Expert Science & Technology

Job ID
REQ-10065366

11月 04, 2025

India

摘要

Design, plan, perform, interpret and report the analytical results of scientific experiments for the preparation and timely delivery of drug substances (DS), drug products (DP), processes and procedures within global ARD. Expertise in analytical method development, method validation as well as technical and strategic background. Manage technical lab/plant activities. Execute the analytical experiments in line with TRD vision. Ensure full portfolio support in line with GDD, NTO and NIBR plans. Maintain and qualify equipment/infrastructure and manage operational aspects in lab or plant as assigned.

About the Role

Major accountabilities:

- Provide analytical and technical support to PHAD/project team at various stages of product

development (e.g. CSF, FMI and LCM)
- Design and author analytical documents (e.g., Analytical methods, Stability protocols/reports, Excipient compatibility (EC) protocol/reports; APS protocols/reports, etc.)
- Support Analytical project leader for setting analytical development strategy.
- Support in data interpretation, results compilations and sharing the information with critical observations and proposals to project team.
- Responsible for project related sample handling (e.g., sampling plans, issuance, storage, distribution, reconciliation/destruction of the samples).
- Support planning for assigned project activities. Accountable to meet KQI (Key quality indicators) and KPI (Key performance indicators) for all assigned project activities.
- Provide requests for lab activities to the associates and stakeholders.
- Manage project activities including logistics at third parties and external testing laboratories.
- Proactively communicate key issues and any other critical topics in a timely manner to the appropriate management level and/or to any other relevant project team member(s).
- Single point of contact for PHAD/project team and other stakeholders for project execution activities.
- Support internal and external audits and ensure no critical findings within the assigned projects.
- Actively contribute to team goals.
- Work according to appropriate SOPs, GMP, GLP, QM, HSE, ISEC & Novartis Guidelines.
- Subway: Author (EC/APS protocol and reports), review of test methods and compatibility study plan.
- ESOPS: Read SOP access and Review of SOPs.

Minimum Requirements:

Work Experience:

- MSc/M Pharm with 6-9 year Industry experience
- Ph.D. with 2-3-year Industry experience

Skills:

· Proficiency in developing and validating analytical methods for Assays, Impurities, Dissolution, Content uniformity for OSD and parental formulations.

· Familiarity with ICH guidelines and regulatory expectations for method validation, Analytical Target Profile (ATP) and lifecycle management of analytical procedures, Good Laboratory Practices (GLP) and ALCOA+ principles.

· Hands-on experience with HPLC and UPLC (with Empower and chromeleon), UV-Vis, DVS, Dissolution testing systems.

· Apply best practices in LC chromatography and sample preparation for reproducibility and accuracy.

· Ability to troubleshoot and maintain analytical instruments

Languages :

- English.

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Development

Business Unit
Universal Hierarchy Node

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India

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Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Accessibility and accommodation

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