C&Q Engineer - Executive

Job ID
REQ-10012076
Juni 24, 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 /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

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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 applying 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 demonstrating and timely Right First Time Documents preparations, execution and compliance of Commissioning & Qualification work
- 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
- Must having the experiences and understanding of cleanroom facility and requirements.
- Must have knowledge of computer system validation requirement and preparation and execution of protocol related to computerized system with relevant customers.

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:

- Good English both spoken and written.

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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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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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IN10 (FCRS = IN010) Novartis Healthcare Private Limited
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Employment Type
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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 diversityandincl.india@novartis.com 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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