# C&Q Engineer-Executive

Job ID REQ-10013551

7月 25, 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

C&Q Engineer - Executive

Location - Hyderabad

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#### 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.

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Business Unit Innovative Medicines
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站点 Hyderabad (Office)
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Functional Area Technical Operations
Job Type Full time
Employment Type Regular
Shift Work No
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any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to <a href="mailto:diversityandincl.india@novartis.com">diversityandincl.india@novartis.com</a> and let us know the nature of your request and

your contact information. Please include the job requisition number in your message.

Operations

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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