Commissioning & Qualification / Compliance Engineer

Job ID
REQ-10044617

3月 21, 2025

Spain

摘要

The Commissioning & Qualification / Compliance EngineerTo manages the Projects Facility, Process, HVAC, Clean room and Utility Services Commissioning & Qualifications activities including developing the Protocols and execution of reports for manufacturing equipment. Responsible for handling multiple projects Commissioning & Qualifications activities considering end to end Project management. Will also be responsible for organizing, budgeting, scheduling, executing & monitoring the performance of project as per required timelines.

About the Role

Major Accountabilities

- Responsible for Preparation/execution/compiling of Facility, Process, HVAC, Clean room and Utility Services Commissioning & Qualifications activities Protocols/reports for the Pharmaceutical facilities which includes manufacturing facilities. Preparations of

Commissioning & Qualifications Protocols/ Standard operating Procedures/ Work instructions.

- Responsible for onsite support C&Q activities by following ISPE/ASTM methodologies utilizing GDP, GEP, C&Q Base line guides, GAMP 5 & cGMP Principles. In depth knowledge of Regulatory Guidelines- USFDA, MHRA, WHO, ISO, 21 CFR part 11 and other regulatory guidelines.
- Planning, developing, execution, reporting of C&Q Deliverables.
- Prepare/ Review of Validation master plan, Validation plans, Validation Documents, Commissioning & Validation execution of Clean Room & HVAC Systems (Such as DQ, IQ, OQ & PQ) in Pharmaceutical Industries as per the required standards.
- Preparations & execution of Pre-commissioning & Commissioning checklists for various systems including Facility & Process/Utility Equipments.
- Preparation & execution of Facility, Utility & process equipment FAT/SAT/IOQ Protocols/Reports.
- Improve and optimize based on requirements qualification activities and qualification activities, including modifying SOPs were required. Document periodic reviews for manufacturing equipment and utilities required onsite.
- Maintain documentation package for qualification, periodic reviews on time in compliance.
- Maintain procedures in compliance for Engineering department. Introduce and implement change when required following Quality Management System from Novartis.

Essential Requirements:

- Education: Degree in Mechanical/Chemical Engineering.
- 8-10 years of experience in Pharmaceutical/ Chemical/ FMCG Industry.
- Deep understanding of Project Commissioning & Qualification activities like Facility/HVAC/Clean room / Black & Clean Utility services/Process equipment within pharmaceutical industry.
- Good Knowledge of Project management like - Project planning, Cost Management, Time Management, Construction management, Quality Management, Contract Administration, Safety Management & required Statutory approvals management.
- Fluent in English and Spanish, written and spoken.

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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.

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部门
Operations

Business Unit
Innovative Medicines

地点
Spain

站点
Zaragoza

Company / Legal Entity
ES45 (FCRS = ES045) AAA Ib é rica S.L.U.

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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