Specialist / Associate Manager - MS&T (Validation, OPV, TechTransfer, Change Control)

Job ID
REQ-10063966

10月 09, 2025

India

摘要

The Purpose of the role is to work collaboratively with Site MS&T team and multifunctional technical operations teams in Large molecules platform. The individual plays a key role in facilitating effective communication between teams and supporting problem-solving activities. Maintain the oversight on Process and Validation activities and executes preparation and updating of Risk assessments and documentation for Validation activities, OPV/CPV, Change Control and Tech Transfer activities

About the Role

- **Key Responsibilities:**
- **Chemical, Biochemical and/or Biotechnological Expertise**

- Good understanding of physico chemical properties of chemicals and buffers (e.g. buffer capacity, stability), including basic analytical methods (e.g. pH, conductivity, density)
- Good understanding of biotechnological processes (e.g. fermentation, cell cultivation techniques), purification techniques (e.g. filtration, chromatography).
- Basic understanding of biochemical processes
- Experiences in preparation of Nitrosamine, Raw material risk assessments and declarations for residual solvents and Elemental Impurities.

- **Essential Requirements:**
- **Validation Expertise**

  - Create validation documentation including Process validation protocol/reports, Risk assessment, ongoing process verification (OPV) plans/ reports, cleaning validation protocol/reports based on alignment with Site Validation Lead.
  - Preparation of Transport Validation/Verification Protocols and conduct the necessary studies in coordination with cross functional teams. Collect the results and create the reports. Ensure all collected data is accurate and comprehensive and that protocols comply with regulatory requirements and organizational standards.
  - Support in prepration and updation of Hazard Analysis Critical Control Point (HACCP), Control strategies and FMEA risk assessments.
  - Ensure the timely availability of technical documentation as per Novartis guidelines.
  - Perform OPV/CPV evaluations, assess process performance and provide insight, recommendation and conclusion to the site MS&T team.
  - Create and update process excursion signals (PES)
  - Review key documents and coordinate input for relevant registration documents to ensure accuracy and completeness.
  - Ensure all site validation activities comply with Novartis requirements and GMP, managing any deviations related to these activities, including oversight of pre validation and validation resulting from technical changes.
  - Possess a fundamental understanding of pharmaceutical analytical testing.
  - Ensure project tracking documentation/tools are updated according to plan.
  - Collaborate closely with the development organization (or sending site) for technical transfers and new product launches to ensure knowledge transfer, appropriate control strategies, risk analysis and control, and readiness for commercial process validation
  - Coordinates prerequisites for PPQ batches (Qualification status, Status of the analytical methods, raw materials, consumables), updates Risk Assessments for Microbio buffer hold validation, and generates deviation lists for PPQ batches
  - Preparation, approval and life cycle management of Gxp documents
  - 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.
  - Coordinates documentation review with the site MS&T, QA, and QC, also Reg CMC where applicable

- **Manufacturing Excellence**

  - Desired to be familiar with Manufacturing Process Transfer.
  - Contribute to process improvement and optimization for product transfers.

- **Change Control**
    - Good Understanding of Change control process and able to advice on Global and Local Change request strategy.
    - Align between cross functional teams including 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 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.

- **Training**
    - Contribute to process improvement and optimization for product transfers.

- **Ideal Background / Requirements for the role**
    - Bachelor's degree in pharmacy, Pharmaceutical Technology, Chemical Engineering, Biotechnology, Chemistry, or equivalent science streams. Desirable MSc/MS. or equivalent experience.
    - Min 8 years of experience in MS&T (Process validations) or in the manufacturing of pharmaceutical Drug substance in Large Molecules facility
    - Should be familiar with regulatory guidance on validation, product filing and post approval changes.
    - Proven project management experience in a cross-functional environment (e.g. multi-site, technical development, other functions).
    - Expertise in reviewing and writing technical reports
    - Good communication, Presentation and Interpersonal skills.
    - Proficient and excellent in English (oral and written) is a requirement

- **Desirable Requirements:**
    - Quality / Accuracy / Right First Time
    - Timeliness
    - Deviations / Escalations
    - **Languages :**
    - English.
- **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-cultureYou ' 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-rewardsCommitment 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

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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

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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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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