NOVARTIS

QA Compliance Specialist

Job ID
REQ-10081196
Июн. 25, 2026
США
Available in: English

Сводка

Location: Indianapolis, United States

Play a pivotal role in ensuring the highest standards of quality and compliance in a cutting-edge radioligand therapy environment. As a QA Compliance Specialist, you will help shape and sustain robust quality systems that enable safe, reliable, and inspection-ready operations. Partnering across site functions, you'll drive compliance excellence, support regulatory readiness, and contribute to continuous improvement—making a direct impact on delivering innovative therapies to patients.

Relocation Support: This role is based in Indianapolis, United States. Novartis is unable to offer relocation support: please only apply if accessible.

About the Role

Key Responsibilities

- Support implementation and oversight of site quality systems aligned with regulatory and Novartis standards
- Lead Quality Management Review activities, including KPI monitoring, reporting, and continuous improvement actions
- Drive inspection readiness programs for internal audits and global health authority inspections
- Facilitate and deliver training on quality assurance compliance programs and requirements
- Support execution of compliance programs, including training, product quality reviews, and compliance alerts
- Provide guidance on audit planning, preparation, and interactions with regulatory authorities
- Partner cross-functionally to ensure adherence to good manufacturing practices, data integrity, and compliance standards

Essential Requirements

- Bachelor's degree in a scientific or health-related field and at least 5 years of experience in a GMP regulated environment including at least 3 years of experience in quality compliance in the biopharmaceutical industry with environmental monitoring and cleanliness zones.
- Experience in establishing and maintaining quality systems, as well as successfully managing inspections from major Health Authorities including USA, EMEA, Canada, Japan, Brazil
- Previous Quality Assurance experience must include Data Integrity, (ALCOA+) compliance, and technical writing.
- Strong knowledge of global regulatory standards, including United States, European Union, and International Council for Harmonization requirements
- Strong communication and organizational skills, with ability to manage complex compliance activities across teams

Desirable Requirements

- Experience supporting radioligand or radiopharmaceutical manufacturing operations and associated quality requirements

The salary for this position is expected to range between $89,600 and $166,400 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 clickhere.

#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.

Дивизион
Operations

Business Unit
Quality
Место
США
Состояние
Indiana
Сайт
Indianapolis
Company / Legal Entity
U469 (FCRS = US469) AAA USA Inc.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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