

C&Q Engineer

Job ID
REQ-10045568
Apr 15, 2025
Malaysia

Summary

The C&Q engineer is responsible to perform commissioning & qualification for CAPEX project and routine maintenance such as Requalification and Periodic Review to ensure facilities/equipment/systems are maintained in a validated state. All C&Q activities are carried out in accordance to the global/site SOPs and the current version of GMP (Good Manufacturing Practice).

About the Role

The responsibilities of the C&Q Engineer includes but not limited to:

- Ensure commissioning and qualifications are in compliance with Quality Manual/Quality Modules/STDs/GOPs/site SOPs etc. Create & revise relevant SOPs for commissioning & qualification.
- Perform gap assessment due to revision of GOP and Work procedures etc.
- Annual update of Master Equipment Inventory (MEI) in COMOS
- Drafting of all required Commissioning & Qualification Deliverables (e.g URS, GMP-FRA, Concept Paper, Qualification Plan, Commissioning Test Plan, CTS, Design Qualification, TSIQ, TSOQ, TSPQ, CIP, SIP, Sterile Hold Studies, Qualification Release documents, Qualification Summary Reports etc etc)
- Perform Pre-Requisite checks for each Commissioning & Qualification Phases prior to protocol execution and support routine maintenance of the validated system status (e.g Periodic Review etc) thereafter
- Drafting of project documents (e.g Project Quality Plan, Master Qualification Plan, etc). Management of project deficiencies, project deviations, 1QEM (Deviation) etc and lead investigation (e.g root cause analysis) during commissioning & qualification. Perform project reviews/audit (e.g. Technical Quality Review (TQR), constructability, sustainability, HSE etc)
- Engineering compliance oversight for approval of Equipment/Instrument Data Form & Spare parts material master change request form from all functions. Conduct regular compliance self-inspection within Engineering functions
- Perform monthly checks on CSE PM01 & PM02 Work Orders in SAP to check for overdue and provide data for monthly SQC reporting.

Requirements

- Degree in engineering (Dipl. Ing. / M. Sc. / B. Sc.) or equivalent
- Fluent in English and proficient in local language.
- > 5 years of engineering project/commissioning /qualification /Compliance in Pharma
- Excellent technical knowledge with demonstrated ability to deliver safe, effective and fully compliant projects
- > 5 years of demonstrated leadership abilities, leading both internal and external team members

- Excellent interdisciplinary knowledge (process, HVAC, automation, etc.)
- Outstanding GxP and regulatory knowledge
- Advanced HSE knowledge

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>

Division

Operations

Business Unit

Universal Hierarchy Node

Location

Malaysia

Site

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-10045568

C&Q Engineer

[Apply to Job](#)

Source URL: <https://prod1.novartis.com/careers/career-search/job/details/req-10045568-cq-engineer>

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/Novartis_Careers/job/Selangor/C-Q-Engineer_REQ-10045568-1
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Selangor/C-Q-Engineer_REQ-10045568-1