Process Expert

Job ID
REQ-10064591

10月 21, 2025

USA

摘要

As a Process Expert you will provide front line support to manufacturing, working with the production teams to ensure each batch is manufactured safely and in compliance with the batch instructions and quality requirements. You will act as our Subject Matter Expert (SME) for product and process knowledge and will be the first point of contact for product and process related issues. Drives investigations to true root cause, and implementation of corrective and preventive actions.

About the Role

Major accountabilities:

- Manage and maintain manufacturing documentation including Master Batch Record, applicable SOPs, risk assessments, protocols, and other documentation as needed.
- Technical writing/Reviewing to support manufacturing operations including but not limited to, Standard Operating Procedures (SOP), batch records and white papers.

- Collect data for ongoing process verification (OPV), support tracking and evaluation of product performance and implementation of CAPAs.
- Authoring/Owning investigations related to material transfer, API synthesis, Drug Substance formulation, Drug product filling, inspection, and packaging.
- Ensure processes are inspection ready at all times.
- Support process optimization and new technology introduction for continued productivity improvement, as appropriate.
- Review validation protocols and reports. Support the execution of process validations, and short-term improvement projects.
- Provide guidance and support to production team through training and knowledge sharing.
- Will demonstrate leadership capabilities and guide processes to closure/completion, while following all required guidelines and procedures.

Minimum Requirements:

- Bachelor's degree in Engineering, Pharmacy, Pharmaceutical Technology, Chemistry or relevant experience in lieu of degree.
- 3 years ' experience in a process support shop floor role in GMP manufacturing and/or QA/QC.
- Proven process understanding (Pharma, GMP, Regulatory aspects).
- Strong awareness of quality issues. Compliance investigations experience required.
- Excellent technical writing skills

Desirable Requirements:

- Previous Radio pharma experience a plus
- Prior leadership and/or high cross-functional experience preferred.

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U469 (FCRS = US469) AAA USA Inc.

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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