

Process Expert

Job ID
REQ-10045027

4月 09, 2025

Malaysia

摘要

You will provide front line technical and scientific expert support for all manufacturing compliance and process-specific issues to ensure execution of processes on-time (business continuity); in compliance to cGMPs, SOPs and applicable guidelines and functional standards (e.g. HSE, NOSSCE) and continuously improve quality, productivity efficiency.

About the Role

Operational Activities

- Provide expert support for all quality and compliance issues related to production, act as a Subject Matter Expert (SME) for quality processes, and ensure real-time shop floor support for compliance or quality problems
- Coordinate and ensure the completion of all production operations on time, perform real-time batch follow-up and technical review, manage change-over activities, and ensure all

production documents are up to date

- Execute training and education programs for operators, support the T&L organization in defining and maintaining qualification criteria, deliver instructor-led training, and promote Quality and HSE culture on the shop floor

Compliance Activities

- Lead area walkdowns, Gemba, and environmental monitoring governance on the shopfloor to identify and address facility maintenance, housekeeping, process, or personnel issues. It also includes ensuring timely treatment of deviations, complaints, out-of-specification (OOS) results, and implementing effective corrective and preventive actions (CAPAs).
- Collaborate with MS&T experts for multi-product risk assessments and validation strategy definition. It also involves preparing, supporting, and following up on health authority and internal inspections, and collaborating with Regulatory Compliance QA for dossier submissions and revisions.
- Manage GMP documentation, master manufacturing documents, and validation, revalidation, and qualification activities. Periodic review of production unit equipment and consistent reporting of trending and evaluation reports required

Operational Excellence and Continuous Improvement

- Lead and participate in continuous improvement projects, provide support for the implementation of improvements, and actively develop production staff in the continuous improvement process
- Manage various projects, conduct risk analyses, draft and validate documents, collaborate on technology transfers, and define technical needs to achieve strategic objectives

Quality and HSE

- Promote and improve the Quality and HSE culture in collaboration with Quality Assurance and the HSE Lead. This includes upgrading and checking the practical application of Quality and HSE systems on the shop floor and within the team
- Ensure overall inspection readiness and compliance with the principles and practices described in the "Novartis Manufacturing Manual" for the site.

Requirements

- Minimum 2 years experience in GMP manufacturing process support role
- University degree in Science in Pharmacy or Chemical Engineering, Pharmaceutical Technology
- Minimum 8 years experience in the field of expertise for lower Education levels
- Advanced English and proficient in site local language

Competencies

- Good scientific and technical (automation) understanding
- Team player with strong team spirit
- Good negotiator, Influencing and persuading
- Change management, adaptability, ability to work under pressure
- Good understanding or capacity to quickly understand production processes
- Quality and compliance skills
- Good understanding of regulatory requirements across multiple health authorities
- Good working knowledge/understanding of manufacturing execution systems (e.g. MES, SAP)
- Office software applications

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

[Apply to Job](#)

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.



Job ID
REQ-10045027

Process Expert

[Apply to Job](#)

Source URL:

<https://www.novartis.com.cn/careers/career-search/job/details/req-10045027-process-expert>

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://talentnetwork.novartis.com/network>
3. <https://www.novartis.com/careers/benefits-rewards>
4. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Selangor/Process-ExpertREQ-10045027>
5. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Selangor/Process-ExpertREQ-10045027>