Global GMP Auditor

Job ID
REQ-10048543

4月 20, 2025

India

摘要

Lead, support and report independent GMP audits according to the Novartis Quality System and the current GMP regulations to assess compliance with applicable regulations, standards, and guidance documents. Review and approve corrective action plans in support of the audit observations. The audits performed include internal and external targets of manufacturing sites, development centers, quality systems, contract manufacturers, laboratories, warehouses, country organizations, and suppliers.

About the Role

Key Responsibilities:

Plan, lead, conduct, document, report, and follow-up of GMP audits according to the requirements specified in the respective Novartis procedures as well as applicable regulations, standards, quality

agreements, and guidance documents. Audits will be focused to mid-low risk manufacturing and other GMP activities, on the basis of actual experience/expertise Provide technical guidance and training on audit activities. Ensure appropriate escalation to responsible management in case of critical findings and support immediate follow-up measures according to NVS requirements on Management Escalations and other relevant procedures. Ensure adequate definition and recording of mitigation plans when applicable. Assess the adequacy of responses (CAPA plans) to audit findings in cooperation with the stakeholder QA representative and Auditee. Maintain current knowledge of regulations, standards, and guidance documents.

Commitment to Diversity & Inclusion: :

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

Essential Requirements:

- Execution of audits according to the audit schedule
- Ability to meet audit report and CAPA Plan review timelines as defined in local SOPs
- Perform follow up and escalation activities as defined in local SOPs Support compliances activities as defined
- Timely, complete and accurate communication, consultation and support to business partners
- Successfully completes Novartis Basic GxP Systems Auditing training

Desirable Requirements:

Financial responsibility:(Budget, Cost, Sales, etc.)

- According to NVS rules

Impact on the organization:

- Timely execution of comprehensive and targeted audits and timely communication of audit results to appropriate Novartis management is crucial to prevent GMP compliance related incidents and regulatory enforcements.
- Add value to Novartis business by supporting Audit and Incident Management and other business partners to operate in compliance with global regulations, standards, and guidance documents and to initiate quality improvement measures. Both items help to minimize any adverse regulatory impact.

Ideal background:

Education (minimum/desirable):

- Degree in Chemistry, Pharmacy, Biology, Engineering or another related science
- Other degrees with relevant experience may be accepted

Languages:

- Excellent oral and written English communication skills. Preferable: Good knowledge/mother tongue of an additional language (e.g. German, French, Italian, Chinese, or Spanish) is preferred

Experience:

- At least 10 years broad experience in Pharmaceutical or Medical Device Industry.
- The operational experience should include QA/QC management and manufacturing, or development or other relevant experience e.g. working at a regulatory health authority.
- 3 years auditing experience preferred, and excellent knowledge of regulatory requirements. Willingness to travel approx. 60% of the time.
- Expertise in at latest, one of the following areas: DP Manufacturing, Laboratories activities, Medical Devices, API, Excipients, Sterile, Biologics, Microbiology, Computer System Validation, Packaging activities, Quality Systems.
- Experience and/or interaction with local Health Authority and sporadically with other Health Authorities.
- Strong interpersonal skills, including diplomacy and persuasion, used in obtaining cooperation and consensus with Novartis colleagues, vendors and customers.
- Sound and practical judgement in the interpretation and application of regulations and standards

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.
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

部门
Operations

Business Unit
Innovative Medicines

地点
India

站点
Mumbai (Head Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Alternative Location 1
Hyderabad (Office), India

Functional Area
Quality

Job Type
Full time

Employment Type

Regular

Shift Work
No

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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.

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