Associate Process Expert

Job ID
REQ-10056685

7月 01, 2025

Mexico

摘要

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 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 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

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients ' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
Operations

Business Unit
Innovative Medicines

地点
Mexico

站点
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

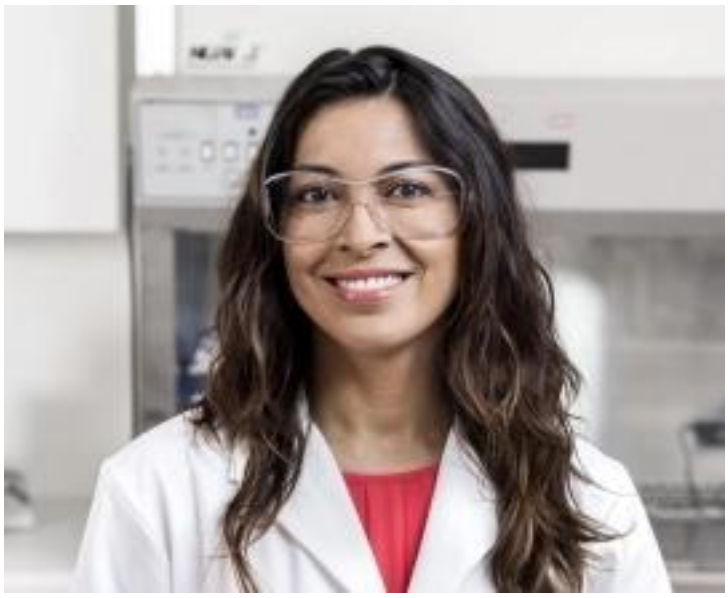
Shift Work
No

Apply to Job

Accessibility and accommodation

Novartis is committed to work with and provide reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to tas.mexico@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.



Job ID
REQ-10056685

Associate Process Expert

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10056685-associate-process-expert

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/INSURGENTES/Associate-Process-ExpertREQ-10056685-1
5. mailto:tas.mexico@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/INSURGENTES/Associate-Process-ExpertREQ-10056685-1