

# **C&Q Engineer - Senior Executive**

Job ID REQ-10013943 Juli 04, 2024 Indien

# **Summary**

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 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 - Senior 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 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 10 12 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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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Division

Operations

**Business Unit** 

Innovative Medicines

Standort

Indien

Site

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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## Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for 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.

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