Specialist – Quality Operations

Job ID
REQ-10015991
Sep 03, 2024
India

About the Role

Major accountabilities:

- Coordination and management of analytical method transfers and stability studies. Compilation of data reports
- · Life-cycle management of analytical methods, including control of method performance, pharmacopoeia and health authority compliance and definition of method improvements. Handling of deviations, investigation, OOS/OOE/OOT cases as well as changes and complaints· Perform statistical data analysis to report Out of Expectations (OOE), out of trends (OOT), etc· SAP master data management: Maintenance of master data, creation of Q-info records and other SAP related activities.· Validate spreadsheets· Collect, transcribe and/or compile data from various repositories (SAP, LIMS, external COAs)· Author, approve and archive Impurity risk assessments – Nitrosamines, residual solvents, etc· Trend and report all QMS elements as per the request· Monitor, trend and report Health Safety and Environmental parameters· Implementation of GMP requirements. Compilation and Review of documents (analytical protocols and reports, annual performance quality reports, ongoing process verification reports, registration documents (Common Technical Document modules)).· Perform activities of a Quality Control expert as defined by the respective sites· Support regulatory requirements – routine queries, Chromatogram requests· Compile Quality performance management decks· Create and review GxP documents including SOPs, working procedures, trend reports, qualification reports and technical investigations, as and when needed

Key performance indicators:

- · On-time and GMP-compliant release of dosage forms -No complaints about inspections by authorities in your own area of responsibility without these being noticed and communicated beforehand -Successfully support continuous improvement projects -Executes batch release in compliance with registration

Minimum Requirements:

· Pharmacy/ Science/ MBA / Engineering/ equivalent from a reputed institute

· Min 5 years of experience in Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substances/ products/ medical devices

· GxP knowledge, Basic IT knowledge

· Good communication, presentation and interpersonal skills

· Experience of working closely with the global stakeholders

Skills:

- Analytical Method Development/ Method Validations/Method Transfers
- Quality Control / In-process / Raw materials /
- Stability studies / Supportive stability studies
- Investigations like OOS/OOE/OOT
- Pharmacopoeia / Health Authority / Regulatory requirements
- GxP / Data Integrity / Quality and Compliance.
- SAP/HPLC/UV

Languages :

- · Fluent in English (written and spoken)

Role Requirements

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