

Process Expert

Job ID
REQ-10053843

7月 11, 2025

China

摘要

The Process Expert can work with shopfloor technicians and provide direct front line support to production activities using technical understanding and knowledge of cGMPS, SOPs, and process steps. This individual is accountable to support Manufacturing activities, develop training materials for production operators, train production staff, support process issues, protocol generation, general documentation support, deviation investigations, CAPA ownership, change record ownership, and continuous improvement of the process.

About the Role

Major Activities

- Support a culture of safety, quality, diversity, and inclusion.
- Work with shopfloor technicians and provide front line support to manufacturing shifts to ensure safe, quality, and timely completion of product batches.

- Manage and maintain manufacturing documentation including Master Batch Record, applicable SOPs, risk assessments, protocols, and other documentation as needed.
- Track and trend critical process parameters and in process checks as the lead for ongoing process verification (OPV) and identify CAPAs to address any trends.
- Identify, assess, and own technical changes through GMP change control processes.
- Investigate deviations and determine root causes and identify CAPA.
- Act as Subject Matter Expert (SME) for the product and process knowledge and provide input to the Annual Product Review.
- Ensure processes are inspection ready at all times.
- Support continuous improvement through identification of opportunities, technologies, and owning changes to implement improvements.
- Support validation protocol generation and execution.
- Support on going self-learning and ensuring training is up to date.
- Provide guidance and support to production team through training and knowledge sharing.
- This position will involve wearing protective clothing and working in a Manufacturing Grade C clean room environment.
- This position may require shift work including weekends and off hours support.
- Strong interpersonal, written, communication skills along with problem solving and follow-up skills.
- Well organized, flexible and work with minimal supervision.

Education

Bachelor ' s degree in engineering, Pharmacy, Pharmaceutical Technology, Chemistry or other science related field

Language

Proficiency in Chinese and advanced English in listening/speaking/reading/writing

Experience

Minimum requirements:

3+ years of experience in a GMP, R&D, or related Biopharmaceutical environment

1+ years of experience in a process support role in manufacturing

Continuous Improvement Methodology

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部门

Operations

Business Unit

Innovative Medicines

地点

China

站点

Haiyan (Zhejiang Province)

Company / Legal Entity

CN27 (FCRS = CN027) Novartis Pharmaceutical Technology Zhejiang Co., Ltd.

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

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