



Job Description – Quality Systems Engineer

Job Title: Quality Systems Engineer

Reports to: Director, Quality Assurance

Weekly Hours: 37.5

Location: Cheadle Royal Business Park, Cheadle

Job purpose

We are seeking a highly experienced Quality professional to manage and lead the selection, installation, and validation of E-Systems at Seda's GMP manufacturing facility.

As the Quality Systems Engineer you will provide Quality Management System validation (all IT systems within the Quality System) oversight and leadership to the wider Clinical Manufacturing Services division, to ensure that the products manufactured in our facility comply with GMP standards and meet appropriate quality, safety and efficacy standards.

Key responsibilities

Regulatory Compliance & Quality

- Ensure all IT GxP systems/ processes comply with cGMP, MHRA, FDA and relevant industry standards and guidance.
- Maintain validation activities in alignment with the Site Validation Master Plan (SVMP) and applicable regulations.
- Support internal and external audits, providing documentation, expertise and follow-up actions as required.
- Deliver key Quality metrics, including monitoring and completing periodic reviews of computerised systems.

Validation Activities

- Draft, execute and review validation protocols, test scripts and reports for bespoke and configured computerised systems.
- Ensure protocol objectives and outcomes are fully documented in accordance with procedural and regulatory requirements.

- Lead the execution of validation activities, ensuring all deliverables are completed within agreed project timelines.
- Author and review validation reports ensuring accuracy, completeness and compliance.
- Ensure validation incident reports are raised, investigated, resolved and closed promptly.

System Documentation & Technical Writing

- Author and review Functional Design Specifications (FDS) for complex computerised systems.
- Write technical protocols, reports, Standard Operating Procedures (SOPs) and Work Instructions (WRKs).
- Provide guidance on procedural updates to maintain compliance with evolving regulatory requirements.

Risk Management & Issue Resolution

- Lead and author risk assessments, including FMEA and root cause analysis, to support computerised system validation.
- Identify appropriate mitigation actions and ensure completion and effectiveness.
- Investigate validation-related issues and assign corrective and preventative actions (CAPA) where required.

Subject Matter Expertise & Cross-Functional Support

- Act as SME for computerised systems validation, advising colleagues, project teams and business stakeholders.
- Support process improvement initiatives and technology transfer activities for new products.
- Review and assess potential suppliers, supplier responses and audit questionnaires.
- Collaborate with cross-functional teams to ensure successful system implementation and qualification.

System & Project Support

- Support administration of validated systems as required.
- Recommend, develop and implement improvements to validation processes and system efficiencies.
- Communicate issues, risks or concerns promptly to the Validation Manager.
- Perform other reasonable duties to support departmental and business needs.

Skills & Experience



- Strong understanding of cGMP, MHRA and FDA regulatory requirements for GxP systems.
- Proven experience writing and reviewing CSV documentation including protocols, reports, specifications and SOPs.
- Demonstrated ability to lead system installation and validation projects and deliver within defined timelines.
- Skilled in risk assessment methodologies (e.g., FMEA, RCA) and CAPA management.
- Excellent communication, technical writing and stakeholder management skills.
- Ability to work collaboratively across functions in a fast-paced, regulated environment.