

C&Q Engineer- Executive

Job ID REQ-10029109

11月 11, 2024

India

摘要

To manage the Projects Facility, Process, HVAC, Clean room and Utility Services Commissioning & Qualifications activities including developing the Protocols and execution of reports for Pharmaceutical OSD/Injectable/API/Oncology/Biotechnology /Vaccine manufacturing facilities. 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

Key Responsibilities:

 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 OSD/Injectable/API/Oncology/Biotechnology/Vaccine manufacturing facilities.

- Responsible for onsite support C&Q activities by following ISPE/ASTM methodologies utilizing GDP, GEP, C&Q Base line guides, GAMP 5 & cGMP Principles.
- Planning, developing, execution, reporting of C&Q Deliverables.
- Coordination with different package design engineers & Clients, Project managers to enable effective leveraging and timely Right First Time Documents preparations, execution and compliance of Commissioning & Qualification deliverables
- In depth knowledge of Regulatory Guidelines- USFDA, MHRA, WHO, ISO, 21 CFR part 11 & other regulatory guidelines
- Preparations of Commissioning & Qualifications Protocols/ Standard operating Procedures/ Work instructions
- as applicable
- 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
- Preparation and review of qualification protocols, Temperature mapping protocols, Layouts and SOPs as per established procedures.
- Preparations & execution of Pre-commissioning & Commissioning checklists for various systems including Facility & Process/Utility Equipments
- Preparation & execution of Facility, Utility & process equipment FAT/SAT Protocols/Reports

Essential Requirements:

- Degree in Mechanical/Chemical Engineering with 5-8 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 OSD/Injectable/API/Oncology/Biotechnology
- Good Knowledge of Project management like Project planning, Cost Management, Time Management, Construction management, Quality Management, Contract Administration, Safety Management & required Statutory approvals management.

Desirable Requirements:

- Degree in Mechanical/Chemical Engineering or equivalent.
- Fluent in English and proficient in local language.

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

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部门 Operations **Business Unit Innovative Medicines** 地点 India 站点 Hyderabad (Office) Company / Legal Entity IN10 (FCRS = IN010) Novartis Healthcare Private Limited **Functional Area Technical Operations** Job Type Full time **Employment Type** Regular

Shift Work

No

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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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