Senior Expert, Science & Technology (Analytical Expert)

Job ID
REQ-10008885
Mayo 27, 2024
India

Resumen

5! The typical number of projects you will participate in as the new Analytical Expert based at Novartis Hyderabad sit. As part of the Global Drug Development (GDD) team, this role is essential in ensuring the development of highest quality small molecule drug substances throughout the life cycle of each project, required to support clinical trials.

About the Role

Your responsibilities include, but are not limited to:

· Working as an Analytical Expert in the External Partner Management (EPM) unit of Chemical and Analytical development (CHAD) in their new group in Hyderabad.

· Guiding external partners to develop analytical methods to control and monitor the performance of synthetic drug substance manufacturing processes, with a focus on analytical separation sciences (e.g. HPLC, LC-MS etc.).

· Supervising GMP activities such as method validation, specification setting, release testing, deviation handling and change control management.

· Helping to define the overall analytical control strategy for the manufacture and timely delivery of drug substance.

· Providing scientific guidance to external analytical teams, supporting daily business, troubleshooting etc.

· Supporting CMC document writing and regulatory submissions.

· Actively managing interactions between internal and external partners to ensure a constructive and well-functioning collaboration.

· Participation in technical DS project teams (internal and external) and contribute to overall strategies and goals of chemical development projects.

· Supporting the set up of data bases and document flow process within the EPM unit.

· Contributing to evaluation, selection and onboarding process of new external partners.

· Reviewing technical and GPM-relevant documents

· Contribution to scientific exchange groups within Novartis and externally.

What you'll bring to the role:

· Desirable: PhD in analytical chemistry or equivalent and a minimum 3 years' experience in the pharmaceutical industry in analytical development

· Recognized achievements in the development of new analytical methods: main focus on separation sciences, e.g. HPLC, LC/MS, GC as well as physico-chemical methods (Karl Fischer water determination, titrations).

· Successfully demonstrated expertise in a specific scientific/technical area

· Proven experience in a GMP analytical environment.

· Fluent English (oral and written).

· Strong coordination and communication skills, collaborative spirit, determined attitude, high level of learning agility are key attitudes

· Excellent knowledge of laboratory and/or technical tools.

Good knowledge of software and computer tools such as Office package, LIMS, chromatography data-evaluation software (e.g. Chromeleon) etc.

Why Novartis?

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we

achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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Functional Area
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