Specialist – Quality Operations

Job ID
REQ-10015988
Sep 03, 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. Manage Quality aspects & projects within area of responsibility.

About the Role

Major accountabilities:

· 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

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 -Executes batch release in compliance with registration

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.

· Quality Standards.

· 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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

Division
Operations
Business Unit
Innovative Medicines
Emplacement
Inde
Site
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Qualité
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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.

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

iframe{ width: 100%; margin-top: 3rem; } @media screen and (max-width: 767px){ iframe{ height: 30vh !important; } } @media screen and (min-width: 768px){ iframe{ height: 34vh !important; } }
Job ID
REQ-10015988

Specialist – Quality Operations

Apply to Job

Source URL: *https://prod1.adacap.com/careers/career-search/job/details/req-10015988-specialist-quality-operations*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Specialist---

Quality-Operations_REQ-10015988

5. mailto:diversityandincl.india@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Specialist---Quality-Operations_REQ-10015988