Manager - MS&T

Job ID
REQ-10058190

7月 17, 2025

India

摘要

The Global Change Control Manager oversees the entire process of managing GxP-impacting changes within the global manufacturing network. This role is responsible for the change control process from initiation, through impact assessment, planning, execution tracking, documentation, CAPA effectiveness, continuous improvement in change governance, and metrics reporting. The manager works closely with cross-functional teams such as Regulatory, Quality, Operations, to support timely implementation, risk management, and ongoing improvement in change governance. The role also contributes to audits, inspections as well.

About the Role

Key Responsibilities:

- Good Understanding of Global Change control process and able to advice on Global and Local Change request strategy. Align between sites and Regulatory team regarding

Change control plan, impact / implementation on sites. Prepare the change request plans and present them for endorsement at the Change review board (CRB) Open global change requests, assign impact assessment actions, and manage the lifecycle of Change Requests (CR). Track and report the implementation status of change requests with cross-functional teams. Manage and maintain change control documentation, including updates, version control, and compliance with cGMP and regulatory standards. Facilitate change control review meetings, capturing key information and translating it into actionable and clear documentation. Provide support during audits and inspections by ensuring accurate and readily available change control documentation. Collaborate with cross-functional teams (Quality, Operations, Engineering) for accurate documentation. Track and report metrics related to documentation timeliness, compliance, and quality. Comply with internal processes like KPI reporting, ticket management, and functional requirements. Contribute to process improvement initiatives by identifying and addressing gaps in change control documentation workflows. 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. Good Understanding of Process/Cleaning Validation and Technology transfer concepts and requirements including transfer protocols, validation protocols & reporting and comparability reports Collaborate with site teams for Transport Validation / Shipping verification activities including validation risk assessment, testing protocols and reports. Act as SPOC to drive key Global projects within the platform and collaborate with sites to ensure timely execution of tasks/ deliverables

Desirable Requirements:

- Bachelor's/Master degree in Pharmacy, Pharmaceutical Technology, Biotechnology, Chemistry, or equivalent science streams. Desirable MSc/MS. or equivalent experience.
- Good understanding of Radio Ligand Therapies (RLT) platform
- Minimum 10 years of experience in MS&T, Quality Assurance in Manufacturing of Biologics Drug substance and Drug Product.
- Hands on experience in 1-QEM tool.
- Strong understanding of Global change control processes, cGMP, and regulatory requirements
- Proven project management experience in a cross-functional environment (e.g. multi-site, technical development, other functions). PMP is added advantage.
- Expertise in document management system and writing technical reports
- Experience in Health authority audits and Self inspections.
- Good communication, presentation and Interpersonal skills.
- Proficiency in English (oral and written) is mandatory.

Essential Requirements:

- Quality / Accuracy / Right First Time
- Quality System Management (Change Control, CAPA, Risk Assessment and EC) Support
- Accuracy and compliance of change control documentation
- Timeliness of documentation updates and approvals
- Stakeholder satisfaction with documentation quality and usability

- Adherence to regulatory requirements during audits and inspections
- Effectiveness of standardized documentation processes

Skills:

- Change Control Process
- Effective communicator
- Strong cross functional collaboration
- Biologics Manufacturing Process
- Project Management
- Good Documentation Practice
- Effective stakeholder engagement
- Report writing
- Knowledge Of GMP (Good Manufacturing Practices)
- Deviation management
- Corrective and preventive action (CAPA)
- General HSE Knowledge
- Manufacturing (Production)
- Manufacturing Technologies.
- Process And Cleaning Validation

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部门
Operations

Business Unit
Universal Hierarchy Node

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India

站点
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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