Tech. Steward - Project Support

Job ID
REQ-10061348

9月 09, 2025

Malaysia

摘要

-Technical Transfer LeadResponsible 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.).Product StewardOwns the process knowledge of the product(s) assigned throughout the commercial lifecycle, maintains the oversight on process capability, through data trending and statistical analysis of critical variables, ensuring process(es) are robust, in continued state of validation and continuously improving.Ensures seamless flow of knowledge and information across functions, and with other Sites when applicable, with focus on the assigned product(s). Provides second line technical/scientific process support.Technical StewardProvides 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.Validation LeadResponsible for developing, implementing and managing the site process validation, primary packaging validation, cleaning validation and revalidation strategies to meet cGMP and quality requirements on time and on budget to ensure that programs are compliant with Regulatory Authorities’ expectations and related SOPs.Senior Scientist MSAndTDesign, plan,

perform, interpret and report scientific experiments under the lead of the department head to contribute to overall MSAndT strategies and objectives.

About the Role

Major accountabilities:

- Technical Transfer Lead -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 -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.
- Product Steward And -Maintain the oversight and knowledge for entire manufacturing process performed on site and throughout the entire commercial lifecycle, since transfer from development to date, act as SPOC.
- Create and maintain a product specific Quality Risk Analysis (QRAs).
- Monitor all critical variables and key variables as appropriate using statistical analysis and conducting regular product specific data trending.
- Review APQR and decide on state of control.
- Technical Steward -Act as the SPOC for the interface with global MSAndT 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).
- Provide technical expertise for validation activities around technologies within area of responsibility.
- Harmonize and optimize technical processes across the site.
- Validation Lead -Support Product Steward in maintaining the process control strategy.
- Provide technical expertise and facilitate establishment of Quality Risk Assessment (as needed).
- Define and implement validation strategy (process, cleaning, ongoing verification) and defend to authorities.
- Overall responsibility for establishment, prioritization, execution and tracking of Validation Master Plan for process, cleaning, packaging validation and ongoing process verification (OPV), ongoing cleaning verification.
- Senior Scientist MSAndT -Complex projects with deep understanding of development process requirements -Difficult to solve topics (eg.
- new by-product investigation, complex deviations) -Cross product alignment in support approach (larger sites) -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Cost, C-Sat and productivity targets -Achievement of project plans & milestones -Internal customer satisfaction with quality of services provided -Validation Master Plan (VMP) completed and up to date.
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Minimum Requirements:
Work Experience:

- Fix-its/Turnarounds.
- Operations Management and Execution.
- Collaborating across boundaries.
- Project Management.

Skills:

- Applied Statistics.
- Assembly Language.
- Change Control.
- Chemical Engineering.
- Continual Improvement Process.
- Cost Reduction.
- Data Analytics.
- Electronic Components.
- General Hse Knowledge .
- Including Gdp.
- Knowledge Of Capa.
- Knowledge Of Gmp.
- Lean Manufacturing.
- Manufacturing (Production).
- Manufacturing Process.
- Manufacturing Technologies.
- Process And Cleaning Validation.
- Process Control.
- Process Simulation.
- Risk Management.
- Root Cause Analysis (Rca).
- Scientific Method.
- Six Sigma.
- Statistical Analysis.
- Technology Transfer.

Languages :

- English.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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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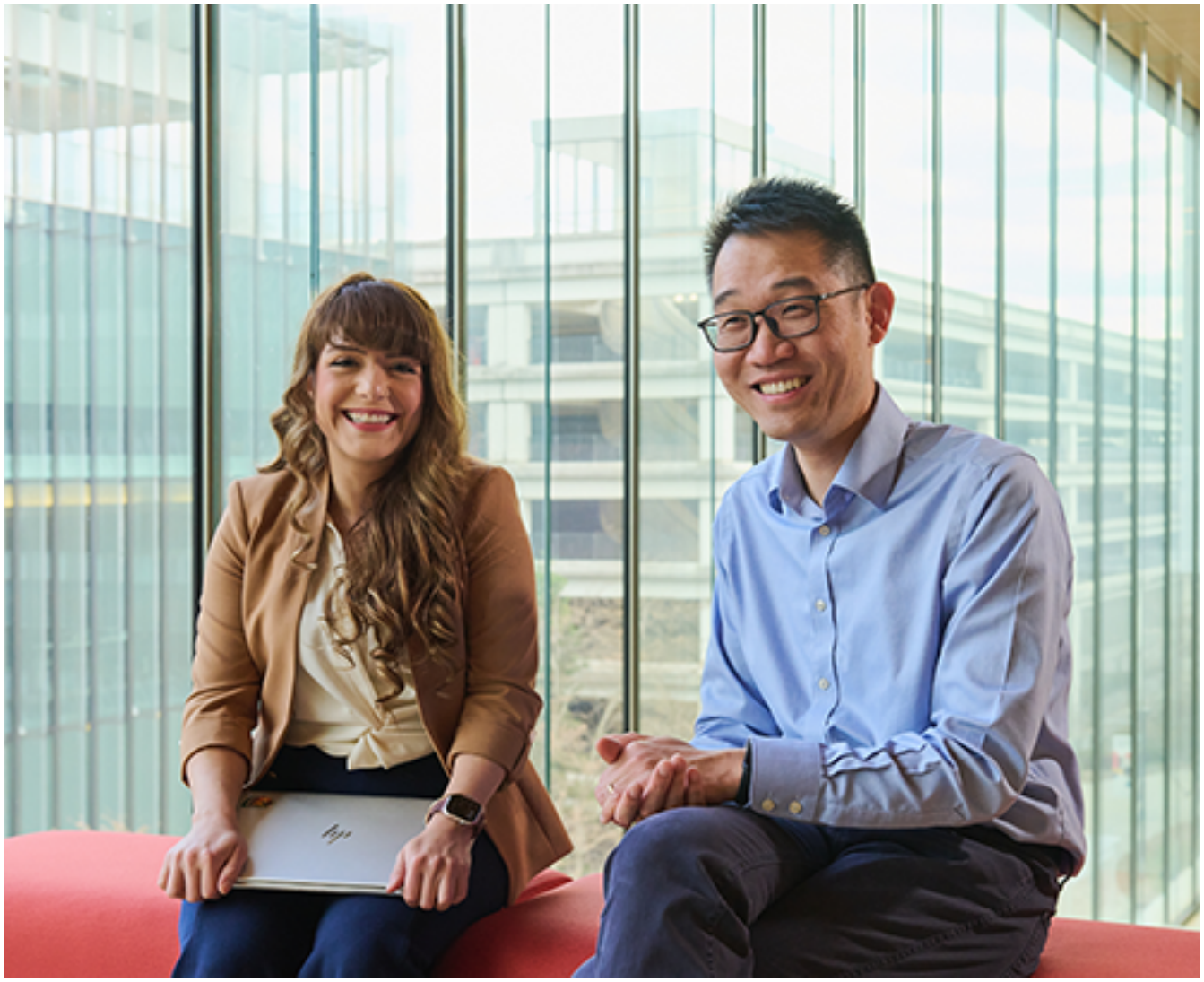

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