NOVARTIS

Specialist– MS&T

Job ID
REQ-10076198
апр 20, 2026
Индия

Сводка

The purpose of the Specialist role is to work collaboratively with Biologics 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, Transport validations, Extractable and Leachables activities, preparation and up dation of Risk assessments for Validation activities.

About the Role

Job description:

Chemical Expertise

- Good understanding of Physico chemical buffer stability risk assessment, evaluation of corrosive agents as part of facility comparability assessment.
- Monitoring compliance alerts related to raw materials, (e.g. check ß-Lactam structure, EG/DEG)
- Experiences in preparation of Nitrosamine, Raw material risk assessments and declarations for residual solvents and Elemental Impurities.
- Experienced in performing Extractable and Leachable (E&L) risk assessments, Gathering E&L data from suppliers, coordinating E&L studies, and maintaining accountability for the site during audits.
- Preparation of Extractables and Leachables data for toxicological assessment

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 preparation and up dation of Hazard Analysis Critical Control Point (HACCP), Control strategies.
- Ensure the timely availability of technical documentation as per Novartis guidelines. Write Manufacturing Process Transfer Documents (Protocol, Report).
- 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 Microbial 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.

Ideal Background / Requirements for the role

- Master's degree in biotechnology, Pharmacy, Chemistry, or equivalent science streams. Desirable MSc/MS. or equivalent experience.
- 5 to 9 years of Biologics Drug substance MS&T experience in Process, Cleaning Validations and Extractable and Leachables.
- 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.
- Proficiency in English (oral and written) is required, and Knowledge of German is an advantage.

Skills:

- Biologics Manufacturing science and technology/Technology transfer
- Upstream and Down stream
- Process Validation
- Cleaning validation
- Extractables and Leachables
- Biologics Manufacturing (Production)

- Change Control.
- Continual Improvement Process.
- Good Documentation Practice.
- Deviation and OOS/OOT
- Knowledge Of CAPA.
- Knowledge Of GMP (Good Manufacturing Practices).
- Manufacturing Process.
- Risk Management.
- Root Cause Analysis (RCA).

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)

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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

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' 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.

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