LivaNova

Health innovation that matters

The **Senior Quality Engineer** supports the Senior Quality Engineering Manager in managing all aspects related to the design and manufacture of the products of the franchise in compliance with the Quality Management System requirements and the regulations of the countries where the franchise distributes and sells products.
This senior position will focus primarily on sustaining changes to the disposable products. The position co-operates in managing internal & external audits, interacting with auditing organizations and reporting on the QMS to the company managers.

Primary focus:

1) Design Control, Production and Process control.

- Establish product quality control plans commensurate to product risk.
- Coordinate with Engineering to establish product design verification/validation and process or software validation plans for the change or new product/process development.
- Review and provide input into process validation planning, protocols, and reports.
- Performs preliminary review of the change impact assessment to confirm that quality requirements are met.
- Coordinates investigations of the cause of V&V failures using root cause analysis problem solving methodologies.
- Identify opportunities of quality improvements in the production area and lead improvement plans or projects.

Secondary focus:

1) Nonconforming product handling. This role will:

- Collect and critically analyze data and make disposition decisions on nonconforming products. The Sr. QEs will also provide NCR decisions for less experienced QEs to ensure that regulatory and patient risk are minimal.
- Lead failure investigations and ensure that systematic problem solving methods are employed and results are properly documented for nonconforming products and complaints.
- Generate the evaluation of the risk posed by the observed NC on products already distributed (HHE) to determine if Stop Shipment and/or FSCA should be proposed. Ensure the maintenance and update of Risk Management reports to document new issues or increases in severity or occurrence.
- Identify and implement improvements within the QMS.Own input into the CAPA process and trend data to identify opportunities for CAPA. Support CAPAs either through ownership of the CAPA or as part of a CAPA team. Ownership of the CAPA Process is also a potential for this position.
- For escalated and larger scope issues, support Supplier Quality with external manufacturers of components, semi-finished and finished products or external service providers in the management of any detected non conformities.

2) Analysis of Complaint data and Returned Products. This role will:

- Provide daily support, as needed for: Complaint evaluations and investigations and c ustomer-related processes involving use of the device.

- Provide support to meet Customer Quality complaint and MDR reporting quality metrics.
- Develop and maintain effective relationships with internal and external stakeholders to assist customers and drive the resolution of customer complaints.
- Interface with customers to understand details to issues trending up for all customers or issues specific to a particular account.

3) Company Process Improvements as well as Business or Compliance changes. This role will:

- Monitor and maintain compliance to regulatory and company requirements. Understand and implement FDA, ISO 13485, MDSAP, MDR, etc requirements.
- Act as a leader during these projects and be responsible to communicating the project status and being accountable for the results of the project. Act as the Quality representative to understand and communicate the needs of all quality functions when assigned to large facility or process change projects.
- Frequently seek and use information from other departments to determine the appropriate response to issues and regulatory impact.
- Serve as a role model and help to develop the skills and competence of less experienced engineers and technicians.
- Conduct or assist with the review and evaluation of personnel performance.

Skills and Abilities Required

• Successfully demonstrates an in-depth or breadth of engineering skill(s).
• Ability to work within a changing environment.
• Ability to work with a wide variety of personnel on all levels and utilize constructive confrontation
• ASQ Certified Quality Engineer or other ASQ Certifications is a plus.
• Ability to analyze and problem-solve.
• Excellent communication and presentation skills.
• Able to communicate across functional lines.
• Sitting 60-80%, standing & walking 20-40%
• Repetitive work on computer 80%
• Oral and written comprehension
• Must be willing to take on related duties as required in support of company and departmental objectives.

Minimum requirements

-Bachelors Degree in Technical and Scientific disciplines (Physics, Chemistry, Engineering or Biology).
-Minimum related work experience of 6 to 8 years in Class II/III medical device manufacturing.
-Proficiency with quality tools such as flowcharts, statistical data analysis, mathematical reasoning
-Previous experience with process validation and verification of changes to design requirements.
-Knowledge of regulatory requirements (e.g., FDA, ISO) as required for the position.
-Must be able to work in a clean room environment and tolerate chemical odors.

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https://livanova.wd5.myworkdayjobs.com/en-US/Search/job/Arvada-Colorado-US/Sr-Quality-Engineer_JR-8562