

C&Q Engineer

Job ID
REQ-10045568

4月 15, 2025

Malaysia

摘要

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

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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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