

## **IT Quality Assurance Specialist**

We are looking for a professional with experience in both information technology and basic logistics business information. The successful applicant will serve as the liaison between the Commercial and IT departments of our company, leveraging the data the IT team extrapolates while also overseeing the selection and implementation of software programs and hardware resources (Optional). The ideal candidate for this position is detail-oriented and highly innovative. He or she will also be responsible for translating business needs to IT solutions, overall assist of Director/CIO on product feature planning.

### **Responsibilities**

- Collaborating with stakeholders (e.g. System Owners, Process Owners, Data Owner and manufacturing IT Owner) to assess and select computerized systems to support UrbanFox business processes; to ensure technologies selected meet the high-level business needs; and ensure the initial project tailoring is appropriate for the complexity and risk to accommodate the full scope of work.
- Providing the independent quality approval of key qualification /validation documentations such as policies, procedures, acceptance criteria, plans, protocols, requirements, reports and computerized system related changes to ensure compliance to company standards and applicable regulations throughout the computerized system lifecycle (including changes/modifications/deviations/variances/compliance investigations).
- Assuring site/above site system owners have Operating Level Procedures/Plans, approved by Quality, in place and routinely followed to ensure computerized system(s) remain in a validated status (e.g. problem and incident management, change control, periodic review, investigations, backup/restore, System Use and Administrative SOPs, disaster recovery plans, business continuity plans).
- Reviewing processes and supporting documentary evidence to verify that compliance activities related to computerized systems are in place and effective.
- Supporting regulatory inspection and audit activities as needed. This includes the review of audit or inspection reports, responding to findings related to IT applications, automated manufacturing equipment, automated lab systems and infrastructure (at local sites) and taking appropriate actions to ensure UrbanFox compliance.
- Driving resolution of regulatory non-conformance for UrbanFox computerized systems.
- Monitoring and communicating system health, compliance and other metrics updates to key stakeholders.
- Promoting UrbanFox awareness and a culture of continuous improvement and facilitating manufacturing process improvements, laboratory operational excellence and validation activities, including latest trends in validation and best practices.
- Representing QA IT management upon request in local site or system specific meetings regarding computerized systems selection, operation and/or compliance related issues.
- Contribute in the development and maintenance of training programs in the principles of computerized systems validation and regulatory requirements in validation, maintenance and use of computerized systems.

## Requirements

- Bachelor's degree. Preferably Information Technology, Engineering or equivalent.
- Hands-on experience and understanding of automated systems supporting pharmaceutical manufacturing, IT infrastructure and/or laboratory operations.
- At least two years of experience in delivering validated IT solutions or an application support role.
- Good understanding of the current IT industry and applicable regulations (IT General and Application Controls), with emphasis in ISO, ITIL and local regulatory expectations.
- Must demonstrate working knowledge of the principles, theories and concepts of computerized system validation / compliance.
- Familiarity or practical experience in the implementation of quality systems in IT company.
- Operate as part of a self-directed team in carrying out day to day functions and assigning priorities.