

Process Engineer

Job ID

REQ-10044482

Mar 17, 2025

USA

Summary

The Process Engineer will execute engineering activities (design, implementation, maintenance, etc.) within technical area of expertise by using reliable and cost-effective technical solutions, ensuring technical quality to enable the overall site / project objectives. Responsible for execution of maintenance and calibration activities and commissioning activities for projects at site level. Supervise plant engineering team providing technical assistance to the function and ensuring that the best possible maintenance, repair and/or modifications are undergone. Execute for design, execution and hand-over projects within cost, time schedule, quality and functionality within technical area of responsibility.

Location: Onsite

About the Role

Major accountabilities:

- Guide and supervise onsite installation of equipment
- Install subsystems owned by Novartis in production line
- Implement equipment optimizations and modifications
- Participate on the assessment or implementation of special projects or initiatives with cross-functional teams.
- Lead complex root cause investigations
- Performs change assessments
- Preparing, scheduling, coordinating, and monitoring of assigned engineering projects.
- Reviews equipment and engineering systems to support root cause analysis investigations and trend investigations.
- Second line escalation in case of equipment failures
- Driving continuous improvement from an asset perspective
- Reducing safety risks through simplification and error proofing machines
- Improving equipment reliability through equipment design modifications
- Maintain Master Instrument Inventory (MII) and Master Equipment Inventory (MEI).
- Set-up maintenance for new equipment (incl. spare part needs).
- Assist with preparation of plans for maintenance / calibration / qualifications.
- Manage technical / engineering changes: originate Change Request, approve Change Request, close Change Request.
- Assist with preparation of estimates for bids and proposals.
- Create/Execute DQ, IQ and OQ protocols and reports.
- Perform GMP risk assessments (incl. Sensors SRA).

- Independently manage and resolve deviations on equipment and systems.
- Support internal and external audits.
- Provide technical trouble shooting during Startup, PQ and validation activities
- Develop periodic requalification plan
- Execute periodic requalification plan
- Utilize automation (Scada / PLC's / Control Networks hardware) for data gathering and equipment optimization opportunities
- Assist in troubleshooting of process / plant equipment including isolator, filling line and utilities.
- Interpret P&IDs, equipment/system layouts, wiring diagrams, and specifications and update as needed.
- Write/revise accurate engineering documents for various production system.
- Supply information and technical data for securing spare parts.
- Provide responsive customer support with emphasis on customer satisfaction.
- Perform startup and commissioning activities as required.
- Support and/or perform investigations / deviations from an engineering/maintenance perspective and help with data for timely closure of deviations and CAPAs
- Complete and provide accurate documentation, as required in cGMP operations.
- Use of CMMS system for documentation of relevant work.
- Other related duties as assigned.

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:

- Bachelor's Degree in Engineering or related field is required
- 3+ years of relevant experience in a GMP environment is required
- Previous experience in the Pharmaceutical or Medical Device industry is preferred.
- Pharmaceutical aseptic filling experience is preferred
- Vendor management experience is a plus
- Knowledge/experience in automation or computer system validation (CSV) is a plus
- Experience managing projects is 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!

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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