NOVARTIS

Sr. Specialist QA Compliance - Document Control & Training

Job ID
REQ-10091955
Ноя. 16, 2026
США

Сводка

Imagine helping build the quality foundation of a brand-new pharmaceutical manufacturing site from the ground up. As a Sr. Specialist QA Compliance, Document Control & Training, you will play a critical role in establishing the quality systems, training programs, and document control processes that enable safe, compliant, and efficient manufacturing operations. Partnering across Quality, Manufacturing, Engineering, Validation, and Technical Operations, you will help drive GMP compliance, inspection readiness, and continuous improvement while supporting the delivery of innovative medicines to patients worldwide.

About the Role

Location:

- This position will be located in Morrisville, 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.

Key Responsibilities:

- Manage document control processes, including creation, review, approval, issuance, and archival of GMP documentation.
- Coordinate site training programs, curricula, qualification activities, and compliance monitoring.
- Support implementation, maintenance, and continuous improvement of the Quality Management System.
- Review and approve quality records, including deviations, CAPAs, change controls, and exceptions.
- Lead and support inspection readiness activities for FDA, customer, corporate, and regulatory audits.
- Provide oversight of Data Integrity programs, compliance plans, and quality risk management activities.
- Partner with Manufacturing, Engineering, Validation, and Technical Operations to support site start-up activities.
- Support technology transfers, equipment qualifications, validation activities, and GMP manufacturing operations.
- Drive continuous improvement initiatives that enhance quality performance and operational efficiency.
- Help establish a strong quality culture and compliant operating environment at a new manufacturing site.

Essential Requirements:

- Bachelor of Science degree in Life Sciences, Pharmacy, Chemistry, Biotechnology, or a related scientific discipline.
- Minimum 5 years of Quality Compliance experience within a pharmaceutical, biotechnology, or regulated manufacturing environment.
- At least 3 years of experience supporting Document Control programs and GMP documentation management.
- Experience with Quality Systems including deviations, CAPAs, change control, and compliance oversight.
- Experience managing or supporting GMP training programs, curricula, qualification, and training compliance activities.
- Demonstrated experience supporting FDA inspections, audit readiness activities, and regulatory compliance initiatives.
- Working knowledge of Data Integrity, validation, risk management, and quality compliance requirements.
- Proven ability to collaborate effectively across Quality, Manufacturing, Engineering, Validation, and Technical Operations functions.

Desirable Requirements

- Experience supporting Oral Solid Dosage (OSD) pharmaceutical manufacturing operations.
- Experience within Small Molecule pharmaceutical manufacturing environments.
- Experience supporting site start-up, expansion, or technology transfer activities.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $89,600 and $166,400 annually

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.

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List of links present in page

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