

C&Q Engineer - Senior Executive

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REQ-10013943
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India

Resumen

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

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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.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <https://www.novartis.com/careers/benefits-rewards>

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División
Operations
Business Unit
Innovative Medicines

Ubicación

India

Sitio

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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