NOVARTIS

Specialist– MS&T

Job ID
REQ-10038160
jan 26, 2025
Inde

Résumé

The purpose of the Specialist role is to work in close collaboration with the Site MS&T team and multifunctional technical operations teams within the Large Molecules Platform. The individual plays a key role in the execution and support of Technical Transfers and Life Cycle Management activities with a strong focus on preparation and updating of Risk assessments and Validation related documentation.

About the Role

Key Responsibilities:

Validation and Life Cycle Management Expertise

- Preparation of process and cleaning validation documentation as well as change evaluations, executing change tasks to meet cGMP requirements on time and with quality, ensuring that site validation programs meet global regulatory expectations
- Supporting process validation lifecycle activities
- Creating local templates for the respective validation documentation
- Participating in pre-validation activities and risk assessments to ensure the success of commercial process validation
- Providing technical expertise and facilitating the creation of a quality risk assessment
- Profound background in organic chemistry to support physico-chemical buffer stability risk assessments, evaluation of corrosive agents as part of facility comparability assessments
- Preparation of Nitrosamine, raw material risk assessments and declarations for residual solvents and elemental impurities
- Support in Extractable and Leachable (E&L) risk assessments, gathering E&L data from suppliers, coordinating E&L studies, calculating AET threshold and maintaining accountability for the site during audits
- Support in prepration and updation of Hazard Analysis Critical Control Point (HACCP), Control strategies.
- Support OPV/CPV preparation and assessment of process performance to support site MS&T team.
- Create and update process excursion signals (PES) in the OPV/CPV monitoring system
- 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
- Coordinate prerequisites for PPQ batches (Qualification status, Status of the analytical methods, raw materials, consumables), update of 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
- Coordination of documentation review with the site MS&T, QA, and QC, also Reg CMC where applicable

Training:

- Own the Training Curriculum for Own Job Profile

Essential 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 (Process and Cleaning and Transport Validations) or in the manufacturing of pharmaceutical Drug substance in Sterile/Large Molecules platform/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.
- Proficiency in English (oral and written) is required, and Knowledge of German is an advantage.

Desirable Requirements:

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

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.

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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