NOVARTIS

Specialist / Associate Manager - MS&T (Investigation and Deviation management)

Job ID
REQ-10085238
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Индия
Available in: English

Сводка

The purpose of the Investigation & Deviation Owner role is to work collaboratively with process experts and the multifunctional operations teams in large molecules platform (Biologics site) and take ownership of the deviation management for the site. The individual shall actively participate in investigations of Deviations/Complaints/OOXs by interacting with Cross Functional Teams (CFT) and implementation of Corrective and Preventive Actions (CAPA), Effectiveness Check (EC), Risk assessment and Quality management.
The individual plays a key role in facilitating effective communication between teams and supporting problem-solving activities.
The individual shall contribute to the enhancement of quality, productivity, and efficiency by supporting and driving improvements within the organization.

About the Role

Major accountabilities:

- Lead and support complex investigations and deviation management activities related to manufacturing processes, products, and equipment within biologics manufacturing.
- Apply structured Root Cause Analysis (RCA) methodologies, including 5 Whys, Fishbone Diagrams, impact assessments, timeline analysis, and process mapping to identify and resolve issues.
- Conduct quality risk assessments and utilize Quality Risk Management (QRM) frameworks to support robust decision-making and compliance.
- Author and review high-quality investigation reports, ensuring accurate documentation, scientific rationale, and effective CAPA implementation.
- Provide technical and scientific expertise on process-related issues, supporting continuous improvement and operational excellence.
- Ensure compliance with cGMP requirements, SOPs, health, safety and environmental standards, and other applicable regulatory and quality guidelines.
- Support validation, manufacturing operations, and process monitoring activities, including sampling, routine monitoring, and ongoing process support.
- Drive inspection readiness and support internal audits, health authority inspections, and regulatory interactions, including management of technical complaints and adverse events where applicable.
- Maintain compliance with Novartis quality standards, regulatory requirements, product quality standards, KPIs, service agreements, and internal processes and tools.
- Collaborate effectively with stakeholders and business partners, support departmental priorities and ad hoc initiatives, and contribute to a culture of safety, quality, and continuous improvement.

Essential requirements:

- Bachelor's degree in pharmacy, Pharmaceutical Technology, Chemical Engineering, Biomedical engineering, Biotechnology, Chemistry, or equivalent science streams. Desirable MSc/MS. or equivalent experience.
- 5-12 years of experience in MS&T, Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substance in Large Molecules platform/facility (Biologics/Biosimilar)
- Proficient knowledge on deviation handling, incident investigations, root cause analysis, CAPA management, risk assessment and risk management programs.
- Familiar with regulatory guidance on validation, product filing and post approval changes.
- Basic knowledge of statistical analysis, results interpretation, and usage of statistical tools (Example: Minitab, Statistica etc.).
- Good communication, presentation and interpersonal skills.

Commitment to Diversity and Inclusion

Novartis is committed to building an outstanding, inclusive work environment and diverse team 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

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
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No

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