NOVARTIS

Specialist - MS&T

Job ID
REQ-10043635
Mar 12, 2025
Inde

Résumé

The Purpose of the Specialist role is having expertise in Extractables and Leachables assessment, work in close collaboration with multiple functions such as MS&T, Supplier management, Regulatory, Toxicology, Procurement, Quality and Production. The individual plays a key role in support of Extractable and Leachable activities with a strong focus on data collection, Risk rating, assessments and evaluation.

About the Role

Location – Hyderabad

Key Responsibilities:

Extractable and Leachable (E&L) Expertise

- Understanding of Extractable and Leachable (E&L) risk assessment for materials based on supplier information and the ability to determine the risk level and update the Risk assessment.
- Building a comprehensive material library backed by corresponding E&L test data
- Managing the coordination for Extractables studies or product-specific leachable studies.
- Preparation of E&L Risk assessment, E&L testing Protocol and Report.
- Compile E&L data and provide the information to Toxicologist for assessment.
- Proficient in risk evaluation, decision matrix, Gap Analysis, and outcome understanding manufacturing materials.
- Comprehensive knowledge of the chemical and physical properties (leaching tendency) of MOC materials
- Skilled in defining the Original risk level, Mitigation factor, and Final risk level as part of the Risk Assessment process.
- Expertise in Extractable studies, their methodologies, analytical strategies, and design
- Expertise in setting the AET (Analytical Evaluation Threshold) and SCT (Safety concern threshold) for extractables and leachables detected during testing.
- Detailed understanding of E&L guidelines (SOPs, Pharmacopoeia and ICH standards)
- Proficient in identifying and assessing the Worst-case material representative approach.
- Collect the material list and data information from development centers and manufacturing sites.
- Active participation in E&L taskforce and network meetings. Also responsible for coordinating with the development, Supply management, QC, and Production department.

Commitment to Diversity & Inclusion: :

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Essential Requirements:

- Preparation of process and cleaning validation documentation (Protocols, reports) as well as change evaluations for new product launches and Life cycle management activities.
- 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
- 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
- Coordination of documentation review with the site MS&T, QA, and QC, also Reg CMC where applicable
- Preparation, approval and life cycle management of Gxp documents

Training

- Own the Training Curriculum for Own Job Profile

Desirable Requirements:

- Bachelor's degree in pharmacy, Pharmaceutical Technology, Chemical Engineering, Biotechnology, Chemistry, or equivalent science streams. Desirable MSc/MS. or equivalent experience.
- Min 5 years of experience in MS&T or in the manufacturing of pharmaceutical Drug substance and Product for Small and Large molecules.
- Should be familiar with regulatory guidance on ICH Q3,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.
-

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-culture You’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-rewards 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. 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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Division
Operations
Business Unit
Innovative Medicines
Emplacement
Inde
Site
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Opérations techniques
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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.

Job ID
REQ-10043635

Specialist - MS&T

Apply to Job

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Specialist---MS-T_REQ-10043635
5. mailto:diversityandincl.india@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/Specialist---MS-T_REQ-10043635