



JOB DESCRIPTION

Position Title: Senior Quality Engineer

Reports to: Quality Supervisor/Manager or Director of Quality Engineering

Function: Clinical, Quality Assurance & Regulatory Affairs

Location: Arvada, CO.

Creation Date: September 15, 2026

To apply, go to:

https://livanova.wd5.myworkdayjobs.com/Search/job/Arvada-Colorado-US/Senior-Quality-Engineer_JR-14812

Position Summary:

Under limited supervision, performs complex quality engineering work of a broad nature to achieve and maintain the highest possible product quality levels and regulatory compliance in their assigned area. Leads and supports team efforts to improve quality systems and tools company wide. Frequently uses and applies technical standards, principles, theories, and concepts. Successfully demonstrates a broad and in-depth understanding of the company's practices, policies, and therapies, and uses the knowledge effectively in its application while exercising a considerable amount of judgment and originality. Along with leading teams and demonstrating expertise in the quality systems and tools, this position may also coordinate or supervise other quality engineering employees reporting into this position.

General Responsibilities:

- He/she supports Quality Engineering Management for managing all aspects related to the design and manufacture of the company's products in compliance with the Quality Management System requirements and the regulations of the countries where the franchise distributes and sells products.
- The position co-operates in managing internal & external audits, interacting with auditing organizations and reporting on the QMS to the company managers.
- With respect to Nonconforming product handling, He/She will:
 - Collect and critically analyze data and make disposition decisions on nonconforming products. The Sr. QEs will also provide NC 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 Field Action should be proposed. Ensure the maintenance and update of Risk Management reports to document new issues or increases in severity or occurrence.
 - Own input into the CAPA process and trend data to identify and propose 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. Identify and implement improvements within the QMS.

- 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.
- With respect to the Design Control & Production and Process control, He/She will:
 - 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 for the cause of V&V failures using root cause analysis problem solving methodologies.
 - Identify opportunities for quality improvements in the production area and lead improvement plans or projects.
- With respect to Analysis of Complaint data and Returned Products, He/She will:

Provide daily support, as needed for:

 - Complaint evaluations and investigations;
 - Customer-related processes involving use of the device;
 - Provide support to meet Customer Quality complaint and Medical Device Report/Vigilance 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 of issues trending up for all customers or issues specific to a particular account.
- With Respect to Company Process Improvements as well as Business or Compliance changes, He/She will:
 - Monitor and maintain compliance with regulatory and company requirements. Understand and implement FDA, ISO 13485, MDSAP, Medical Device Requirements, etc. requirements.
 - Act as the Quality representative to understand and communicate the needs of all quality functions when assigned to large facility, product or process change projects. Act as a leader during these projects and be responsible for communicating the project status and being accountable for the results of the project.
 - 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 Quality Engineers, engineers and technicians.
 - Conduct or assist with the review and evaluation of personnel performance for direct reports or when requested otherwise.

Skills and Experience:

- Excellent communication and presentation skills. Minimum related work experience of 6 to 8 years in medical device manufacturing, preferably Class II/III.
- Successfully demonstrates an in-depth or breadth of engineering skill(s).
- Must have proficiency with quality tools such as flowcharts, statistical data analysis, mathematical reasoning
- Ability to work within a changing environment.
- Ability to work with a wide variety of personnel on all levels and utilize constructive confrontation while maintaining positive work relationships.

- ASQ Certified Quality Engineer or other ASQ Certifications is a plus.
- Knowledge of regulatory requirements (e.g., FDA, ISO) is required for the position.
- Ability to analyze and problem-solve.
- Able to communicate across functional lines.
- Sitting 60-80%, standing & walking 20-40%
- Repetitive work on computer 80%
- Must be able to work in a clean room environment and tolerate chemical odors as well as the site and smell of blood.
- Must be willing to take on related duties as required in support of company and departmental objectives.

Education:

- Bachelor's Degree in Technical and Scientific disciplines (Physics, Chemistry, Engineering and Biology) or equivalent experience.

Travel Requirements:

20%