NOVARTIS

Sr. Specialist QA Compliance - Engineering & Supplier Quality

Job ID
REQ-10091950
Ноя. 16, 2026
США

Сводка

Join Novartis and play a critical role in building the quality foundation of a new pharmaceutical manufacturing site. As a Sr. Specialist QA Compliance, Engineering & Supplier Quality, you will help ensure facilities, equipment, computerized systems, suppliers, and manufacturing processes meet the highest standards of GMP compliance and inspection readiness. Working across Quality, Engineering, Manufacturing, Validation, and Technical Operations, you will provide quality oversight for key startup initiatives while helping establish compliant, efficient, and inspection-ready operations that support 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:

- Provide Quality Compliance oversight for commissioning, qualification, validation, and requalification activities.
- Support qualification of facilities, utilities, equipment, computerized systems, and manufacturing processes.
- Manage Supplier Quality activities, including supplier qualification, onboarding, and compliance oversight.
- Support implementation and continuous improvement of the site's Quality Management System.
- Review and approve quality records, including deviations, CAPAs, change controls, and exceptions.
- Drive inspection readiness activities and support FDA, customer, corporate, and regulatory inspections.
- Provide oversight of Data Integrity programs, compliance plans, and quality risk management activities.
- Partner with Engineering, Manufacturing, Validation, and Technical Operations to support site startup activities.
- Support technology transfers, process validation, and qualification strategies for new products and equipment.
- Lead continuous improvement initiatives that enhance quality performance and operational efficiency.

Essential Requirements:

Bachelor of Science degree in Life Sciences, Pharmacy, Chemistry, Biotechnology, Engineering, or a related scientific discipline.

Minimum 5 years of Quality Compliance, Quality Engineering, Validation, or pharmaceutical manufacturing experience.

Experience supporting equipment, facility, utility, or computerized system qualification activities within a GMP environment.

Experience supporting process validation, commissioning, qualification, or requalification programs.

Experience with Supplier Quality programs, supplier qualification, or supplier compliance oversight.

Strong knowledge of Quality Systems including deviations, CAPAs, change control, Data Integrity, and compliance oversight.

Demonstrated experience supporting FDA inspections, audit readiness activities, and regulatory compliance initiatives.

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 startup, facility 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.

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

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