Theragenics
Position Description

POSITION TITLE: Quality Engineer **DATE: September 9, 2021**

POSITION SUMMARY

This position utilizes Quality Engineering and Quality Assurance techniques and expertise to provide functional support for new product development, existing manufacturing line and processes as well as maintenance of the Risk Management Program.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Provide support for the manufacturing areas (internal and external). Work with production personnel and supervision to determine and monitor quality metrics, samples plans and address non-conforming product issues. Lead corrective and preventive action investigations to resolve the root cause of problems.
- Participating on project teams as a contributing member by providing quality engineering support in the development of new products and processes, and continuously improving company's products.
- Experience or knowledge with all phases of the Design Control and Validation processes in the context of FDA and ISO 13485 regulations and understanding of disciplined product development processes, regulatory and quality requirements for medical products.
- Thorough knowledge and application of ISO 14971
- Writing and reviewing of procedures, plans, protocols and reports to ensure regulatory compliance.
- Develop acceptance criteria and measurement techniques for new product release.
- Lead Design Control and Transfer for release of new product development projects.
- Assists and/or leads in the development and execution of verification & validation plans, testing, and generation of test reports.
- Author and assist in the development and execution of process validations
- Perform statistical analysis for testing requirements and develop MSAs and TMQs.
- Assisting project teams on compliance with design control requirements per FDA QSR, European MDD/MDR, ISO 13485 and other applicable ISO/EN standards
- Participate in risk management activities in compliance with ISO 14971 as expressed in the company's Quality Management System.
- Develop relationships with employees to ensure team-oriented operation.
- Accurately represents quality processes to 3rd party auditors (FDA, ISO 13485, MDSAP, etc.)
- Other duties as assigned

Minimum Qualifications, Skills, and Abilities:

- Bachelor's Degree in Engineering.
- 5+ years of experience within the medical device space, R&D, regulatory or design development.
- Expertise in scalability of process and product design for growth
- Well versed with metrics and data driven approaches leading to quick and efficient adoption of continuous improvement initiatives
- Expertise in MDR and Product standard experience.
- Class III Medical devices.
- Experience working on project teams resulting in PMA and 510k submissions.
- Willingness and capability to take ownership of projects and drive them to successful completion Self-starter, driven to take initiatives to solve problems

ORGANIZATIONAL RELATIONSHIPS

LOCATION: Theragenics, Buford, GA
DEPARTMENT: Quality and Regulatory Systems
REPORTS TO: Director of Quality and Regulatory Systems
SUPERVISES: No Direct Reports

WORK ENVIRONMENT

Some duties and responsibilities are performed in an office environment and some are performed in a radionuclide production environment with radioactive materials. The job is typically performed under comfortable working conditions; any disagreeable elements are generally absent during normal performance of job.

CONFIDENTIALITY

This position has access to or may be exposed to confidential and propriety Company information. Therefore, a high level of confidentially must be maintained at all times with any Company information.

LIMITATIONS AND DISCLAIMER

The above position description is meant to describe the general nature and level of work being performed; the position description is not a comprehensive or exhaustive list of all duties, responsibilities of skills required for the position. Management has the right to assign or reassign duties and responsibilities to or from this position at any time.
To perform this position successfully, the employee must be able to satisfactorily perform each essential position duty and responsibility. All position requirements are subject to possible modification to reasonably accommodate individuals with disabilities.