QUALITY ENGINEER
JOB DESCRIPTION

POSITION SUMMARY

The Quality Engineer applies insight, experience, knowledge and skill, as well as implements and determines best practices and procedures, to support complex quality-related engineering activities (including, but not limited to, product development, verification and validation) and to solve multifaceted quality issues that relate to the implementation, maintenance and support of new and existing products. This role serves as a leadership as well as an individual contributor role, which assures consistent quality of product development and production by developing and enforcing good manufacturing practice systems.

ESSENTIAL DUTIES AND RESPONSIBILITIES

The essential functions include, but are not limited to the following:

- Develop and maintain 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.
- Provides expertise and guidance in interpreting policies, regulatory and/or governmental regulations, and internal regulations to assure compliance.
- Facilitates execution of projects to improve the quality systems.
- Monitors the health of the Quality System through identification of key metrics.
- Participate in audit and inspection preparation, resolution of audit and inspection findings.
- Prepares reports and/or necessary documentation (e.g., Corrective and Preventative Actions) and provides to applicable stakeholders, both internal and external.
- Manage/participate and harmonize all QMS processes and ensures that Quality & Regulatory requirements are effective in all QMS processes in scope.
- Lead quality planning activities; ensure design control and risk management compliance according to regulations.
- Write, review, and approve validations ensuring systems, utilities and processes comply with regulations and standards.
- Participate in validation project teams; maintain and communicate appropriate schedules, budgets, etc.
- Participate risk assessment teams and problem-solving activities related to product or process quality issues; lead investigations of non-conformances, identify root cause, and determine/implement appropriate corrective action plans.
- Develop and implement statistical process controls and sampling plans.
- Participate in design control project teams; ensure predetermined requirements are met and that compliance is maintained.
- Lead continual improvement activities to enhance the quality system, processes, products, and standards by applying quality tools and statistical analysis.
- Lead activities that ensure products and processes comply with the requirements of the quality management system and external regulating agencies.
- Maintain the quality management system.
- Monitor product quality to ensure product compliance; work to identify and implement improvements.
- Participate in internal and external audits.
- Create and maintain company quality documentation.
- Prepare reports as needed; provide in-depth statistical analysis.
- Provide functional training to build quality awareness.

- Maintain up-to-date knowledge of Quality Systems Regulations (QSR).
- Continually ensure all projects/processes comply with relevant regulations and other applicable requirements.

Minimum Qualifications (Knowledge, Skills, and Abilities)

- Bachelor's degree, or equivalent, plus a minimum of two (2) years previous experience preferred, preferably within a regulated medical device or pharmaceutical environment; completion of some post graduate course work, or equivalent, preferred
- Knowledge of quality engineering principles required
- Knowledge of Quality System Regulations required
- Technical writing skills required
- Excellent communication and presentation skills
- Knowledge of Microsoft Office required; knowledge of statistical software, and experience with large enterprise resource planning (ERP) system preferred
- Excellent problem-solving skills required
- Excellent planning and organizational skills required