NOVARTIS

Head Quality Systems and Compliance (Assoc Dir)

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REQ-10083720
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США
Available in: English

Сводка

Location: Morrisville, NC

Join Novartis as our QA Compliance and Systems Head and help shape the quality foundation that enables the delivery of medicines to patients worldwide. This is a unique opportunity to join our new Small Molecule manufacturing site in Morrisville, playing a critical leadership role in building and advancing the site's quality culture, systems, and compliance programs from the ground up. You will oversee Quality Systems, Compliance, Audit and Inspection Readiness, Data Integrity, Supplier Quality, and Validation programs while partnering across Quality, Manufacturing, Engineering, and Regulatory functions. As a key member of the site Quality leadership team, you will drive a culture of compliance, continuous improvement, and operational excellence while ensuring inspection readiness and supporting the site's long-term growth and transformation journey.

About the Role

Key Responsibilities

- Lead the site Quality Management System and ensure compliance with Novartis Quality Manual, current Good Manufacturing Practice requirements, and regulatory standards.
- Drive continuous inspection readiness and lead preparation for corporate audits, customer audits, external audits, and Health Authority inspections.
- Provide oversight of quality systems including deviations, corrective and preventive actions, exceptions, change controls, data integrity, eCompliance, key performance indicators, and key quality indicators.
- Partner with Manufacturing, Quality Control, Validation, Technical Operations, Engineering, and Regulatory teams to support site operations, technology transfers, qualifications, and validation activities.
- Lead investigations of deviations, out-of-expectation events, complaints, and compliance issues, ensuring timely and effective resolution.
- Oversee supplier quality, regulatory compliance, training governance, and risk management programs that support sustainable inspection readiness.
- Lead, coach, and develop the QA Compliance and Systems team through effective resource planning, performance management, talent development, training governance, and sustained training compliance.
- Promote a strong quality culture built on accountability, collaboration, continuous improvement, employee development, and proactive risk management.
- Advance digital enablement and continuous improvement initiatives that strengthen quality performance, simplify processes, and support site transformation.

Essential Requirements

- Bachelor of Science or Master of Science in Life Sciences, Pharmacy, Chemistry, Biotechnology, or related scientific discipline; advanced degree preferred.
- Minimum 8-10 years of experience in pharmaceutical manufacturing, which may include expert roles in Production, Manufacturing Science and Technology, Quality, or Engineering. Prior experience in oral solid dose manufacturing preferred.
- Demonstrated leadership experience managing teams, developing talent, driving performance, fostering training compliance, and building a culture of accountability and collaboration.
- Significant experience leading FDA inspections, regulatory interactions, audit readiness activities, and inspection remediation efforts.
- Strong experience leading Quality Systems programs, including deviations, corrective and preventive actions, change control, data integrity, validation, and compliance oversight.
- Proven ability to lead risk management, continuous improvement, and compliance initiatives in highly regulated manufacturing environments.

Desirable Requirements

- Previous involvement with facility start-ups, qualifications, validations, transfers
- Qualifications or certification in Lean Management, Operational Excellence, or comparable continuous improvement methodologies.

The salary for this position is expected to range between $138,600 and $257,400 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.

To learn more about the culture, rewards and benefits we offer our people click here.

#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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Место
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Состояние
North Carolina
Сайт
Durham
Company / Legal Entity
U473 (FCRS = US473) Novartis Gene Therapies
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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