

Commissioning and Qualification Engineer

Job ID
REQ-10083755
июл 24, 2026
Малайзия
Available in: English

Сводка

#LI-Hybrid
Location: Selangor, Malaysia
Relocation Support: This role is based in Selangor, Malaysia. Novartis is unable to offer relocation support: please only apply if accessible.

As a Commissioning and Qualification Engineer, you will play a pivotal role in ensuring equipment, facilities and systems are commissioned, qualified and maintained in a validated state throughout their lifecycle. From supporting major capital investment projects to driving requalification and periodic review activities, your work will directly contribute to product quality, patient safety, and operational excellence. Working in close partnership with Engineering, Quality, Manufacturing, and project teams, you will help ensure all commissioning and qualification activities are executed in compliance with Good Manufacturing Practice standards and site procedures, enabling the reliable delivery of medicines to patients worldwide.

About the Role

Key Responsibilities

- Lead commissioning and qualification activities for capital projects, ensuring compliant and timely execution.
- Maintain facilities, equipment, and systems in a validated state through re-qualification and periodic reviews.
- Ensure all commissioning and qualification activities comply with quality standards, site procedures, and regulatory requirements.
- Develop, review, and maintain commissioning and qualification documentation, plans, protocols, and reports.
- Perform gap assessments and implement actions following updates to procedures, standards, and quality requirements.
- Drive project reviews, audits, and readiness assessments to support successful qualification and compliance outcomes.
- Manage deviations, deficiencies, and investigations, including root cause analysis and corrective actions.
- Partner with Quality Assurance, Manufacturing, Manufacturing Science and Technology, Engineering, and project teams to achieve qualification objectives.
- Provide engineering compliance oversight, conduct self-inspections, and support quality review activities.
- Monitor qualification deliverables, training completion, and system maintenance activities to ensure ongoing compliance.

Essential Requirements

- Degree in Engineering or an equivalent technical discipline.
- Fluent English communication skills with proficiency in the local language.
- More than 5 years of pharmaceutical engineering, commissioning, qualification, or compliance experience.
- Proven technical expertise delivering safe, effective, and fully compliant engineering projects.
- Deep understanding of Good Manufacturing Practice requirements and regulatory compliance standards.
- Advanced knowledge of Health, Safety, and Environment principles within a regulated manufacturing environment.

Commitment to Diversity and Inclusion

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

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>

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
[Read our handbook \(PDF 30 MB\)](#)

Дивизион
Operations
Business Unit
Production / Manufacturing
Место
Малайзия
Сайт
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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