RxLogix Corporation

Title: Manager – IT QA & CSV

Location: Noida, India **Date**: 15th April 2020

Job Status: Full Time

Essential Duties & Responsibilities:

Note: This opportunity is **not** a fit for the software testing professionals. The candidate **must** possess experience in the Pharmaceutical IT Compliance areas and CSV and a good understanding of regulations for LifeScience industries such as GAMP 5, CFR , EU Annex 11, ICH etc.

1. CSV:
    - Provide application validation expertise on GxP products for drug safety space.
    - Be accountable for reviewing and supporting key CSV deliverables – Requirement Specifications, Validation Plan, Test Plan, Traceability Matrix, Test Summary Report, Qualification Scripts and Validation Summary Report
    - Understanding of implementing projects on SaaS Models
    - Understanding needs of Infrastructure , Operation and Performance qualification in alignment with Software Engineering Practices.
    - Requirements Analysis and Risk Assessment, Profiling and Mitigation in collaboration with the SME
    - Sound Defect management skills
    - Provide adequate understanding and expertise on Change Control Procedure, Deviation Handling, Document Management and CAPA management
    - Understanding of risk-based system validation approach and V-Model
2. Quality Assurance Operations:
    - Knowledge of GxP, QA best practices
    - In depth understanding of the regulatory guidelines for IT systems– primarily FDA, EMA, MHRA and PMDA
    - In depth understanding of 21 CFR Part 11, EU Annex 11 compliance
    - Minimum 10 years' experience of client, internal and regulatory audits
    - Anchor updates to QMS
    - Engage in Continual Improvement programs
    - Coordinates the revision, review, and approval of IT SOPs and other GxP documents
3. Team and Stakeholder Management Skills:
    - Client engagement and ability to convince based on RxLogix Best Practices
    - Ability to manage Stakeholder needs and do multi tasking
    - Oversee work of direct reports and cross-train staff on different quality areas
    - Interview, hire, train, develop and manage employees
    - Capacity planning and forecasting resource requirements
    - Performance evaluation and appraisals
    - Motivating agent for the team and fosters the spirit of teamwork
    - Coach, mentor and develop staff, including overseeing new employee onboarding and providing career development planning and opportunities
    - Closely work with clients, project team and product owners to support product releases and implementations

4. Other Must-have skills:
    - Well-organized and detailed oriented professional, with strong verbal and written communication skills
    - Self- motivated with ability to manage, organize and prioritize multiple tasks
    - Should be able to achieve the optimum balance for Quality vs. Productivity

Minimum Requirements:

1. Exposure to pharmacovigilance domain and drug safety applications – Argus or ArisG/J – strong preference
2. Experience with electronic QMS/DMS is a plus.
3. Experience in Manual execution and ALM Tool based executions
4. Experience with training coordination and management
5. Worked in Agile / Scrum team structure
6. Experience in SQL and PLSQL writing

Preferred Qualifications:

1. BE/ B.Tech./ MCA/ B.Pharma/ M.Pharma from recognized institute with good academic scores
2. IT Quality Assurance professional with **09-12 years** of experience with computerized system validation in Life Sciences industry. Hands on experience is performing Validation activities both Manual and ALM tools based.

Travel Expectations:

0-5%