NOVARTIS

Head of QA Operations (Assoc Dir level)

Job ID
REQ-10083625
Jul 20, 2026
LOC_US

About the Role

Key Responsibilities

- Lead the QA Operations organization, providing quality oversight for Drug Product (DP) Manufacturing and Quality Control operations, including Shop Floor QA, QA Engineering, and final product disposition.
- Ensure compliant and timely product disposition decisions while maintaining patient safety and regulatory compliance.
- Drive quality oversight across manufacturing operations, promotinginspection readiness and operational excellence.
- Lead resource allocation, capacity planning, and operational prioritization to support quality, compliance, and business objectives.
- Lead investigations, deviations, corrective actions, and change controls to resolve quality issues effectively.
- Ensure preparation, review, and delivery of validation plans supporting compliant manufacturing and quality operations.
- Support escalation management, FDA interactions, and commercial product field actions while maintaining inspection readiness.
- Build, coach, and develop high-performing leaders and teams while strengthening site quality culture.
- Partner cross-functionally to achieve production goals, address risks, and support business priorities.
- Monitor quality performance metrics and drive continuous improvement initiatives to strengthen compliance and execution.

Essential Requirements

- Bachelor of Science in Chemistry, Biology, Pharmacy, Biochemistry, Engineering, or related experience.
- 10+ years of experience in Quality Assurance, Quality Control, Quality Systems, Compliance, or operational GxP area (Manufacturing / Development) within the pharmaceutical, diagnostic, or medical device industries.
- Prior experience leading a Quality Assurance organization, including developing high-performing teams and talent.
- Prior experience supporting aseptic pharmaceutical manufacturing operations.
- In-depth knowledge of current GMPs, Quality Assurance, Quality Control, and applicable regulatory requirements and standards.
- Direct experience conducting investigations and root cause analysis for pharmaceutical or medical device products.
- Experience reviewing manufacturing and Quality Control validation documents and supporting validation activities in a regulated environment.
- Proven experience leading Health Authority inspections and audits within a regulated manufacturing environment.

Desirable Requirements

- Experience in advanced therapy platforms, including Radioligand Therapy, Cell and Gene Therapy, or other novel therapeutic technologies.
- Experience with continuous improvement methodologies such as Lean, Six Sigma, or 5S and leading projects.

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

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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DIV_TO
Business Unit
Quality
Location
LOC_US
Site
Indianapolis
Company / Legal Entity
U469 (FCRS = US469) AAA USA Inc.
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Regular
Shift Work
No
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