Analyst – Quality Operations

Job ID
REQ-10030263
nov 22, 2024
Inde

Résumé

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

Major accountabilities:

- 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
- Support to Stability management eg: Draft reports/assessments of temperature excursion assessments (TEA), transport category assignment (risk assessment (TRA)).
- Support to QC release activities eg: Create, modify and review: Inspection Plans, Inspection Lot Numbers, Certificate Of Analysis, Certificate of Compliance, Specifications etc.
- Support to Testing Monograph management eg: Author testing monograph, Perform impact assessments etc.
- Authoring of risk evaluation reports for Nitrosamines both Step-1 & Step-2. Handling of risk evaluation reports with respect to country specific/local ones. Preforming authoring activity in Subway software. Data collection and slides preparation which are required for weekly work stream leads call/Steerco meetings.
- Perform Statistical support, Performance trending and Business support.
- 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
- Learn & develop understanding to generate insights through data and digital
- Provide active support during internal and external audits.
- Adhere to the current GxP and compliance policies of Novartis

Key performance indicators:

- On-time and GMP-compliant release of dosage forms -No complaints about inspections by authorities in your own area of responsibility without these being noticed and communicated beforehand -Successfully support continuous improvement projects

Minimum 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

Skills:

- Continuous Learning.
- Dealing With Ambiguity.
- Gmp Procedures.
- QA (Quality Assurance).
- Quality Control (Qc) Testing.
- Self Awareness.
- Technological Expertise.
- Technological Intelligence.

Languages :

- Fluent in English (written and spoken)

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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Division
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Innovative Medicines
Emplacement
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Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Qualité
Job Type
Full time
Employment Type
Regular
Shift Work

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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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