

MS&T Expansion Lead RLT Sasayama

Job ID
REQ-10001508

12月 16, 2024

Japan

摘要

The purpose of the job is to lead and execute the technical activities related to site according to project timeline without delays in the execution. The person must ensure process, technology and product is transferred to the site and will act as the go-to person for MS&T related activities withing the project and during transfer and implementation.

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

- Technical transfer milestones achieved in time and in full. Including schedule for registration and launches.
- Robust manufacturing process, delivering critical quality attributes.

- Analytical methods in place, meeting cGMP standards.
- No critical observations during internal and external GMP inspections and Pre-Approval Inspections (PAI).
- Adheres to project / Capital Approval Request CAR costs

Stewardship - Manage change control for process transfers and process adaptations and modifications

Validation - Ensure that all relevant technical information and documentation for validation is available.

Launch & Transfer - Act as SPOC on site for technical transfer

Manufacturing Excellence - 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.

Essential Requirements:

- 8 years of relevant experience in pharmaceutical manufacturing; comprehensive know how in pharmaceutical technology, project management experience.
- BSc. in Pharmacy, Pharmaceutical Technology, Chemistry or equivalent scientific degree. Desirable MSc. or equivalent experience.
- Fluent in English and proficient in site local language

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部门
Operations

Business Unit
Universal Hierarchy Node

地点
Japan

站点
Sasayama

Company / Legal Entity
JP99 (FCRS = JP999) Ciba-Geigy Ltd.

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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