

Senior Expert, Science & Technology (EPM Specialist)

Job ID
REQ-10037171
Jan 21, 2025
India

Summary

5, The typical number of projects you will participate in as the new EPM Specialist based at Novartis Hyderabad site. 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

Major accountabilities:

- Owning and leading process improvement activities related to externalized process R&D
 - Supporting oversight/documentation/workflows related to externalized business (non-GMP/GMP).
 - Managing data and readouts related to externalized activities (compilation of relevant KPIs for regular evaluations with external partners)
 - Supporting CMC document writing and regulatory submissions
 - Contributing to evaluation, selection and onboarding process of new external partners.
 - Actively managing interactions between internal and external partners to ensure a constructive and well-functioning collaboration.
 - Participating in scientific/technical exchange with internal stakeholders and external partners.
 - Supervising GMP activities such as master batch record and executed batch record handling, deviation handling and change control management.
 - Support external manufacture and timely delivery of drug substance.
 - Reviewing technical and GPM-relevant documents.
 - Identifies and supports continuous improvement initiatives related to external partners and internal processes.
 - Supporting/leading set up of data bases and document flow process within the EPM unit.
 - Owning, developing and maintaining team SharePoint.
- What you'll bring to the role:**
- Desirable: PhD/MSc in chemistry, chemical engineering or equivalent and a minimum 3 years' experience in the pharmaceutical industry in chemical development and/or commercial.
 - Proven experience in a GMP environment (equipment/facilities, manufacturing, deviation handling, change control, documentation etc.)
 - Successfully demonstrated expertise in a specific scientific/technical area.
 - Fluent English (oral and written).
 - Strong coordination and communication skills, collaborative spirit, self-driven attitude, high level of learning agility are key attitudes.
 - Excellent knowledge of data management and software/tools such as Office package (e.g. Excel, SharePoint, MSTeams), SAP, planning tools etc.
 - Personal inclination for IT solutions and data management is a plus.
 - Experience in operational excellence and Six Sigma certification is a plus.
 - Experience and knowledge in procurement of API, intermediates, raw materials and services incl. management of RFPs and RFIs is a plus.

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>

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <https://www.novartis.com/careers/benefits-rewards>

Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <https://www.novartis.com/about/strategy/people-and-culture>

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

Division

Development

Business Unit

Innovative Medicines

Location

India

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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