Better Health, Brighter Future

Job Description: Quality Control (MIS) Trainee

Primary Objectives of the Job:

This position is required perform all tasks associated with the QC MIS (Method Introduction and Support) operations which include test method introduction/transfer/validation, equipment qualification, control trend establishment, reference standard/reagent qualification, invalid results tracking/trending/investigation, lab deviation/investigation, compendial review, continuous improvement and other tasks as assigned.

Primary Responsibilities Include:

Core Responsibilities:

- Complete 8 Core Modules together with elective modules in Biologics conducted in Singapore Polytechnic and On-the-Job Training (OJT) with Takeda
- Liaise with QC Analytical/Raw Material/Microbiological labs and participate in Method validation/verification/transfer to introduce new/remediated QC methods for testing existing and new products
- Liaise with QC Analytical/Raw Material/Microbiological labs and participate in equipment qualification
- Maintain validated status of assays by establishing a control and monitoring strategy to ensure that the method is in the state of control, and the data generated from the method is reliable.
- Coordinate QC method documents changes for regulatory submission
- Perform invalid results tracking, periodic trending for laboratory invalid assays
- Prepare control assignment Protocol/Report for controls as require.
- Prepare qualification protocol and qualification report for reference critical materials
- Coordinator of new/revised compendial document assessments on local methods and raw material
- Initiate and participate in Out Of Specification (OOS), Invalid test and Lab Deviation Investigation Write-Up and assist in timely closure of laboratory invalid results, lab investigation and CAPA.
- Write/revise SOPs, forms, training qualifications (TQ) and risk assessments (RA) as required.

General Responsibilities:

- Coordinates a subset of team members or entire group for specific tasks/topics/projects
- Assist Supervisor to support internal and external compliance audits.
- Responsibility to adhere to any applicable EHS requirements.
- Commitment to a fair and respectful relationship to others and behavior in accordance with Takeda's Code of Conduct.
- Participate in projects towards improving safety performance and continuous improvement initiatives.
- Any other duties as assigned by supervisor.

Education and Experience Requirements

- Bachelor Degree in Chemistry, Biochemistry, Biotechnology or equivalent, preferably with more than 1 year of experience in Pharmaceutical, Biopharmaceutical or related manufacturing environment.
- Demonstrated ability to collaborate with cross functional or cross sites to achieve objectives.

Key Skills and Competencies

- Project Management Skills
  - Organization and planning skills
  - Analytical and Logical thinking skills
  - Ability to work and collaborate within the team
- Technical Skills
  - Basic GMP knowledge
  - Knowledge in Microsoft Office.
- Problem solving
  - Basic problem solving skill