

Process Expert

Job ID
REQ-10036714
Feb 04, 2025
USA

Summary

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 Manufacturing professionals to help us reach our ambitious goals.

As a Process Expert you will provide front line support to manufacturing, working with the production teams to ensure each batch is manufactured safely and in compliance with the 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. Drives investigations to true root cause, and implementation of corrective and preventive actions.

Location: Onsite

Please note the shift for this role is Friday - Monday (12 pm - 10 pm)

About the Role

Major accountabilities:

- Manage and maintain manufacturing documentation including Master Batch Record, applicable SOPs, risk assessments, protocols, and other documentation as needed.
- 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.
- Authoring/Owning investigations related to material transfer, API synthesis, Drug Substance formulation, Drug product filling, inspection, and packaging.
- Ensure processes are 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 validations, and short-term improvement projects.
- Provide guidance and support to production team through training and knowledge sharing.
- Will demonstrate leadership capabilities and guide processes to closure/completion, while following all required guidelines and procedures.
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The pay range for this position at commencement of employment is expected to be between \$77,000 to \$143,000/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, 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.

Minimum Requirements:

- Bachelor's degree in Engineering, Pharmacy, Pharmaceutical Technology, Chemistry or relevant experience in lieu of degree.
- 3+ years' relevant experience in a process support shop floor role in GMP manufacturing and/or QA/QC.
- Proven process understanding (Pharma, GMP, Regulatory aspects).
- Strong awareness of quality issues. Compliance investigations experience required.
- Excellent technical writing skills.
- Previous Radio pharma experience a plus.
- Prior leadership and/or high cross-functional experience preferred.

Why Advanced Accelerator Applications?

Thousands of people die of cancer around the world every day. At Advanced Accelerator Applications, a Novartis company, our mission is to transform lives through radioligand therapy in nuclear medicine to fight several leading types of cancer. How will we continue to be on the cutting edge of medicine? We believe new groundbreaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working. We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world's toughest medical challenges. Because the greatest risk in life, is the risk of never trying! Imagine what you could do here at Novartis!

Commitment to Diversity & Inclusion:

Novartis embraces diversity, equal opportunity, and inclusion. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to learn more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>.

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. 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.

Division

Operations

Business Unit

Innovative Medicines

Location

USA

State

Indiana

Site

Indianapolis

Company / Legal Entity

U469 (FCRS = US469) AAA USA Inc.

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

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