NOVARTIS

Specialist – Quality Operations

Job ID
REQ-10019221
Sep 03, 2024
India

Resumen

Provide quality services in compliance with cGMP requirements and Novartis Quality Management System as defined and agreed between QOP and business partners. Manage Quality aspects & projects within area of responsibility.

About the Role

Specialist – Quality Operations

Location – Hyderabad

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Provide quality services in compliance with cGMP requirements and Novartis Quality Management System as defined and agreed between QOP and business partners. Manage Quality aspects & projects within area of responsibility.

Key Responsibilities:

- Coordination and management of analytical method transfers and stability studies. Compilation of data reports
- Life-cycle management of analytical methods, including control of method performance, pharmacopoeia and health authority compliance and definition of method improvements. Handling of deviations, investigation, OOS/OOE/OOT cases as well as changes and complaints
- Perform statistical data analysis to report Out of Expectations (OOE), out of trends (OOT), etc
- SAP master data management: Maintenance of master data, creation of Q-info records and other SAP related activities.
- Validate spreadsheets
- Collect, transcribe and/or compile data from various repositories (SAP, LIMS, external COAs)
- Author, approve and archive Impurity risk assessments – Nitrosamines, residual solvents, etc
- Trend and report all QMS elements as per the request
- Monitor, trend and report Health Safety and Environmental parameters
- Implementation of GMP requirements. Compilation and Review of documents (analytical protocols and reports, annual performance quality reports, ongoing process verification reports, registration documents (Common Technical Document modules)).
- Perform activities of a Quality Control expert as defined by the respective sites
- Support regulatory requirements – routine queries, Chromatogram requests
- Compile Quality performance management decks

- Create and review GxP documents including SOPs, working procedures, trend reports, qualification reports and technical investigations, as and when needed

Essential Requirements:

- Pharmacy/ Science/ MBA / Engineering/ equivalent from a reputed institute
- Min 3 years of experience in Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substances/ products/ medical devices
- GxP knowledge, Basic IT knowledge
- Good communication, presentation and interpersonal skills
- Experience of working closely with the global stakeholders

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

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IN10 (FCRS = IN010) Novartis Healthcare Private Limited
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Job Type
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Employment Type

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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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