NOVARTIS

Specialist - MS&T

Job ID
REQ-10034329
Dez. 20, 2024
Indien

Zusammenfassung

The Technical Writer – Change Control Management is responsible for developing, managing, and maintaining documentation related to change control processes within a regulated manufacturing environment. This role ensures documentation accuracy, consistency, and compliance with regulatory and organizational standards. The Technical Writer will leverage their knowledge of science and manufacturing technologies to collaborate effectively with cross-functional teams, streamline documentation workflows, and support the organization's change control management processes.

About the Role

Key Responsibilities

- Develop, revise, and maintain high-quality documentation related to change control processes, ensuring alignment with cGMP and other regulatory standards.
- Collaborate with cross-functional teams, including Quality, Operations, and Engineering, to ensure all change control documentation is accurate, comprehensive, and aligned with organizational objectives.
- Utilize scientific and technical knowledge to accurately interpret and document manufacturing processes, equipment, and technology changes.
- Manage the lifecycle of change control documentation, including updates, version control, and accessibility for stakeholders.
- Facilitate change control review meetings, capturing key information and translating it into actionable and clear documentation.
- Standardize templates and formats for change control documentation to enhance consistency and usability across the organization.
- Provide support during audits and inspections by ensuring accurate and readily available change control documentation.
- Track and report on metrics related to change control documentation, including timeliness, compliance, and quality.
- Train and mentor team members on documentation best practices and change control management processes.
- Contribute to process improvement initiatives by identifying and addressing gaps in change control documentation workflows.
- Ensure that data integrity checks are conducted to verify that all the data is complete, consistent, and free from errors before proceeding with any further analysis or reporting.

Key Performance Indicators

- 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:

- Good Documentation Practice
- Effective communicator
- Strong cross functional collaboration
- Adaptability to Embrace Change
- Effective stakeholder engagement
- Manufacturing Process
- Knowledge Of GMP (Good Manufacturing Practices)
- Change Control
- Deviation management
- Corrective and preventive action (CAPA)
- Continual Improvement Process
- General HSE Knowledge
- Manufacturing (Production)

Background

- **Education**:
  Bachelor's degree in a science or engineering-related field (e.g., Biology, Chemistry, Mechanical Engineering, or similar disciplines).
- **Languages**:
  English fluent
- **Experience**:
  - 5+ years of experience in technical writing, preferably within a regulated manufacturing or scientific environment.
  - 2+ year of experience in in drafting and managing change control documentation within GxP settings.
  - Strong understanding of change control processes, cGMP, and regulatory compliance.
  - Fundamental knowledge of science and/or manufacturing technologies, with the ability to interpret technical and scientific information.
  - Proficient in document management systems and technical writing tools.
  - Excellent attention to detail, organizational skills, and the ability to manage multiple priorities.
  - Experience supporting audits and inspections is a plus.
  - Familiarity with Lean principles or continuous improvement methodologies is advantageous.
  - Proficiency in English (oral and written) is required

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Business Unit
Innovative Medicines
Ort
Indien
Website
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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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.

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