Associate Process Expert

Job ID
REQ-10036849

1月 17, 2025

Mexico

摘要

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

About the Role

Deviation and Investigation Management:

- Open deviations within required timeframes
- 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 defendable) 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 Preventative 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 behaviours.
- **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 requirement

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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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