NOVARTIS

Senior Document Control Specialist

Job ID
REQ-10029763
Nov 15, 2024
Estados Unidos

Resumen

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 Document Control Specialist with previous experience in a GMP pharmaceutical manufacturing environment to help us reach our ambitious goals.

As the Senior Document Control Specialist, you will be responsible for the control, management and retention of GxP electronic and paper records at our new Radioligand Therapy (RLT) Isotope Manufacturing site in Indianapolis ensuring compliance to quality objectives and regulatory requirements.

About the Role

Key responsibilities:

- Provide GxP document control support for operations, engineering, supply chain, quality and other departments as required. Manage the preparation, routing, review, approval, distribution, and archival of new and revised controlled/managed documents.
- Ensure site documentation fully adheres to cGMP, including data integrity. Support internal and external audits. Ensure timely escalation to management of all applicable incidents. Review documents submitted to ensure the correct use of templates, correctly entered metadata and document types.
- Perform super user duties for all document quality management systems. Provides training to new staff on document management system and document management processes and procedures.
- Work closely with SMEs to execute workflows and business processes that align with best practices. Provide guidance and advice on approved procedures, standardization and requirements associated with the document management system.
- Collaborate with cross-functional departments to ensure timely implementation of document change requests.
- Support metric tracking of documentation to ensure continuous improvement.

Essential Requirements:

- High school diploma, Bachelor's Degree, preferred.
- 4 years of experience in pharmaceutical-based GMP manufacturing operations, including at least 2 years of experience with Electronic Document Management Systems, specifically related to GMP document control.
- Excellent knowledge of applicable GxP regulations.
- Proficient with the Microsoft Office suite (ie, Word, Excel, Visio, PowerPoint, etc.) and Adobe.
- Ability to work independently and perform detail-oriented work with a high degree of accuracy.

- Effective written and oral communication skills, time management and interpersonal skills.

#LI-Onsite

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: novartis-life-handbook.pdf.

Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. 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. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

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.

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