NOVARTIS

Quality Operations Specialist

Job ID
REQ-10076822
май 14, 2026
Индия

Сводка

The Quality Operations Specialist performs batch release activity to support stakeholders in overall management of their projects. Regulatory Compliance Check for batches and their release in SAP.
Ensures that the operational business is in compliance with cGMP (Current Good Manufacturing Practices), the Quality Assurance Agreement, regulatory requirements & the Novartis Quality Manual and is conducted according to the relevant Standard Operating Procedures.
Supports in batch release preparatory activities and timely implementation for new projects.

About the Role

Major Accountabilities

- Perform and deliver Quality Operations services in support of product quality compliance and regulatory workflows.
- Assist the department on any other ad hoc activities/ requests to meet the business requirements.
- Regularly communicate with partners and obtain feedback on services delivered.
- Focus on timely completion of all relevant and assigned training and ensure responsibility and ownership of the assigned tasks.
- Create and review GxP documents including SOPs, working procedures, trend reports, qualification reports and technical investigations, as and when needed.
- 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.
- Provide active support during internal and external audits by collecting and presenting the requested process data/reports.
- Support implementing service quality and process improvement projects, CAPA management within Quality Service Centre.
- Perform regulatory compliance checks and Batch Document Review as per the defined process.
- Create and review GxP documents, such as mismatch trend reports and send it to the stakeholders.
- Preparatory activities support for Batch release to required sites.

Minimum Requirements:

- **Education:** B.Pharm/ M.Pharm/MSc/equivalent from a reputed institute.
- **Experience:** Minimum 2-4 years' experience in Quality Assurance, Quality Control, Regulatory or in the manufacturing of pharmaceutical drug substances or products/ medical device/ expertise in Learning management system.
- Basic awareness of GxP compliance requirements.
- **Languages:** English fluent, written and spoken
- Stakeholder management and good communication with stakeholders
- Technological Expertise and intelligence
- Project coordination
- Proficiency in MS Office tools

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

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.
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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Operations
Business Unit
Production / Manufacturing
Место
Индия
Сайт
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

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.

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