

Senior Expert Science & Technology (GxP & Compliance)

Job ID
REQ-10049939

5月 22, 2025

India

摘要

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.

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部门

Development

Business Unit

Innovative Medicines

地点

India

站点

Telangana

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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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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