NOVARTIS

Expert GMP Auditor

Job ID
REQ-10005048
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Summary

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.

Align strategic direction with senior leaders of Novartis and help establish programs to implement. Provide expert consultation to Novartis business units through risk based assessments. Act as SME for assigned areas of responsibility. Represent the company in external interactions with Health Authorities and industry groups.

About the Role

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Location - Mumbai

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Key Responsibilities:

- Contribute to establishing the strategic direction of an effective global risk-based audit strategy and program. Collect, collate, and incorporate input into the audit strategy and plan.
- Plan, lead, conduct, document, and follow-up of GMP audit according to the requirements specified in the respective Novartis Quality procedures as well as applicable regulations, standards, quality agreements, and guidance documents.
- For this expert role, the leader in this position is able to audit complex and high-risk sites and activities.

The leader in this position is considered an expert and SME in one or more manufacturing areas, such as sterile manufacturing, combination products, biologics, etc.

- Provide technical guidance, mentoring, and training on audit activities.
- Provide regulatory guidance for timely remediation and recommendations regarding acceptability of the proposed filing.
- Prepare audit reports according to NVS requirements and timelines.
- 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.
- Act as GMP compliance consultant for GMP trainings, task forces, continuous improvement projects as needed.
- Review and advise on relevant policies and procedures.
- Mentor junior GMP staff as required. Ability to perform training for non-certified and junior GMP staff.
- Maintain current, expert knowledge of regulations and elaborate best practices auditing guideline (when applicable). Support development/training of GMP auditors.
- Support HA commitments and global commitments/initiatives as an outcome of inspection findings.

Essential Requirements:

- At least 15 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.
- At least 3+ years auditing experience, and excellent knowledge of regulatory requirements. · Willingness to travel approximately 60% of the time.
- Expertise in at least 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.
- Excellent interpersonal skills, including diplomacy and persuasion, used in obtaining cooperation and consensus with Novartis colleagues, vendors and customers. The Associate must be able to effectively represent the department both internally and externally.
- Sound and practical judgement in the interpretation and application of regulations and standards
- Ability to independently manage and objectively evaluate complex compliance issues with minimal supervision.
- Excellent leadership and facilitation skills

Desirable Requirements:

- Degree in Chemistry, Pharmacy, Biology, Engineering or another related science
- 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.

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

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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

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Indien
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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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