



Job Description – Highland Circle Innovations

Project Manager - Product Development

PM-PD Position Description:

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

The main objective of the Product Development Project Manager (PM-PD), is to support and execute on development projects alongside the engineering team for the development of Highland Circle Innovations' portfolio of products and, as needed, its consulting clients. A well organized, flexible and quick learner with an entrepreneurial spirit is a must.

The PM-PD is responsible for preparing, tracking, managing and communicating project plans across multiple product development programs. This person plays an essential role as part of the project teams, working with the core team members to develop and execute project and business plans, and support efforts from product concept through commercial launch across a variety of HCI clients.

The PM-PD would report to the Managing Director of Highland Circle Innovations.

Responsibilities Include:

- Design and develop primarily class II medical devices
- Ensure designs meet performance specifications, regulatory and manufacturing requirements
- Manage product development projects
- Prepare, track, and communicate project plans that specify project phases, tasks, task interdependencies, durations, resource assignments, and costs. Coordinate tasks and schedule.
- Use software to develop detailed 3-D CAD models and drawings
- Proactively communicate with management to ensure an ongoing two-way exchange of information
- Maintain Design History Files
- Prepare documentation release packages, including detail drawings, bills of material, and/or procedures
- Approve Document Change Orders (DCOs) and obtain approvals from others as required
- Working with all internal groups, identify trends and process gaps and suggest and assist in the implementation of corrective actions and process improvements
- Help manage and direct activities with various vendors and contract manufacturers
- Promptly respond to product issues, taking appropriate action within the Highland Circle Innovations' Quality System and continually building strong rapport with customers and suppliers
- Collaborate with all departments to develop optimal work order routings and Device History Records
- Lead the generation of redlined documentation and review prior to sign off
- Oversee the generation of process validation/qualification documentation (e.g., validation protocols, IQ/OQ/PQ) and lead the implementation of protocols and completion of reports
- Perform other activities as directed

Position Must Haves:

Minimum Qualifications

- BS or BA in engineering is desired
- Minimum of 3 years of medical device product design and development experience



- An understanding of the scientific, technical, manufacturing, marketing and regulatory processes involved in the development of a medical device product
- Familiarity with Microsoft Project or other equivalent project management tools
- Familiarity with FDA, QSR, and ISO 13485 medical device regulations and standards
- Flexibility, persistence, passion, resourcefulness, a drive to succeed and an entrepreneurial spirit

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

Travel: Yes, <10% of the time

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