

# Change Control Coordinator

Job ID  
REQ-10009889

6月 03, 2024

India

## 摘要

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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部门

Operations

Business Unit

Innovative Medicines

地点

India

站点

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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