NOVARTIS

QA Engineering Manager

Job ID
REQ-10093635

十一月 23, 2026

USA

摘要

Location: Millburn, NJ

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

Please note that Novartis is unable to provide visa or immigration support for this position. Applicants must have authorization to work in the United States without requiring current or future sponsorship.

Schedule: This is an onsite, Monday-Friday role supporting 24/7 operations. Flexibility for off-hours support may be required based on business, validation, inspection, investigation, or operational needs.

Bring your Quality and validation expertise to a leadership role that helps ensure Radioligand Therapy operations deliver reliably for patients. As QA Engineering Manager, you will lead Quality oversight for qualification and validation activities across facility equipment, computerized systems, and laboratory systems at the Millburn site. You will guide and develop a small technical team while partnering across Production, Quality Control, Engineering, Supply Chain, and site leadership. Your

Quality judgment and technical expertise will help strengthen inspection readiness, right-first-time execution, and continuous improvement across site operations.

#LI-Onsite

About the Role

Key Responsibilities

· Serve as the site Quality Assurance validation lead, providing oversight and approval of qualification and validation strategies and plans.

· Provide Quality oversight for facilities, equipment, computerized systems, laboratory systems, and associated qualification and validation activities.

· Review and approve deviations, investigations, corrective and preventive actions, change controls, risk assessments, procedures, and validation documentation.

· Provide Quality Assurance oversight for aseptic production, Engineering, Supply Chain, and Quality Control activities through review and approval of CAPAs, Deviations, change controls, process validation documents and shop floor oversight). Provides the production, engineering MS&T, and supply chain teams with QA/Compliance guidance and decisions.

· Lead, coach, and develop Quality Assurance team members while strengthening accountability, collaboration, and a strong culture of Quality.

· Support Health Authority inspections, internal audits, regulatory filings, and inspection-readiness activities across the site.

· Drive compliant, right-first-time execution and continuous improvement while supporting timely qualification, validation, and operational activities.

Essential Requirements

· Bachelor ' s degree in Life Sciences, Engineering, Pharmacy, or a related scientific or technical field.

· 5-7 years of experience in Good Manufacturing Practice pharmaceutical manufacturing, including at least 3 years of combined relevant experience in aseptic GMP manufacturing operations and/or Quality Assurance.

· Proven track record and practical experience in supporting a GMP Manufacturing Operations unit and operating in full compliance with global cGMP requirements. Successfully managed inspections by major Health Authorities (e.g. US FDA, EMA).

· In-depth knowledge of cGMP, FDA regulations (21 CFR Parts 211, 212), and ICH regulations. In depth knowledge of QC regulations.

· Proven ability to manage multiple projects, collaborate across functions, and influence stakeholders in a regulated manufacturing environment.

Desirable Requirements

· Master ' s degree in Life Sciences, Engineering, Pharmacy, or a related scientific or technical field.

· Experience with Radioligand Therapy operations.

The salary for this position is expected to range between $98,700 and $183,300 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.

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.

部门
Operations

Business Unit
Quality

地点
USA

状态
New Jersey

站点
Millburn

Company / Legal Entity
U473 (FCRS = US473) Novartis Innovative Technologies Inc

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work

No

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