

Documentation Specialist

Job ID
REQ-10039141
Feb 20, 2025
Mexico

Summary

This Role provides oversight of all GMP documents (SOPs, FRMS, WPS) and ensures that all documents are updated, trained and effective in alignment with the department needs

About the Role

Major accountabilities:

- Revise existing or create new SOPs in time to support Manufacturing Strategy.
- Ensure periodic review is completed on time
- Coordinate updates with cross functional teams for CAPAs, QEs, Health Authority inspections
- Ensure proper training compliance of all associates in
- Develop appropriate Individual training plans in collaboration with team leads
- Stay current regarding industry standards and ensure that all SOPs are cutting edge and incorporate all latest regulatory and quality requirements
- Support Quality Manual implementation through support of gap assessments and implementation of relevant content into SOPs and daily operation.

Key performance indicators:

- MBR right first time
Reduction of batch record cycle time
Reduction of operational errors
98% training compliance of all associates
No critical audit findings pertinent to SOPs/MBRs

Work Experience:

- 3-5 or more years of related experience in cGMP/FDA regulated industry.
- Pharmaceutical GMP's – strong knowledge of Good Manufacturing Practices and regulatory knowledge is a requirement.
- Proficient in MS Office applications and other related IT Systems.
- Knowledgeable in ESOPs; LMS (Learning Management Systems),
- TrackWise; MES knowledge is a plus

Skills:

- Assembly Language.
- Cooperation.
- Efficiency.
- Electronic Components.

- Flexibility.
- General Hse Knowledge .
- Good Documentation Practice.
- Installations (Computer Programs).
- Iso (International Organization For Standardization).
- Job Description.
- Knowledge Of Gmp.
- Lean Manufacturing.
- Manufacturing (Production).
- Manufacturing Process.
- Nuclear Medicine.
- Physics.
- Product Distribution.
- Production Line.
- Scheduler.

Languages :

- English.

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Division

Operations

Business Unit

Innovative Medicines

Location

Mexico

Site

INSURGENTES

Company / Legal Entity

MX06 (FCRS = MX006) Novartis Farmacéutica S.A. de C.V.

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

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