

Process Engineer

Job ID

REQ-10047769

Apr 14, 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.

The Process Engineer is responsible for identifying, designing and implementing continuous improvement initiatives using advanced engineering principles in a GMP environment to ensure the delivery of high-quality radioligand therapy (RLT) products. Responsible for reliable, efficient and sustained operation of the facility and all production equipment. Additionally supports current project operations and site goal objectives and ensures compliance with regulatory, corporate, and site requirements related to Engineering.

About the Role

Major accountabilities:

- Provide technical troubleshooting throughout equipment lifecycle (startup, qualification, commercial production)
- Perform investigations / deviations from an engineering perspective to allow for timely closure of deviations and CAPAs
- Lead or contribute to process equipment and utility improvement projects
- Interpret P&IDs, equipment/system layouts, wiring diagrams, and specifications and update as needed
- Write/revise engineering documents for operation of various production systems
- Ensure compliance with industrial standards and GMP guidelines
- Develop project cost estimation and value improvement review
- Perform GMP risk assessments
- Manage technical / engineering changes through site change control process
- Participate in preparation of calibration/maintenance risk assessments for new equipment
- Create/execute Design Qualification (DQ), Installation and Operational Qualification (IOQ), and Performance Qualification (PQ) protocols
- Support internal and external audits

The pay range for this position at commencement of employment is expected to be between \$85,400 to \$158,600/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:

- B.S. degree in Chemical, Electrical, Mechanical or Nuclear Engineering, or related technical field, with a 3+ years experience providing automation, engineering, or equivalent support within the pharmaceutical, biotechnology, or related industry
- Proven skills in project management and problem solving
- Exceptional time management, planning, organizational, negotiating and influencing skills
- Highly self-motivated with a willingness to assume responsibilities and take ownership for work
- Must be able to adhere to all applicable procedures, cGMPs, company policies and any other quality or regulatory requirements. (For example: OSHA, FDA, EMEA, HS&E, etc.)
- Proficient computer skill utilizing MS Office suite applications, Building Management Systems, and Computerized Maintenance Management Systems (CMMS) and similar GMP systems
- Ability to climb ladders and lift up to up to 50 lbs.
- Aseptic Filling line, packaging operation experience is preferred
- Training/experience in radiochemistry or radio safety is desirable

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>

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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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