Senior Expert Science & Technology (GxP & Compliance)

Job ID
REQ-10049939

May 22, 2025

India

Summary

Leads and supports establishing and maintaining the GxP management system of the ARD Line Units at site level, serves as a contact point between local QA and the local ARD Line Units for general inquiries, represents the ARD in GxP-related committees and networks. Lead and manage all compliance/project/local network activities, support/coach team members, participate in sub-teams and contribute to overall TRD strategies and goals.

About the Role

Responsibilities include, but are not limited to:

- Oversee and lead all activities of assigned teams /projects to meet customer needs.
- Work according to appropriate standards for quality, ethics, health, safety, environment, protection and information security.
- Establishes and maintains GMP management system and monitors compliance with internal

and external regulations. Ensures compliance to cGMP.
- Oversees all GMP activities within the Unit, Advises and supports the team heads and staff regarding GMP issues, Monitors quality exception management and drives timely completion,
- Supports training programs and implementation of SOPs, GMP, GLP, QM, HSE, ISRM and Novartis Guidelines.
- Prepares, performs, and supports GMP audits as appropriate, including organizing and tracking any follow-up action items.
- Lead initiatives to ensure continuous improvement
- Perform complex tasks without having established procedures.
- Oversee and write protocols, scientific reports, lab procedures or process related SOPs. Write scientific documents intended for external partners or for generation of registration documents.
- Communicate, address and solve problems within own and broader area of responsibility. Communicate effectively across organizational interfaces.
- Lead the transfer of know-how to other departments or external contractors, including troubleshooting and on-site training.
- Lead the optimization of project related scientific /technical activities or processes, co-ordinate local team(s) and guide development and implementation of new technologies.
- Provide scientific and technical guidance; actively foster knowledge exchange.
- Develop, mentor and coach other scientific associates, present scientific /technical results internally and contribute to publications, presentations and patents.
- Meet quality, cost and timelines in all assigned projects.

WHAT YOU'LL BRING TO THE ROLE:

- M. Pharm/MSc with 10+ years of experience or PhD in Science (e.g. analytical/Pharmacy/Chemistry or equivalent) with 5+ years of experience.
- Recognized expertise in a GxP area with scientific as well as strategic background.
- Understanding of drug development processes and proficiency in quality principles driving drug development such as GMP and applicable regulations and policies.
- Clear understanding of current and anticipated regulatory and quality expectations.
- Broad scientific as well as strategic background Advanced coaching skills.
- Track record of innovation, creativity, problem solving and productivity.
- Successful work experience in inter-disciplinary and cross-cultural teams is preferred.
- Successful work experience in a matrix organization is preferred.
- Good oral, written (good experience in writing of scientific reports and filing documentation) and presentation skills are essential.

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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IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work
No

Apply to Job.

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.

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

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