NOVARTIS

Process Expert, Aseptic Drug Products (ADP) Process Support

Job ID
REQ-10073448

3月 17, 2026

USA

摘要

The Process Expert will work within the Aseptic Drug Products (ADP) Process Support team for drug products, assembly, and packaging operations. This position will support critical project lifecycles from technology transfer and qualification of new processes, leading into commercial operations. This position will also play a key role in ensuring seamless integration of new technologies, process optimization, and compliance into various ADP process workstreams.

This position will be a full-time site-based role that will provide front line expert support for all process specific issues for manufacturing, to ensure execution of processes on time, continuously improving in quality and productivity, and performed in compliance with cGMPs, SOPs and applicable guidelines and functional standards.

About the Role

Location:

- This position is located in Durham, NC and will be an On-Site role.
- Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Key Responsibilities:

- Provides front line support to manufacturing, working with the shift teams, focusing on manufacturing each batch safely, on time, in compliance with the batch instructions and quality requirements.
- Authors, Revises, and/or Reviews master manufacturing documents of assigned products (e.g. Standard Operating Procedures, Master Batch Records, Bill of Material (BOM), and Recipe, Quality Risk Assessment, Hazard Analysis).
- Performs first line evaluation of product and process related issues such as deviations, product complaints, OOS, and OOE.
- Oversee that all critical parameters are within written Instruction (e.g. Master Batch Record, Quality Risk Assessment, and Standard Operating Procedures).
- Reviews /supports assessment and execution of technical transfer, technical changes, establishment of root - cause analysis, Quality Risk Assessment, process control strategy.
- This position will play a key role in supporting regulatory inspections and be a font line representative in presenting Deviations, manufacturing documentation, CAPAs, Change Controls, and associated records to regulatory agencies.
- Approves and ensures that all process changes in assigned products are managed through appropriate change control procedure.
- Oversee the creation of production SOPs and revisions to Master Batch Records and/or Electronic Records.
- Subject Matter Expert (SME) for the product and process knowledge, be highly knowledgeable of product and process trends by providing input for analysis and driving process technology innovations.
- Oversee and/or authors manufacturing investigations and meets all targets for timely closure and CAPA completion.
- Supports data collection for ongoing process verification, supports manufacturing lead in tracking and evaluation of product performance and implementation of CAPAs.
- Provides and supports assessments of technical changes, establishment of root - cause analysis, Quality Risk Assessment, and process control strategies.
- Maintains processes at inspection readiness level.
- Initiates and/or supports process optimization and new technology introduction for continued productivity improvement.
- Reviews validation protocols and reports for technical correctness.
- Leads and/or supports the execution of process validations and improvement projects, collaborating with all the relevant parties at shop floor to ensure accurate execution. Launch and Transfer- for the product(s) assigned.
- Revisions to the master manufacturing documents of assigned products.
- Other related duties as assigned.

Essential Requirements:

- B.S. degree in Engineering or the life sciences and 7 years of work experience in biopharmaceutical based GMP manufacturing operations.

- Experience in the development of manufacturing documentation and in the investigation of complex manufacturing deviations.
- In - depth knowledge of FDA regulations and GMP systems and experience providing process support in a highly regulated or pharmaceutical / biotech facility.
- Applied knowledge of Quality by Design, six - sigma, and operational excellence tools in creating efficient and high - quality processes and end products.
- Excellent oral and written communication skills. Strong technical writing ability required.
- Travel, as required, to other internal sites and equipment vendors (up to 20%).

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $108,500 and $201,500 per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

#LI-Onsite

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: Learn about all the ways we ' ll help you thrive personally and professionally. Read our handbook (PDF 30 MB)

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

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
North Carolina

站点
Durham

Company / Legal Entity
U473 (FCRS = US473) Novartis Gene Therapies

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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VIDEO

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