NOVARTIS

Head, QA Ops and Compliance (Associate Director Level)

Job ID
REQ-10071483
May 12, 2026
LOC_US

About the Role

#LI-Onsite

Location: Durham, NC

This role is on-site 5 days a week and does not have the ability to work remotely. This role is located in Durham, NC and will eventually move to Morrisville, NC at a later date

Role scope, level, and compensation are set at the Associate Director level; Director-level appointment is not within scope for this position.

Key Responsibilities:

- Provide end-to-end leadership for Quality Operations and Compliance across manufacturing, Quality Control, AS&T, and logistics, ensuring adherence to cGMP, regulatory requirements, and internal quality standards.
- Serve as the final QA authority for review, approval, and release of batch documentation and patient or commercial product lots manufactured at the site.
- Ensure strong on-the-floor QA presence, delivering real-time quality oversight, decision-making, and guidance to support compliant and efficient operations.
- Lead investigations of deviations, OOX/OOS events, complaints, and adverse events, ensuring timely root cause analysis, effective CAPA implementation, and sustainable corrective actions.
- Implement and maintain site Quality Systems, including SOP governance, training compliance, documentation control, and inspection readiness for internal, external, and regulatory audits.
- Drive QA Operational Excellence through performance metrics (KPIs/KQIs), continuous improvement initiatives, and proactive identification of quality and process risks.
- Provide QA leadership for technology transfers, process validation, and new equipment commissioning, including review and approval of validation strategies and OQ/PQ execution.
- Lead, develop, and retain a high-performing QA team through hiring, coaching, performance management, and resource planning, while supporting budget and capacity planning in alignment with site strategy.

Essential Requirements:

- BS or MS in Life Sciences, Pharmacy, Chemistry, Biotechnology, or related scientific discipline; advanced degree preferred.
- Minimum 10+ years of experience in pharmaceutical, biotechnology, or cell and gene therapy industry within cGMP regulated environments.
- Demonstrated experience supporting Small Molecule Operations (SMO), including small molecule drug product and/or drug substance environments.
- Demonstrated hands-on leadership in Quality Operations and Quality Systems & Compliance, with direct responsibility for product release, quality systems, and audit readiness within Small Molecule Operations (SMO).
- Minimum 6-10 years of direct people leadership, including team development, performance management, and cross-functional collaboration.
- Strong working knowledge of FDA, EMA, and global regulatory requirements, including experience supporting regulatory inspections and audits.

- Proven experience leading deviation investigations, CAPA management, and continuous improvement initiatives in an operational QA setting.
- Experience supporting manufacturing operations, Quality Control, validation, and technology transfer activities.
- Excellent communication, decision-making, and organizational skills, with the ability to operate effectively in a fast-paced CGT manufacturing environment.
- Fluency in English (written and verbal).

Novartis Compensation and Benefit Summary:

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

Role Requirements

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)

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Location
LOC_US
Site
Durham
Company / Legal Entity
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List of links present in page

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