Technical Transfer Lead

Job ID
REQ-10045049

3月 25, 2025

Malaysia

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.
Leads 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

Stewardship - for transfer assigned

- Review and update Quality Risk Assessment (QRA) prior to transfer and prior to validation, adapt control strategy if needed.
- Review first APQR after transfer to ensure adequate product performance.

Validation - for transfer assigned

- 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.
- Review validation protocol and report.
- Initiate monitoring and Ongoing Process Verification phase.

Launch & Transfer

- Act as SPOC on site for technical transfer.
- Perform technical feasibility assessment for supply point decision in close collaboration with other stakeholders. Determine scope / design of technical batches for transfer.
- Provide input into overall project strategy and plans including timelines.
- Initiate local change control in system on site and ensure approval and closure.
- 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 that project tracking documentation/tools are up-dated according to plan.
- 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.
- Contribute to inspection (Pre Approval Inspection PAI) readiness.
- Ensure site readiness for campaign start-up.
- Establishes local procedures & templates for technical transfer.

Manufacturing Excellence - for transfer assigned

- Contribute to process improvement and optimization for product transfers.

Training

- Own the Training Curriculum for own Job Profile and direct reports.

Novartis Manufacturing Manual

- Support implementation of Novartis Manufacturing Manual principle 3.

Travel Required

- Required to travel to Singapore at least 1 or 2 in month.

Relevant Experience

- 8 years of relevant experience in pharmaceutical manufacturing; comprehensive know how in pharmaceutical technology, project management experience.

Education & Qualification

- BSc. in Pharmacy, Pharmaceutical Technology, Chemistry or equivalent scientific degree. Desirable MSc. or equivalent experience.

Languages

Fluent in English and proficient in site local language.

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部门
Operations

Business Unit
Universal Hierarchy Node

地点

Malaysia

站点
Selangor

Company / Legal Entity
MY01 (FCRS = MY001) Novartis Corporation (Malaysia) Sdn. Bhd. (19710100054)

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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