

Senior Expert, Science & Technology (Analytical Expert)

Job ID
REQ-10020397
Sep 03, 2024
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Summary

400! This is the number of associates in Global Analytical R&D, across 4 countries, working tirelessly on innovative and patient centric medicines. As part of this group, you design, plan and/or perform scientific/technical studies. By bridging the analytical science to the clinical performance, you will drive the transformation of our molecules into medicines that improve and extend patient's lives. The position is based in the Genome Valley, Hyderabad, within the Technical Research and Development Organization (TRD) of Global Drug Development (GDD).

About the Role

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Your responsibilities will include, but are not limited to:

- Design, plan and interpret scientific experiments for projects at different clinical phases of drug substance and drug product development with minimal guidance. Well versed with regulatory guidelines, scientific literature, technology transfer and interpretation of the results to draw conclusions in reports.
- Provide scientific guidance to the laboratory associates
- Write, review and/or approve analytical documentation in timely and high-quality manner, such as releases, analytical batch records, method validations, stability, technical reports, SOP's etc. ensuring compliance with Novartis and health authorities' guidelines
- Helping to define the overall analytical control strategy
- Contribution to scientific exchange groups within Novartis
- Report and present scientific/technical results internally and contribute to publications, presentations, and patents
- Manage interactions and contribute to a high level of collaboration with internal and external stakeholders.
- Adhere to Quality metrics, Compliance and Good Documentation Practices following ALCOA+ principles, GLP, OQM, HSE, ISEC and Novartis guidelines.
- Should be a Team player by adding value in collaborating with other teams to support project deliverables within agreed timelines, mentoring new joiners, active participation in project meetings / networks / meetings and contributing to team goals while meeting individual objectives.
- Ability to perform investigations, guide team members, communicate proactively and clearly to global stakeholders and handle multiple priorities.

- Provide input into CMC documents to support regulatory submission and respond to HA queries.

Role Requirements

- PhD in analytical chemistry or equivalent and a minimum 6 years' experience or M. Pharma/M. Sc with a minimum of 12 years' experience in the pharmaceutical industry in analytical research and development
- Experience in driving analytical activities in NCE across various phases of drug development, complex injectables, parenteral, oligonucleotides, peptides and late phase method validation.
- Good knowledge of software and computer tools such as Office package, LIMS, chromatography data-evaluation software (e.g. Chromeleon) etc.
- Fluent English (oral and written).
- GMP experience in analytical laboratory
- Successfully demonstrated expertise in a specific scientific/technical area
- Good presentation skills and scientific/technical writing skills.
- Good communication skills.

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Division
Global Drug Development
Business Unit
Innovative Medicines
Standort
Indien
Site
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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