

Specialist- MS&T (Extractables and Leachables)

Job ID
REQ-10065083

10月 22, 2025

India

摘要

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

Key Responsibilities:

- 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 on understanding of 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.

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.
- Minimum 5 years of experience in MS&T or in the manufacturing of pharmaceutical Drug substance and Drug 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.

Key Performance indicators:

- Quality / Accuracy / Right First Time
- Timeliness
- Deviations / Escalations

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部门
Operations

Business Unit
Production / Manufacturing

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

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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