

QA Operations Specialist

Job ID
REQ-10029370
Nov 14, 2024
USA

Summary

#LI-Onsite

This role is located on-site in Indianapolis, IN. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

At Advanced Accelerator Applications, a Novartis company, we are committed to leading innovation in nuclear medicine and delivering the next generation of targeted radioligand therapy to cancer patients. We are looking for experienced Quality Control professionals to help us reach our ambitious goals.

Our QA Operations Specialist manages Quality aspects and projects within area of responsibility as well as ensuring and supporting overall GxP conformity and Compliance with the Novartis Quality Management Systems.

About the Role

Major accountabilities:

- Provide shopfloor quality oversight of all production, quality control and supply chain departments to ensure their practice fully adheres to cGMP, including data integrity. Ensure timely escalation to management of all applicable incidents.
- Perform live review of manufacturing batch records in preparation for batch release and escalate any discrepancies immediately.
- Assist functional areas with achieving timely and compliant final product disposition of the product.
- Review, approve and support procedures and production/testing records as required and assist in the training of site associates.
- Ensure compliance of site personnel and application of aseptic techniques and full compliance to sterile manufacturing regulations.
- Support FDA/Regulatory interactions for the Indianapolis site activities and products to ensure successful regulatory submissions and inspections.
- Support QA Operations as a valued business partner, with a culture of safety, quality, delivery to patients, cost, compliance and data integrity.
- Other related duties as assigned.

Shift: This role will be Wednesday - Sunday, 6:00am - 4PM. This position may involve mandatory overtime as needed.

Essential Requirements:

- Bachelor's Degree, preferably in Life Sciences, chemistry or related relevant degree.
- 2+ years of experience in a GxP Biopharmaceutical manufacturing operations
- 1+ years of experience in a quality assurance role
- Collaborating across boundaries
- Functional Breadth
- QA and QC experience in biotech pharmaceutical industry with environmental monitoring & cleanliness zones

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>

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EEO Statement:

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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.

Division

Operations

Business Unit

Innovative Medicines

Location

USA

Site

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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