TRD Pilot Plant CQV Engineer

Job ID
REQ-10038895
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Italia

Resumen

The CQV (Commissioning, Qualification and Validation) Engineer provides the Pilot Plant with Subject Matter Expert (SME) knowledge and skills related to commissioning, qualification and validation activities and requirements of facility, utilities and equipment. He is responsible for timely planning and correct execution of needed CQV activities, as well as management of related Changes and Deviations, in full compliance with all GxP, HSE and business requirements. The CQV Engineer oversees processes and standards to maintain and improve existing manufacturing technologies and to drive CQV phases during the implementation of changes or improvements. Manages and collaborates with external consultants and suppliers, as well as internal resources to achieve timely document generation and execution according to regulatory and project requirements.

About the Role

Key responsibilities:

- Prepare monthly engineering reports with key KPIs
- Support internal and external audits
- Implement technical standards
- Implement GOPs
- If needed, create regional / site SOPs & templates
- Contribute to equipment, utility, facility improvement projects driving the CQV phases.
- Ensure know-how and competencies in the CQV function are always available.
- Implement sharing and leveraging of best practices and expertise in the CQV area
- Manage external resources efficiently
- Being responsible for the generation and maintenance of the Commissioning and Qualification relevant procedures and documents (Risk Assessment/Periodic Requalification Planning/System Impact Assessment).
- Write, review or approve CQV protocols and reports under its area of responsibility (HVAC, Utilities, Production Equipment, Lab Equipment).
- Manage and support external/internal CQV technicians during planning and execution of activities.
- Establish, maintain and execute relevant external supplier agreements for CQV activities. Ensure efficient vendor management.
- Work with the local Engineering team Pilot Plant Leadership Team to define priorities on the CQV of new equipment as well as process/compliance improvements on existing processes and equipment.
- Being responsible for the management of Change Controls and Deviations related to Facility, Utilities and Equipment.
- Support Maintenance and Calibration Functions to improve compliance and quality

- Supports the Process Experts and the manufacturing team in troubleshooting / root cause investigation by providing a second level of specialist expertise as SME and by harmonizing and optimizing related technical processes across the units
- Interfaces with local and global networks to define and implement new technical standards for existing and new technologies and equipment.

Essential requirements:

- Degree in engineering (industrial field) or equivalent scientific background. Master's degree is desirable.
- Fluent in English and proficient in local language.
- 3+ years of experience in CQV activities and/or GMP manufacturing for Pharma/Chemical industry or equivalent field.
- Leadership experience for the management of external resources and vendors
- Project management skills including resource planning, budget control & quality.
- Soft skills: team-working skills and experience, flexibility as well as showing adequate sense of urgency around given tasks.
- Radiation safety education as well as radio-pharma experience is desirable
- Communications skills with the ability to present reports, ideas & solutions in an efficient and easy-understandable way.
- Excellent professional writing skills
- Extended knowledge of GxP / HSE & Quality systems.

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