Tech. Steward - Project Support

Job ID
REQ-10044453

7月 01, 2025

Malaysia

摘要

Provides to the Site the specialist knowledge and expertise, as Subject Matter Expert (SME), of specific pharmaceutical processes or process technologies (e.g. Technical Steward for galenics, for film coating, biologics - upstream or downstream, etc.).
Oversees processes and standards to maintain and improve existing and to implement new innovative manufacturing technologies.

About the Role

Stewardship - for technology assigned

- Act as the SPOC for the interface with global MS&T network and with technical development organization, for the corresponding global activities, to define and implement new technical standards for existing and new technologies and equipment.
- Owns the knowledge of specific pharmaceutical manufacturing process technologies, locally,

including any pilot scale, scale up or down, and Design of Experiments (DoE).
- Participate in the definition and selection of pharmaceutical equipment, through providing input to User Requirements.
- Collaborate with technical development, other sites and global MS&T network to facilitate transfer of technical knowledge.
- Assure that the necessary benchmark is done internally in Novartis, and externally in the scientific and academic environment, in order to stimulate and to extend the knowledge, increasing the know-how of the associates and expanding it to the rest of the organization.
- Be a recognized scientific expert internally and externally by reporting and presenting scientific/technical work at internal/external meetings/conferences and publish in peer reviewed international scientific journals including patents.
- Maintain their work in inspection readiness level.
- Support Product Stewards in creation of Quality Risk Assessments.
- Support creation of SOPs for Process Unit.
- Provide technical expertise to Engineering for design activities in Capex projects around technologies within area of responsibility.
- Provide technical expertise for equipment qualification around technologies within area of responsibility.

Validation

- Approve validation reports under their area of responsibility (as needed) e.g. packaging validation.
- Provide technical expertise for validation activities around technologies within area of responsibility.

Launch & Transfer

- SME for specific Technology Platform or pharmaceutical processes following process product/process transfer or handover from launch to commercial production.

Manufacturing Excellence- for the technology(ies) assigned

- Harmonize and optimize technical processes across the site.
- Benchmark new technologies and equipment relevant for site.
- Designs and controls optimization projects.
- Provide SME expertise to perform process characterization of the related pharmaceutical processes to increase robustness and sustainability.
- Support Product Stewards / Process Experts in trouble shooting / root cause investigation by providing second level of specialist expertise as SME and by harmonising and optimising related technical processes across the units.
- Perform technical feasibility trials related to process improvement and implementation of new manufacturing technologies.

Training

- Own the Training Curriculum for own Job Profile and direct reports.
- Provide technical trainings and education programs for Process Experts and Production Operators.

Novartis Manufacturing Manual

- Support implementation of Novartis Manufacturing Manual principle 3.
- Provide SME input to Novartis Manufacturing Manual principle 4.
- Represent site in technical stewardship network.

Key Performance Indicators (Indicate how performance for this role will be measured)

- Batch release on time/in quality.
- Line throughput time.
- Deviations - process-related.
- Effective CAPAs.
- Ppk/CpK - process capability.
- OoS, OoE - Out of Specification, Out of Expectation - process-related.
- Yield.
- Customer Complaints - process-related.
- Recalls - process-related.
- Success rate of internal audits and Health Authorities' inspections.

Relevant Experience

- Minimum 8-year experience in GMP manufacturing relevant to the specialist area of expertise.
- Proven process understanding (Pharma, GMP, Regulatory aspects).

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.

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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Benefits and Rewards: Read our handbook to learn about all the ways we 'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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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