NOVARTIS

Quality Assurance Specialist, Batch Disposition

Job ID
REQ-10087944
Сен. 23, 2026
США

Сводка

Every batch released has the potential to impact patients' lives, and that's where you come in. As a Quality Assurance Specialist, Batch Disposition, you will play a critical role in ensuring the quality, compliance, and timely release of clinical and commercial products. Working at the intersection of Quality, Manufacturing, and Operations, you will lead batch review and disposition activities, provide GMP oversight, and help maintain the highest standards of quality and regulatory compliance. This is an opportunity to make meaningful contributions to product release decisions while driving continuous improvement in a fast-paced and collaborative environment.

About the Role

Location:

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

Shift:

- We currently have two openings one first-shift role and one second-shift role (starting at 12:00 PM). Both positions are scheduled Monday through Friday.

Key Responsibilities:

- Lead batch record review and batch disposition activities to support timely product release.
- Make quality-based disposition decisions for raw materials, consumables, intermediates, and finished product.
- Partner with Manufacturing and Quality teams to ensure GMP compliance throughout production operations.
- Support release of clinical and commercial products in accordance with regulatory requirements.
- Issue and manage batch records and associated manufacturing documentation.
- Review, author, and approve SOPs, work instructions, specifications, and other controlled documents.
- Drive investigations, deviations, CAPAs, and Change Controls impacting product quality and release.
- Support internal audits, regulatory inspections, and ongoing FDA inspection readiness activities.
- Monitor quality metrics and contribute to Quality Management Review reporting and site performance initiatives.
- Identify and implement continuous improvement opportunities that strengthen Quality Systems and operational effectiveness.

Essential Requirements:

- Bachelor’s degree in Biology, Engineering, Microbiology, Chemistry, Biochemistry, or a related scientific discipline.
- Minimum 5 years of experience in Batch Disposition and/or Quality Assurance within a GMP-regulated environment.
- Proven experience performing batch record review and supporting product release activities.
- Strong knowledge of GMP regulations and quality systems within the biopharmaceutical industry.
- Experience supporting manufacturing operations, including cell culture, purification, or aseptic fill-finish processes.
- Demonstrated experience managing deviations, CAPAs, and Change Controls.
- Experience supporting regulatory inspections and health authority audits, including FDA inspections.
- Strong attention to detail, sound quality judgment, and the ability to manage competing priorities in a fast-paced environment.
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Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $43.00 and $80.00 per 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.

#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.

Дивизион
Operations
Business Unit
Quality
Место
США
Состояние
North Carolina
Сайт
Durham
Company / Legal Entity
U473 (FCRS = US473) Novartis Innovative Technologies Inc
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

Job ID
REQ-10087944

Quality Assurance Specialist, Batch Disposition

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