NOVARTIS

Manufacturing Specialist

Job ID
REQ-10030823
Nov 25, 2024
USA

Sommario

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 pharmaceutical professional with prior GMP and investigations experience to help us reach our ambitious goals.

As the Manufacturing Specialist, you will provide front line support to manufacturing, working with the production teams to ensure each batch is manufactured safely and in compliance with batch instructions and quality requirements. You will act as our Subject Matter Expert (SME) for product and process knowledge and will be the first point of contact for product and process related issues. You will drive investigations to true root cause and implement corrective and preventive actions.

About the Role

Key responsibilities:

- Manage and maintain manufacturing documentation including Master Batch Records, applicable SOPs, risk assessments, protocols, shipping documents, training materials, and other documentation.
- Technical writing/Reviewing to support manufacturing operations including but not limited to, Standard Operating Procedures (SOP), batch records and white papers.
- Collect data for ongoing process verification (OPV), support tracking and evaluation of product performance and implementation of CAPAs.
- Author and own investigations related to material transfer, isotope manufacturing, and packaging.
- Ensure processes remain inspection ready at all times. Support process optimization and new technology introduction for continued productivity improvement, as appropriate.
- Review validation protocols and reports. Support the execution of process validation and short-term improvement projects. Participate in assigned qualification/validation activities, as necessary.
- Provide guidance and support to production team through training and knowledge sharing.
- Demonstrate leadership capabilities and guide processes to closure/completion.
- Facilitate a “speak up” culture and ensure all cGMP compliance activities are followed.
- Participate in periodic mandatory overtime to ensure process continuity and completion.

Essential Requirements:

- Bachelor's degree in Engineering, Pharmacy, Pharmaceutical Technology, Chemistry or relevant experience in lieu of degree, and 3 years’ experience in a process support shop floor role in GMP manufacturing and/or QA/QC.
- Strong awareness of quality issues. Compliance investigations experience required.

- Good understanding of manufacturing and validation requirements and activities.
- Ability to utilize new technology and techniques to eliminate non-value adding activities and improve productivity / performance through new processes.
- Proficient in MS Office applications.

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Desirable Requirements:

- Training in radiochemistry or radio pharmacy is preferred.
- Knowledge of cGMP regulations and FDA guidance applicable to radioligand therapy or isotope manufacturing.

#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 $40.38 and $60.57 per hour; 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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List of links present in page

1. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://talentnetwork.novartis.com/network
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