SEABROOK
TECHNOLOGY GROUP

Job Description

Sr. Quality Manager

Confidentiality

JOB DESCRIPTION

Job Title: Sr Quality Manager	Exempt

POSITION SUMMARY

The Senior Quality Manager will demonstrate a strong track record of leading and executing quality initiatives across multiple organizations. They will ensure the processes are followed and tools used within the Quality System are appropriately validated and controlled through their life cycle from development, deployment, change control and retirement. This includes ensuring project teams adhere to processes and control mechanisms for software, hardware, data and relevant security to meet regulatory requirements.

GENERAL ACCOUNTABILITY

Key Responsibilities:

- Enforce policies and procedures for System Development Lifecycle Management control for use in Seabrook across all processes that drive, interface with, and provide data for the Quality System.
- Support development of the validation strategy and the validation effort from planning to retirement of Quality-relevant systems and tools including interfaces to and from the system.
- Provide software quality assurance support in design and development of software solutions and facilitate the application of controls and risk management by reviewing and approving IT change-control requests submitted by cross-functional project teams to assess potential quality system impact.
- Ensure that system development projects and changes to existing systems are conducted in compliance with the FDA Quality System Regulation and Medical Device Directives.
- Work alongside other validation professionals to gather data, plan activities, and obtain reviews and approvals of documentation including approving documentation with respect to software development life cycle policies and procedures.
- Provide GxP-related quality assurance oversight, with an emphasis on software validation.
- Develop, manage and execute test plans to ensure product reliability and scalability in mission critical manufacturing software implementations.
- Participate in validation process following customer's validation protocol
    - Authoring / execution of validation documents
        - Installation Qualification (IQ)
            - Verifies Detail Design Specification (DDS)
        - Functional Requirements Specification (FRS)
        - Operational Qualification (OQ)
        - User Requirements Specification (URS)
        - Performance Qualification (PQ)
        - Interface configuration and testing
- Assists and provides hands-on assistance and mentoring related to testing and software validation
- Support documentation process, for user documentation
- Provide superior level customer service and support
- Provide Internal support
    - Lead internal consulting, auditing, training and education of resources for internal

quality initiatives
- Assist internal consultants with problems that arise in the course of an engagement

Travel Required:

- Consultant should be prepared to travel up to 50% of the time
- Travel required based on:
  - Customer requirements
  - Milestone delivery
  - Successful execution of assigned tasks

EXPERIENCE / QUALIFICATIONS

Skills and Abilities Required:

- Demonstrate specific domain knowledge relevant to technology solutions
- Ability to work collaboratively in a team environment
- Strong technical skills
- Ability to multi-task
- Strong communication, organizational and documentation skills
- Attention to detail
- Demonstrated ability to work effectively with US FDA and other regulatory agencies
- Track record of measurable, operational improvements to Quality Systems related functions
- Demonstrated ability to work as a senior leader and to engage the entire senior leadership team as needed.
- Demonstrated ability to work cross-culturally and to develop and maintain strong business partner relationships.

Experience:

Required:

- 8 - 10 years of experience with software testing, certification, and validation and verification (Computer Software Validation (CSV)
- 8 + years of experience in validation of computer systems and system security and control.
- Experience with Medical Device Industry
- Familiarity with standards
  - IEEE 1012 -1998 IEEE Standard for Software Verification and Validation
  - IEEE 829-1998 Standard for Software Test Documentation
  - 21 CFR part 11– Code Of Federal Regulations
  - Good Manufacturing practice in Manufacturing, Processing, Packing, or Holding Of Drugs and Manufacturing Devices (GAMP4-5)

Desired:

- Experience with consultative role working with clients
- Experience in implementing manufacturing execution systems (MES / MOM)

Computer Equipment and Software Requirements:

- Windows Operating Systems
- Microsoft Office Suite

EDUCATION

B.S. in Engineering, Computer Science, or related Field (or the equivalent experience) plus a minimum of

12 years related experience.

Disclaimer

This job description in no way states or implies that these are the only duties to be performed by the employee(s) incumbent in this position. Employee(s) will be required to follow any other job-related instructions and to perform any other job-related duties requested by any person authorized to give instructions or assignments.

A review of this position has excluded the marginal functions of the position that are incidental to the performance of fundamental job duties. All duties and responsibilities are essential job functions and requirements and are subject to possible modification to reasonably accommodate individuals with disabilities. To perform this job successfully, the incumbent(s) will possess the skills, aptitudes, and abilities to perform each duty proficiently. Some requirements may exclude individuals who pose a direct threat or significant risk to the health or safety of themselves or others. The requirements listed in this document are the minimum levels of knowledge, skills, or abilities.