

Change Control Coordinator

Job ID
REQ-10009889
Jun 03, 2024
India

Summary

Handling of technical change control as well as responsibility for the documentation and coordination of the necessary activities during plant changes in Agile

About the Role

Change Control Coordinator

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Handling of technical change control as well as responsibility for the documentation and coordination of the necessary activities during plant changes in Agile

Key Responsibilities:

- Should have good engineering knowledge in the Bio-Pharmaceutical Plant in the areas of
 - Facilities that are involved as infrastructure or in the manufacturing process, e.g. Ultrapure water systems, building services, manufacturing, packaging equipment (direct and indirect impact systems)
 - the qualified status of a room or its classification (cleanroom zone E, D, C, B, A).
 - the software and computer systems managed by Engineering.
 - for new acquisitions of plants and systems/Equipment's
 - on measuring equipment
 - SAP/Quality Management system software skills
 - Project planning Skills
 - Asset life cycle management skills eg maintenance documents and its metrics review
- Should have sound knowledge about the Nomination of all participants in the QMS change phase from reviewer – approver.
- Should be good in all Engineering related changes which requires an evaluation & followed by a Registration Representative
- Changes to ER/ES relevant systems, must be evaluated by eCompliance
- In the case of devices, a DHF (Device Documentation File) evaluation may also be required. In the case of combination products, assembled and/or packaged, the MS&T "device expert" must check for adjustments with regard to device documentation (DHF file).
- Implementation of the change and processing (or delegation) of the tasks defined in the implementation plan
- Coordination of the change until completion

Essential Requirements:

- 5+ years of experience in handling change controls within pharmaceutical sector
- Very good knowledge of German and good knowledge of English (spoken and in writing)
- Experience in the GMP or pharmaceutical sector.
- Technical education, high level of personal responsibility, good communication skills

Desirable Requirements:

- Degree or equivalent experience in Engineering with experience in Pharmaceutical Industry/ specifically GMP background

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Division

Operations

Business Unit

Innovative Medicines

Location

India

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

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