Manufacturing Specialist (weekend night shift)

Job ID
REQ-10068690

12月 16, 2025

USA

摘要

This role is located on-site in Indianapolis, IN. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Shift: Weekend Nights - position may involve mandatory overtime as needed

As a Manufacturing Specialist 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, isotope manufacturing, and packaging.
- Ensure processes remain 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.
- Participation in assigned qualification/validation activities, as necessary.
- Facilitates a culture of "speaking up" and ensuring all cGMP compliance activities are followed.
- Prepares applicable documents and records such as batch records, shipping documents, and training materials.
- Participates in periodic mandatory overtime to ensure process continuity and completion.
- Other duties may be assigned, as necessary.
- Ensure overall inspection readiness for area of responsibility -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Essential Requirements:

- Bachelors degree in Engineering, Pharmacy, Pharmaceutical Technology, Chemistry or relevant experience in lieu of degree.
- Training in radiochemistry or radio pharmacy is preferred.
- 3+ years' experience in a process support shop floor role in GMP manufacturing and/or QA/QC.
- Strong awareness of quality issues. Compliance investigations experience required.
- Good understanding of manufacturing and validation requirements and activities.
- Exploitation of new technology and techniques to eliminate non-value adding activities and improve productivity / performance through new processes.
- Knowledge of cGMP regulations and FDA guidance applicable to isotope manufacturing.
- Proficient in MS Office applications.

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

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

EEO Statement:

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The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Operations

Business Unit
Production / Manufacturing

地点
USA

状态
Indiana

站点
Indianapolis

Company / Legal Entity
U469 (FCRS = US469) AAA USA Inc.

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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