Sr. Specialist, QA Compliance

Job ID
REQ-10052687

6月 03, 2025

USA

摘要

The Senior Specialist, Quality Assurance Compliance supports the implementation of robust Quality Systems for the Durham Site of Novartis Gene Therapies, considering global regulatory and local requirements of the organization. This role contributes significantly to the execution of these systems, authors or contributes to the procedures governing these systems and works towards timely implementation, including support of Quality Management Review, ownership/execution of Self‐Inspection program and in the management of health authority inspections.

Location: Durham, NC #LI-Onsite, Hybrid

About the Role

Key Responsibilities:

- Contributes significantly to the Readiness Program; site inspection preparation, program

management, response and commitment process for health authority inspections.
- Leads site self-inspection program including preparation of risk based annual audit plan, lead auditor responsibilities, audit agendas, inspection reports and CAPA plan approvals.
- Provide strategic quality input on the design and architecture of Novartis Gene Therapies Quality Management System.
- Supports the development and oversight of robust quality systems, including both implementation and operation at site level.
- Supports management to implement and maintain the following programs: Annual Product Quality Review (APQR), Compliance Alert actions, and Novartis Global document assessments required to be performed at the site level.
- Supports supplier monitoring and oversite activities including audit responses, CAPAs, and evaluation of supplier risk levels.
- Supports the site level Quality Management Review (QMR) program including monitoring and reporting key performance indicators, as appropriate.
- Performs duties as assigned to ensure compliance with global and local regulations.
- Represent Quality Assurance Compliance team on project teams and in meetings as needed.
- Support the continuous improvement and oversight of QA Compliance programs through planning and implementation.
- Identifies and implements new technologies to improve compliance an efficiency of QS operations.
- Adheres to all GMP requirements.
- Ownership of Compliance Records relevant to quality systems responsibilities (Change Records, CAPAs, Quality Events, Deviations as needed).

Essential Requirements:

- Bachelor ' s degree in Life Sciences or Chemistry (preferred) or related relevant degree with 7 years of experience in GMP manufacturing operations, Bio-Pharma or Gene therapies preferred.
- Previous experience in QA Compliance including self - inspections, health authority inspections and supplier auditing, preferably with a minimum of 2 year ' s of experience as a lead inspector.
- Experience reviewing systems and analyze data (paper or electronic) to identify specific compliance and data consistency issues.
- Previous Quality Assurance experience required, including Data Integrity (ALCOA+) compliance.
- Ability to apply a phase appropriate, risk - based approach to QA operational decisions.
- Experience supporting cGMP manufacturing operations through administration and enforcement of the Quality Management System.
- Proficient in cGMP/ICH/FDA/EU regulations and guidelines and experience in US and international regulatory agency inspections a plus.
- Proficient in using Microsoft applications (MS Word, MS Excel, MS PowerPoint).
- Strong follow - up and organizational skills and ability to manage cross functional projects.
- Experience with viral gene therapies and/or orphan disease indications a plus.
- Direct experience reviewing and/or authoring standard operating procedures.
- Ability to work well independently and within a team.
- Excellent oral and written communication skills with technical writing experience required.

The salary for this position is expected to range between $73,500 and $136,500 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.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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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.

部门
Operations

Business Unit
Innovative Medicines

地点
USA

状态
North Carolina

站点
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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