Engineering Expert Pharmaceutical Equipment

Job ID
REQ-10030151
Nov 26, 2024
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

Key Performance Indicators

Active collaboration in multi-department teams to guarantee:

- Compliance of the production processes (by equipment and systems compliance)
- Execution of the Production planning (by efficiency and reliability of the equipment)
- GMP compliance and eCompliance of the equipment and systems (by respecting maintenance,

calibration, and requalification plans)
- HSE performance indicators (safety as principal)
- Qualification and Validation of the new equipment or systems respecting scheduling and budget of the Investment projects
- Requalification and Revalidation of the existing equipment / systems up to Validation Activity Schedule (yearly qualification / validation plan) – on time
- Execution of the Site Quality Plan

Job Dimensions

Subordinate Functions: None

Number of Associates: Direct: 0; Indirect: 2-3

Financial responsibility (where appropriate): N/A

Impact on the organisation (where appropriate): High.

Efficiency and Reliability of the equipment as well

as GMP Compliance and eCompliance is

necessary pre-requirement to guarantee:

- Product quality

- Production planning

- Quality Plan respect

Ideal Background (State the minimum and desirable education and experience level)

Education: Batchelor Degree In Engineering (5 years) – preferably electrical or mechanical

Languages: Fluent English spoken and written. Basic Knowledge of the Pharmaceutical and Technical terminology in English

Skills (and Experiences) desired:

- 5-year Direct experience in Pharmaceutical companies or Consultant Companies for Pharmaceutical industry
- Direct experience in managing pharmaceutical equipment (maintenance, calibration, requalification) with particular attention to Aseptic processes (sterilisation, depyrogenation, freeze drying, aseptic filling, WFI loops, …)
- Direct experience and knowledge of GMP documentation (Risk Assesment, Change Request/Management, Root cause analysis, Statistical analysis of production and performance indicators)
- Direct experience in preparation of the GMP documentation for pharmaceutical equipment
- Direct Experience in handling the projects for upgrade or substitution of the existing pharmaceutical equipment
- Direct experience in management (definition, follow-up) of budget for the equipment investments
- Direct experience in management and coordination of external contractors and consultants

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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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