Technical Transfer Lead

Job ID
REQ-10058141

7月 18, 2025

Italy

摘要

The Technical Transfer Lead is responsible for technology transfer activities at site level (within, inbound and outbound), including any scale-up or other process adaptations.
Leading technical transfer project team at site and liaises efficiently with involved functions (e.g. Technical Development, Supply Chain, Production Unit, Quality Control, HSE, other sites.).

About the Role

Major accountabilities:

- Review and update Quality Risk Assessment (QRA) prior to transfer and prior to validation, adapt control strategy if needed.
- Ensure that all relevant technical information and documentation for validation is available.
- Define pre-validation / validation strategy incl. process, cleaning, packaging and supportive studies (e.g., hold times). Coordinate technical, regulatory and validation batches at site.

- Support Validation Lead / Validation Expert in creation of validation protocol and report.
- Perform technical feasibility assessment for supply point decision in close collaboration with other stakeholders. Determine scope / design of technical batches for transfer.
- Establish site project plan, elaborate scientifically sound technical strategies with project team, develop contingency plans, identify hurdles and propose solutions. Assess and plan site resource needs and get management approval for the overall project costs (e.g. FTEs, batch costs, investments and external costs), strategies, and timelines.
- Form and lead site project team - set priorities for project and project team meetings, coordinate project team activities, ensure that Novartis guidelines and HSE and GMP guidelines are met.
- Ensure timely availability of technical documentation according to Novartis guidelines. Write Manufacturing Process Transfer Documents (protocol, report).
- Review key documents and coordinate input for relevant registration documents for accuracy and completeness (as appropriate).
- Liaise with global project manager, giving site (CMC team for development transfers) and site functions. Ensure knowledge transfer from giving site to receiving site including to operators.
- Accountable to coordinate inter-functional evaluation and implementation phases of change requests related to Drug Products

Minimum Requirements:

- Scientific Degree.
- Previous solid experience in a similar role within the Tech Transfer/ MS&T/QA/Production department of a GMP environment.
- Project management experience.
- Fluent in Italian and English.

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部门
Operations

Business Unit
Universal Hierarchy Node

地点
Italy

站点
Torre Annunziata

Company / Legal Entity
IT08 (FCRS = IT008) Novartis Farma S.p.A.

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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