NOVARTIS

Specialist– MS&T

Job ID
REQ-10076198
May 03, 2026
LOC_IN

About the Role

Key Responsibilities:

- 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
- 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.

Essential Requirements:

- 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.

Desirable Requirements:

- Master's degree in biotechnology, Pharmacy, Chemistry, or equivalent science streams. Desirable MSc/MS. or equivalent experience.
- Proficiency in English (oral and written) is required, and Knowledge of German is an advantage.

Commitment 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.

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.

Role Requirements

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
Location
LOC_IN
Site
Hyderabad (Office)
Company / Legal Entity
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Employment Type
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Shift Work
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Specialist– MS&T

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