Specialist-Quality Operations

Job ID
REQ-10035539
Jan 05, 2025
India

Summary

Provide quality services in compliance with cGMP requirements and Novartis Quality Management System as defined and agreed between QOP and business partners.

About the Role

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Major accountabilities:

Common Accountabilities (Applicable to all service teams)

- Perform and deliver Quality Operations services in support of product quality compliance and regulatory workflows
- Hold accounts in workflow applications (such as SAP, Dragon, SUBWAY, etc.) to ensure appropriate execution of service deliverables
- Generate and analyse predefined and ad-hoc reports in various applications (like AGILE PLM, AQWA etc.) and perform follow-up actions if required
- Escalate service related GxP and non-GxP issues and ensure timely investigation and compliance with local and global operating procedures
- Ensure compliance to the Novartis internal quality standards, relevant regulatory requirements, filed product quality standards and service level agreements
- Comply with all internal functional operating procedures like time tracking, KPI reporting, ticket management tools and other internal systems and processes
- Assist the department on any other ad hoc administrative activities as per business requirements.
- Focus on timely completion of all relevant and assigned trainings
- Learn & develop understanding to generate insights through data and digital
- Ensure responsibility and ownership of the assigned tasks
- Comply the accuracy and timeliness of deliverables
- Comply to the applicable Novartis operating procedures as per legal / IT / HR requirement
- Provide active support during internal and external audits by collecting and presenting the requested process data/reports
- Adhere to the current GxP and compliance policies of Novartis.

Key performance indicators:

- Extract data from relevant sources in Novartis tools/ applications.
- Interpret and compile external supplier APQR and/ or extracted data from Internal Novartis systems into a pre-defined template and draft conclusion of product quality review.
- Collect contributory reports for product related evaluations.
- Interact with CMOs and / or manufacturing sites as required.
- Support in updating and maintenance of APQR schedule.
- Perform review of APQR report/ data as applicable to ensure it is complete and correct.
- Complete APQRs within defined timelines.
- Archive the approved APQR as applicable
- Update APQR data in e-compass file followed by interpretation of data to conclude product robustness.
- **Marketing Authorization Holder (MAH) Review:**
- Support in maintenance of MAH/BRS review schedule
- Coordinate with NCQ SPoCs and/ or manufacturing/ packaging/ testing/ batch releasing sites as required to draft MAH/BRS checklist
- Extract data from relevant sources as applicable and compile MAH/BRS as per the requirements in a predefined format
- Interpretation and consolidation of the data
- Review for accuracy and completeness of compiled data /information
- Submit the drafted MAH/BRS reviews for approval to respective Country quality team
- Archive the approved MAH/BRS review documents

Education Background:

- M.Pharm/ MBA / Engineering/equivalent from a reputed institute.
- Min 1 yr Experience in Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substances or products/ Medical device.
- Basic awareness of GxP compliance requirements.

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

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.

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.

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

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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Business Unit
Innovative Medicines
Location
India
Site
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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