RxLogix Corporation

Title: Team Lead – 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
    - Interact with internal product owners and client users to understand business, functional & non-functional requirements or improvements for software product. Review and ensure that the requirements are detailed, un-ambiguous, complete and testable.
    - Author and/or review validation test plan, strategy, requirement traceability matrix, validation test summary report for product releases based on project / product requirements.
    - Lead, mentor & guide the testing team members for all type of testing activities and artefacts including (but not limited to) system testing, functional testing, manual testing, automation testing, OQ, PQ, IQ, etc.
    - Review the work performed by the team members, provide feedback to ensure adherence to the validation and documentation practices and be accountable for the quality of work products created by the team.
    - Accountable for quality testing and release of all product features and product testing documents / artefacts with high quality.
    - Lead validation and UAT activities and artefacts for client product implementation projects.
    - Support and liaise with internal QA team for internal and external audits for product / project documents and artefacts.
    - 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. Overall, 10 Years of experience
3. Experience with electronic QMS/DMS is a plus.
4. Experience in Manual execution and ALM Tool based executions
5. Experience with training coordination and management
6. Worked in Agile / Scrum team structure
7. 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 **10 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%