Engineering Expert Pharmaceutical Equipment

Job ID
REQ-10030151
Apr 28, 2025
Italy

Summary

Guarantee the operation in compliance of all the pharmaceutical end general equipment and systems present in Saluggia site (intended GMP compliance, Guarantee the operation in compliance of all the pharmaceutical end general equipment and systems present in Saluggia site (intended GMP compliance, Normative and Standard compliance, eCompliance) in order to satisfy necessary requirements of pharmaceutical processes and safety requirements, with particular attention to the Aseptic Processes.

About the Role

Major Accountabilities

- Guarantee the correct operation of the equipment, systems, plants present in the production site through the coordination of all the Technical activities, carried out by internal and external resources
- Coordinate the technical activities on the equipment / systems as improvement projects and upgrade projects on the same ones
- Support the production activities participating in the multi-department workshops and projects
- Guarantee the Aseptic process compliance (by equipment upgrade) and Aseptic Process improvement
- Collaborate with MS&T and Production department to understand better their needs and processes for systems compliance, efficiency, and reliability (evaluating needs for upgrade or substitution)
- Accountability and/or responsibility for the GMP documentation both external and internal
- Improvement of the qualification, validation and other GMP / technical documentation adapting it to the corporate standards
- Execute qualification (and sometimes) validation activities or coordinate external resources in the execution under own accountability
- Support the process of Continuous Improvement and Compliance for aseptic processes
- Support eCompliance improvement projects
- Guarantee the safety of internal and external resources working on the equipment, in accordance with applicable normative and corporate procedures (through the implementation of preventive measures).
- Participate in the technical investigations on the GMP deviations on the site production systems and processes

Essential requirements:

- Technical background (i.e. degree in Mechanical/Chemical/Energy Engineering or High school degree in technical field).
- Direct experience in managing pharmaceutical equipment (maintenance, calibration, requalification) with particular attention to Aseptic processes (sterilization, depyrogenation, freeze drying, aseptic filling, WFI loops, …).

- Direct experience in preparation of the GMP documentation for pharmaceutical equipment.
- Direct experience in management and coordination of external contractors and consultants.
- Fluent in Italian. Good knowledge of English.

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Division
Operations
Business Unit
Innovative Medicines
Location
Italy
Site
Saluggia
Company / Legal Entity
IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No

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