
- 5 years of experience in a Quality Assurance role for medical device or pharmaceutical manufacturing.
- Demonstrates excellent knowledge of statistical sampling and analysis tools/methods to support data-driven decision making.

- Demonstrates excellent organizational, verbal and written communication skills
- Proficient with the MS Office Suite, and statistical software.
- Must be able to work independently with minimal supervision.
- Able to prioritize projects and manage assigned Quality resources to meet organizational goals and objectives.

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.