



Job Description – Highland Circle Innovations

Quality Systems Specialist

Position Description:

Join us and become a member of an entrepreneurial team that supports the design and development of innovative, new products within a medical device incubator, Highland Circle Innovations! You will help streamline and speed up our time to market across multiple products and build quality in at every step. As a champion of quality within the organization, you will be on the leading edge of ensuring meaningful impact to patients, physicians, and payors in a small, fast-paced and innovative environment.

The main objective of the Quality Systems Specialist is to successfully manage the everyday quality assurance operational tasks for ongoing product development projects, and commercially released products across a variety of HCI clients.

This position will report to the Managing Director of Highland Circle Innovations.

Responsibilities Include:

- Supports the development and maintenance of quality programs, systems, processes, and procedures that ensure compliance with policies and that the performance and quality of services conform to established internal and external standards and guidelines.
- Supports audit and inspection preparation, resolution of audit and inspection findings and liaises with auditing groups and inspectors through all stages of the audits.
- Influence and provide expert input in new product development programs and resources
- Maintain supplier controls
- Support the management representative as required for management review and external audits
- Help maintain the Document Control system including change orders, document publishing, document archival, and training.
- Help maintain and improve quality management system procedures and processes
- Help maintain medical device complaints including receiving, investigating, determining reportability, generating regulatory reports, analyzing trends, and closing.
- Manage Receiving, Receiving Inspection, and Material Requisition processes.
- Maintain the Corrective Action/Preventative Action (CAPA) system including issuing of CAPAs, operating as a project manager to ensure their timely closure, and routing for signatures
- Manage the Product Release process including communications with CMO.
- Maintain and improve QMS software, streamlining document control processes
- Evaluate QA project issues, develop resolutions, and ensure relevant issues are communicated to the Highland Circle Innovations management team
- Contribute to the implementation, maintenance, and improvement of project management methodology
- Monitor QA aspects of projects from initiation through delivery
- Develop mechanisms for monitoring QA improvement projects and mechanisms for intervention and problem solving with project team members, various third-party resources, various service providers, suppliers, and contract manufacturers
- Other duties as assigned



Position Must Haves:

Minimum Qualifications

- BS or BA in science or engineering is preferred, in lieu of Bachelor's degree, Associate's degree (or equivalent) with applicable relevant experience will be considered.
- Minimum of 3 years of relevant experience
- An understanding of the scientific, technical, manufacturing, marketing and regulatory processes involved in the development of a medical device product
- Experience in the medical device industry, covering supplier controls, corrective action preventative action, control of non-conforming material, product development
- An extensive understanding of Quality System Regulations (ISO 13485), FDA Regulation (21 CFR 820), and the Risk Management Process (ISO 14791)
- Flexibility, persistence, passion, resourcefulness, a drive to succeed and an entrepreneurial spirit

Position Nice to Haves:

- ASQ Certification (CQA, CQE, CMQ, CRE etc.)

Physical Job Requirements:

The physical demands described within Position Description section within this job description are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Significant Work Activities: Continuous sitting for prolonged periods, Keyboard use (greater or equal to 75% of the workday)

Location: Minneapolis, MN but open to remote

Travel: Yes, <10% of the time

Highland Circle Innovations is an Equal Opportunity Employer of Minorities/Women/Individuals with Disabilities/Protected Veterans.