NOVARTIS

Head, QA Ops and Compliance (Associate Director Level)

Job ID
REQ-10071483
май 12, 2026
США

Сводка

The Head, QA Ops and Compliance (Associate Director Level) provides strategic and hands on leadership for Quality Assurance within the Small Molecule Operations division, ensuring excellence in cGMP compliance, regulatory execution, and quality oversight across all operational activities. This role leads and develops Quality Assurance Managers, partners closely with manufacturing and external suppliers, and ensures that all products, manufactured on site, by external partners, or imported, are released to market in full alignment with Novartis Quality Standards, policies, and global regulatory requirements. The Head, QA Ops and Compliance plays a pivotal role in safeguarding product quality, enabling operational excellence, and supporting the reliable and compliant supply of high quality small molecule therapies to patients.

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 remotelyThis 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.

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
Production / Manufacturing
Место
США
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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