QA Compliance Specialist

Job ID
REQ-10029772

4月 10, 2025

USA

摘要

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 an experienced Compliance Specialist with previous experience in a GMP Biopharmaceutical environment to help us reach our ambitious goals.

As a Compliance Specialist, you will be responsible for implementing robust Quality Systems at our new Radioligand Therapy (RLT) Isotope Manufacturing site in Indianapolis incorporating Novartis and regulatory requirements. You will contribute significantly to the execution of these systems, author or contribute to the procedures governing these systems and work towards timely implementation. You will participate in Quality Management Reviews, Self-Inspections, trainings and in health authority inspections.

About the Role

Key responsibilities:

- Support the development and oversight of robust quality systems at site level, including both implementation and operation.
- Lead the site level Quality Management Review (QMR) program including monitoring and reporting key performance indicators.
- Work with the management team to implement and execute the Inspection Readiness program, including Novartis Corporate Inspections and Global Health Authority Inspections.
- Facilitate training on all QA Compliance programs.
- Support management in implementing and maintaining the following programs: Training and Qualification, Quality Management Review (KPIs), Annual Product Quality Review (APQR), Compliance Alerts, Market Actions and Novartis Global document assessments required at the site level.
- Escalate high quality risks per procedure and support agency notifications such as Field Alerts.
- Support the continuous improvement and oversight of QA Compliance programs. Identify and implement new technologies to improve the compliance and efficiency of QS operations.
- Represent QA Compliance on project teams and in meetings.

Essential Requirements:

- B.S. degree, preferably in Life Sciences, chemistry or related relevant degree.
- 6 years of experience in a GMP Biopharmaceutical environment, including at least 2 years of experience in a Quality Assurance role. QA experience must include Data Integrity (ALCOA+) compliance.
- Experience supporting cGMP manufacturing operations through administration and enforcement of the Quality Management System.
- Working knowledge of cGMP/ICH/FDA/EU regulations and guidelines and experience in US and international regulatory agency inspections a plus.
- Excellent oral and written communication skills and technical writing experience.
- Proficient in using Microsoft applications (MS Word, MS Excel, MS PowerPoint).
- Experience reviewing systems and analyzing data to identify specific compliance and data consistency issues. Experience reviewing and/or authoring standard operating procedures.
- Ability to apply a phase appropriate, risk-based approach to QA operational decisions.

Desirable Requirements:

- Experience with radiopharmaceutical therapies
- Previous experience in QA Compliance including self-inspections

#LI-Onsite

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The pay range for this position at commencement of employment is expected to be between $92,800 and $139,200 per year; however, while salary ranges are effective from 1/1/24 through 12/31/24 fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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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+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.

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Functional Area
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Job Type
Full time

Employment Type
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Shift Work
No

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QA Compliance Specialist

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