

Commissioning & Qualification Engineer

Job ID
REQ-10030465
Nov 18, 2024
China

Summary

Responsible for defining, planning, executing and reporting on Commissioning & Qualification for CAPEX projects and/or routine manufacturing operation ensuring GxP compliance of plant/facilities/equipment.

About the Role

Strategy & Organizational Development:

- Support internal and external audits
- Create and maintain GOPs and provide standard training
- Implement GOPs
- If needed, create regional / site SOPs & templates
- C&Q related IT system owner for Haiyan Site

Project Engineering & Control:

- Develop Project schedule
- Perform project risk assessment
- Identify technical solutions
- Prepare project quality plan
- Develop project document management and archiving concept
- Perform project reviews (e.g. Technical Quality Review (TQR), constructability, sustainability, HSE)
- Develop project commissioning plan / strategy
- Establish project change management and manage changes
- Develop project execution plan (e.g. C&Q)
- Prepare / execute Project Health & Safety Risk Assessments (Equipment / Process)
- Expedite and manage project vendors / contractors / 3rd parties in project
- Develop test specification / plan for commissioning & qualification in projects
- Perform new equipment FAT / SAT / inspections in project
- Implement and monitor construction contractor safety and inspection plan
- Execute work orders for projects as per method statement
- Perform commissioning activities
- Manage project deficiencies and deviations
- Perform provisional and final project handover

Maintenance & Calibration:

- Plan initial calibrations

- Coordinate maintenance / calibration activities
- Plan resources for maintenance / calibration
- Allocate work for maintenance / calibration to technicians
- Identify spare parts for maintenance and maintain pick-lists
- Establish Master Instrument Inventory (MII) and Master Equipment Inventory (MEI)
- Get permits for maintenance / calibration / projects
- Execute work orders for maintenance / calibration as per method statement / procedure
- Provide front line support for technicians
- Supervise maintenance and calibration works
- Assess quality impact and release after maintenance work
- Manage technical / engineering changes: originate Change Request, approve Change Request, close Change Request
- Execute change requests
- Investigate deviations (root cause analysis)
- Create / maintain / verify engineering documents (protocols, drawings, lists, schedules, diagrams, layouts, calculations, datasheets)

(Re-) Qualification:

- Develop qualification plan
- Perform GMP risk assessments (incl. Sensors SRA)
- Create DQ, IQ and OQ protocols
- Execute DQ, IQ and OQ
- Create DQ, IQ and OQ reports
- Provide technical trouble shooting during PQ and validation
- Develop periodic requalification plan
- Execute periodic requalification plan

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Division

Operations

Business Unit

Innovative Medicines

Location

China

Site

Haiyan (Zhejiang Province)

Company / Legal Entity

CN27 (FCRS = CN027) Novartis Pharmaceutical Technology Zhejiang Co., Ltd.

Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No
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