

Expert Science & Technology

Job ID
REQ-10085758
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Индия

Сводка

-Design, plan, perform, interpret and report results of scientific experiments for the preparation and timely delivery of drug substances (DS), drug products (DP), processes and procedures within a multifunctional project team coordinated by a Project Leader. Manage technical lab/plant activities. -Management TrackLead a team for the development of pharmaceutical/biological/cell-gene therapies working in a small manufacturing plant environment. Execute the functional strategy and drive operational excellence in line with TRD vision and strategy. Ensure full portfolio support in line with GDD, Sandoz, NTO and NIBR plans. -SANDOZ: -Associate Scientist: Design, plan, perform, interpret and report results of scientific experiments for the development and timely delivery of drug products (DP), processes and procedures within a multifunctional project team coordinated by a Project Leader. Manage technical lab/plant activities. -Scientist: -Design, plan, perform, interpret and report results of scientific experiments for the development and timely delivery drug products (DP), processes and procedures. Lead and manage all project/local network activities, support/coach team members, participate in sub-teams and contribute to overall SZ strategies and goals -Senior Scientist: Design, plan, perform -document and interpret scientific/developmental experiments and GMP testing or pilot plant processes for the preparation and timely delivery of generic products, processes or procedures; maintain and qualify equipment/infrastructure and manage operational aspects in lab or plant as assigned.

About the Role

Key Responsibilities

- Responsible for performing method feasibilities and validation of robust analytical methodologies applied to innovative oral solid dosage forms. Strong experience in chromatography techniques and experience in handling techniques like Dissolution, Titrator etc., used for OSD testing is a pre-requisite.
- Plan, organize, execute, and document scientific experiments (e.g., analytical method developments/ validations/ transfers/ stability/ release testing, formulation development analytics etc.) according to the agreed timelines and appropriate quality standards.
- Accountable for documentation and submission of raw data in an appropriate data system (for e.g., LIMS test activation and results entry).
- Responsible for good documentation practices (GDP) and good laboratory practices (GLP) during execution of laboratory activities.
- Generate and support in evaluation and interpretation of results including investigations on SST failures, OOX/Deviations/Change controls as needed.
- Responsible for assigned laboratory related area/activities (e.g., chemical/reagents/consumables/samples/column/ glassware management etc.). Responsible for implementation and maintenance of lean/efficient/environmentally sustainable practices in the laboratory.
- Proactively communicate key issues and any other critical topics in a timely manner to the manager and/or to any other relevant project team member(s).
- Responsible to meet KQI (Key quality indicators) and KPI (Key performance indicators) for all assigned activities. Support internal and external audits and ensure no critical findings within the assigned scope.

Minimum Requirements

- Ph.D. in Analytical Chemistry or an equivalent qualification with a minimum of 1–3 years of experience, or M. pharm/M.Sc. with at least 8 years of experience within the pharmaceutical industry, specifically in analytical development.
- Understanding of general regulatory and quality expectations. GMP experience is a must
- Good scientific background, communication skills including presentation and scientific/technical writing.
- Good knowledge of software and computer tools such as Office package, LIMS, chromatography data-evaluation software (e.g. Chromeleon) etc.
- Expertise in liquid chromatography separation techniques and dissolution techniques is a pre requisite. Experience in Mass Spectrometry (ranging from mass confirmation to actual quantitative analysis of impurities and sequencing) is an asset.

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Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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