Specialist, Manufacturing Technical Support

Job ID
REQ-10037280

1月 17, 2025

Mexico

摘要

The Specialist, Manufacturing Technical Support, provides expert support for all process-specific issues to manufacturing, to ensure execution of processes on-time, continuously improving in quality and productivity, performed in compliance to cGMPs, SOPs and applicable guidelines and functional standards.

About the Role

Responsibilities:

- Revises master manufacturing documents of assigned products (e.g. Master Batch Record, Bill of Material (BOM), and Recipe, Quality Risk Assessment, Hazard Analysis).
- Ensures that all critical parameters are within written Instruction (e.g. Master Batch Record, Quality Risk Assessment, and Validation Protocol).
- Supports steward for assessment of technical changes, establishment of root-cause analysis,

Quality Risk Assessment, process control strategy.
- Ensures that all process changes in assigned products are managed through appropriate change control procedure.
- Ensures creation of production SOPs and revisions to Master Batch Records and/or Electronic Records.
- Act as Subject Matter Expert (SME) for the product and process knowledge, be highly knowledgeable of product and process trends by providing input for analysis and driving process technology innovations.
- Authors manufacturing investigations and meets all targets for timely closure and CAPA completion.
- Supports data collection for ongoing process verification, support manufacturing lead in tracking and evaluation of product performance and implementation of CAPAs.
- Performs first line evaluation of product and process related issues (deviations, complaints, OOS, OOE).
- Provides and supports assessments of technical changes, establishment of root-cause analysis, Quality Risk Assessment and process control strategies.
- Maintains processes at inspection readiness level.
- Supports process optimization establishment and new technology introduction for continued productivity improvement.
- Reviews validation protocols and reports for technical correctness.
- Revisions to the master manufacturing documents of assigned products.
- Other related duties as assigned.

Requirements:

- B.S. degree in Engineering or the life sciences and 5 years of work experience in biopharmaceutical based GMP manufacturing operations or 3 years relevant GTx experience.
- Experience in the development of manufacturing documentation and in the investigation of complex manufacturing deviations.
- In-depth knowledge of FDA regulations and GMP systems and experience providing process support in a highly regulated or pharmaceutical / biotech facility.
- Applied knowledge of Quality by Design, six-sigma, and operational excellence tools in creating efficient and high-quality processes and end products.
- Fluent in English. Excellent oral and written communication skills. Strong technical writing ability required.
- Travel, as required, to other internal sites (<10%).

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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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