Manufacturing Quality Assurance Specialist

Job ID
REQ-10067689

12月 07, 2025

USA

摘要

Help ensure every dose we produce reaches patients safely. As our onsite Manufacturing Quality Assurance Specialist in Durham, you ' ll be the quality partner from material release through aseptic filling and final product release–providing shop floor oversight, reviewing batch records and alarms, guiding investigations and corrective and preventive actions, and championing data driven continuous improvement. You ' ll collaborate across Production, Quality, and Technical Operations to uphold current Good Manufacturing Practice standards, support health authority and internal inspections, and turn complex regulations into clear, confident decisions. If you love solving problems at the source and empowering teams to deliver consistently, this role lets you make a measurable impact on therapies that can change lives.

#LI-Onsite
Location: Durham, NC
Multiple positions available. Various shifts available.

Relocation Support: This role is based in Durham, NC. Novartis is unable to offer relocation support: please only apply if accessible.

About the Role

Key Responsibilities

- Provide quality oversight for all manufacturing processes from material release to final product release.
- Conduct area walkthroughs, shop floor support, and batch record reviews to ensure compliance.
- Review and approve master and issued batch records, SOPs, and specifications for clinical and commercial manufacturing.
- Collaborate with manufacturing and quality teams to maintain cGMP standards and regulatory adherence.
- Lead projects to address quality gaps and drive continuous improvement in Operations or Quality Systems.
- Manage deviations and CAPA, ensuring thorough documentation and investigation of all incidents.
- Support internal, board of health, and self-inspections, providing guidance and training to team members.

Essential Requirements

- Bachelor ' s degree preferably in microbiology, chemistry, or biochemistry with 5 years ' experience in health authority GMP regulated industry or Associate ' s degree with 7 years ' experience health authority GMP regulated industry; preferably in pharma/biotech/med device.
- Experience with viral gene therapies and/or orphan disease indications is a plus.
- Knowledge and application of the CFR ' s and cGMP ' s and have been involved in regulatory inspections.
- Knowledge of FDA and EU regulations and experience in US and international regulatory agency inspections.
- Direct experience reviewing and/or authoring standard operating procedures and partnering with operations on product - related investigations and deviations.
- Excellent oral and written communication skills with strong technical writing experience.
- Ability to synthesize data and summarize outcomes to provide recommendations on compliant path forward.

Novartis Compensation and Benefit Summary: *The salary for this position is expected to range between $39.03 and $72.50/hour. 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.

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:

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
Quality

地点
USA

状态
North Carolina

站点
Durham

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

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

Apply to Job

Job ID
REQ-10067689

Manufacturing Quality Assurance Specialist

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https://www.novartis.com.cn/careers/career-search/job/details/req-10067689-manufacturing-quality-assurance-specialist

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