C&Q Manager

Job ID
REQ-10013552
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India

Sommario

Provide leadership for Commissioning & Qualification activities and lead the customer interface activities for the various sites (large and small molecule) and 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

Commissioning & Qualification Manager

Location - Hyderabad

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Key Responsibilities:

- Responsible for review/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
- 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 Equipment. 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 stakeholders.
- Execute / supervise with the help of contractors on daily basis for follow up and completion of Qualification, Re-qualification, thermal mapping, other engineering cGMP documentation activities and projects.
- Execute / supervise the Project/ engineering department online documentation all time with respect to Equipment, Qualification / Re-Qualification / Thermal Mapping/ Training / Re-Evaluation
- Acts as authorized designate for the Manager and/or supervisor(s) to approve commissioning documents, SATs, FATs, qualification protocols and reports, and Change Controls within QMS TrackWise

Essential Requirements:

- Degree in engineering or equivalent with 12 plus 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
- Leadership experience for the management of internal and external resources
- Sound knowledge in all aspects (cost, schedule, quality) of project controlling and reporting with special focus on trend analysis and forecasting
- Solid analytical / data interpretation skills
- Sound computer skills (MS office, Track wise, MS project, SAP, PM-Tools)

Desirable Requirements:

- Degree in engineering or equivalent
- Fluent in English and proficient in local language.

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Innovative Medicines
Posizione
India
Sito
Hyderabad (Office)
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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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