

Associate Process Expert

Job ID
REQ-10056685
Jul 01, 2025
Mexico

Summary

This role will author and oversee deviations, investigations, CAPAs, and related reports to ensure closure within the established timelines for the manufacturing department.

About the Role

Deviation and Investigation Management:

- Open deviations and assess the criticality of the deviation within required timeframes
- Assess impact to any products involved in deviations, ensuring product impact is assessed in alignment with batch release activities
- Author investigations
- Owning investigations and developing corrective actions
- Use process knowledge and root cause investigation tools to identify root causes of product and process deviations.
- Ensures robustness (complete, accurate and defensible) of all critical and major investigations
- Author and execute any experiments or runs to support investigations
- Work cross-functionally to assess and analyze deviations and investigations to determine impact
- Work cross-functionally to ensure production continues in a compliant manner in the event of a deviation and document accordingly.

Corrective and Preventive Actions:

- Generation and documentation of effective corrective and preventative actions
- Ensures all CAPAs are implemented through GMP systems (e.g. MBR revision, training, etc.)
- Monitor and ensure effectiveness checks of CAPAs are conducted
- Communicate to the production team any training or awareness events to reinforce quality behaviors.

MES Order Management:

- Generation of manufacturing orders within the MES system, as required.

Training:

- Develop training (as immediate response to unexpected events, for technical document execution, and new products/processes) to the Cell Processing team, as required.
- Maintain compliance with training requirements.

Key Performance Indicators:

- Quality measures (e.g., deviations, oos rate)
- Schedule adherence to operational model
- Opening and closing investigations within time frame
- Production right first time
- Costs and budget (e.g. overtime)

Ideal Background:

Education: Bachelor's degree with 2-5 years of work experience in the pharmaceutical industry or equivalent. An advanced degree is desirable.

Languages: Fluent in speaking / writing in English

Experience:

- 2-5 years of related pharmaceutical experience preferably in a production, QA, and/ or QC related role preferred. Direct experience working in a GMP and aseptic or sterile environment is required. Cell & gene therapy experience highly desired.
- Investigator Certified required
- Knowledge of cGMP regulations and FDA guidance applicable to biologics and cell therapy manufacturing.
- Experience with 1QEM

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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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