Specialist - MS&T

Job ID
REQ-10058784

7月 29, 2025

India

摘要

The purpose of the investigation and deviation expert role is to work collaboratively with process experts and multifunctional operations teams in the Biologics and/or large molecules platform sites, taking ownership of deviation management for the site. The individual will actively participate in investigations of deviations, complaints, and OOXs by interacting with Cross-Functional Teams (CFT) and implementing Corrective and Preventive Actions (CAPA), Effectiveness Checks (EC), risk assessments, and quality management. The role will play a key part in facilitating effective communication between teams and supporting problem- solving activities.

About the Role

Major accountabilities:

- Manage deviations in 1QEM system for the responsible sites using the Novartis quality management framework.

- Conduct root cause analysis according to the established procedures and site practices.
- Use various RCI (Root Cause Investigations) tools and methodologies such as Fishbone diagram, 5 Whys, and timeline and process mapping where applicable to facilitate root cause analysis.
- Coordinate with the site SPOC (Single Point of Contact) and other stakeholders from the Production unit, Quality Assurance, Engineering team, and site leadership team.
- Ensure all stakeholders are informed about the progress of the investigation, manage all necessary communications, and adhere to timelines.
- Participate and Facilitate Deviation and RCI review meetings, capturing key information and translating it into actionable and clear documentation.
- Track and report on metrics related to change control documentation, including timeliness, compliance, and quality.
- Develop, revise, and maintain high-quality documentation related to Deviation management processes, ensuring alignment with cGMP and other regulatory standards.
- Support and contribute to quality management system (QMS) actions such as Change Controls, CAPA, effectiveness checks (EC), risk assessments, and OOXs management. Participate in periodic QMS reviews to identify and contribute to areas of improvement where applicable.
- Provide technical and scientific expertise to address process-specific matters, ensuring compliance with cGMP, SOPs, and relevant guidelines and functional standards, including HSE (Health, Safety, and Environment) and NOSSCE.
- Ensure overall inspection readiness for the area of responsibility.
- Support the creation and review of GxP documents, including SOPs, working procedures, and trend reports, while ensuring compliance with Novartis internal quality standards relevant regulatory requirements, filed product quality standards, and service level agreements.
- Support Health Authority (HA) audits by ensuring compliance with the GxP environment and handling procedural requirements, in alignment with Quality Management System (QMS) standards.
- Support implementation and adhere to all instructions and requirements for safe work, environmental protection, and property protection.
- Comply with internal functional requirements such as KPI reporting, ticket management tools, and other internal procedures and processes.
- Complete tasks determined during the annual objectives setting process and by KPIs, as applicable.
- Assist the team with any ad hoc activities or requests to meet business requirements.

Key Performance Indicators

- Quality / Accuracy / Right First Time
- Timeliness
- Deviations / Escalations
- Quality System Management (Change Control, CAPA, Risk Assessment and EC) Support

Specific Professional Competencies

- cGMP and Good Documentation Practices

- Deviation Handing
- Root Cause Analysis (RCA)
- Corrective Action and Preventive Action
- Change Control Management
- Knowledgeable on Effectiveness Checks
- Continuous Process Improvement
- Drug Substance Manufacturing
- Process Design and Control
- Gap Assessment and Risk Analysis
- Complaints and OOXs Handling
- Technology Transfer
- Report writing
- Data Analytics
- Project Management

Languages :

- English (oral and written).
- German, at Least B1 level proficiency.

Experiences:

- Minimum 6 years of experience in MS&T, Quality Assurance, Regulatory or in the manufacturing of Biologics in large molecules.
- At least 4 years of experience in MS&T or Manufacturing operations.
- Proficient knowledge on deviation handling, incident investigations, root cause analysis, and
- CAPA management.
- Knowledge of risk assessment and risk management programs.
- Should be familiar with regulatory guidance on validation, product filing and post approval changes.
- Should be familiar with and able to perform basic statistical evaluations using tools (like Minitab or Statistica), with basic knowledge of statistical analysis, result interpretation, and usage of these tools.
- Good communication, presentation and interpersonal skills.

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部门
Operations

Business Unit
Universal Hierarchy Node

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Alternative Location 1
Ljubljana, Slovenia

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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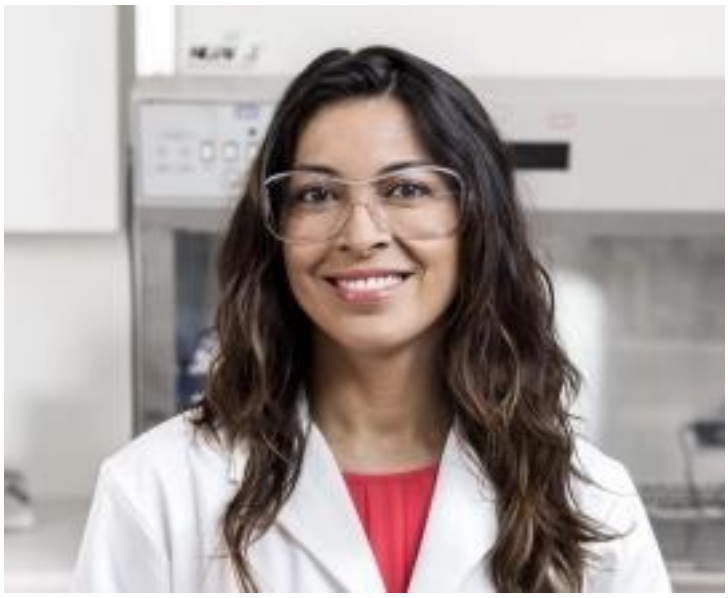

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