Engineering Specialist

Job ID
REQ-10037271

1月 17, 2025

Mexico

摘要

The engineering specialist will help with day-to-day engineering tasks needed to support manufacturing sitefocusing on activities that can be performed remotely. Role will support automation, Commissioning & qualification, process and utility engineering and maintenance functions.

About the Role

Major accountabilities:

Responsibilities:

- Work order review
- Validation Periodic reviews of equipment systems

- System user reviews
- Create and revise engineering owned SOP's
- Periodic reviews of engineering owned documents
- Deviation and CAPA ownership and support
- System alarm trending and reporting and any associated investigations
- Perform and conduct risk assessments.
- Equipment KPI metric generation
- Change control ownership and action item ownership
- Audit trail review
- Engineering library management including maintaining the Validation Document Equipment Lifecycle Index
- Site facility drawing updates and management
- Project administration and associated metrics
- Maintain Engineering dashboards
- Manage workload to ensure timely approval of validation testing and documentation
- Support the engineering department during inspections or audits
- Build productive internal/external working relationships
- Manage end-to-end document workflows for all types of engineering documents
- Exercise good judgment within defined procedures and practices to determine appropriate action
- Update and manage all engineering design and project documentation using AutoCAD, Revit, BIM, Navisworks, Etc.
- Maintain and update all engineering specifications, standards, and design information, including building information modeling data
- Other related duties as assigned

Requirements:

- B.S. degree in Chemical, Electrical or Mechanical Engineering, or related technical field, with 2 years ' work experience in pharmaceutical or biopharmaceutical based GMP manufacturing operations, or equivalent work experience (6 years) in pharmaceutical or biopharmaceutical based GMP manufacturing operations in lieu of degree
- Solid foundation in FDA regulations and GMP systems and experience providing engineering support in a highly regulated or pharmaceutical / biotech facility
- Excellent English oral and written communication skills. Strong technical writing ability required
- Experience with full Autodesk CAD suite
- Proficient in Microsoft Word, Excel, PowerPoint, Teams, and Project
- Knowledge of equipment and computerize system validation concepts

Languages :

- English Proficiency

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部门
Operations

Business Unit
Innovative Medicines

地点
Mexico

站点
INSURGENTES

Company / Legal Entity
MX06 (FCRS = MX006) Novartis Farmac é utica S.A. de C.V.

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work

No

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Accessibility and accommodation

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