

Process Engineer, Multidiscipline

Job ID
REQ-10016529
Jul 22, 2024
USA

Summary

The Process Engineer, Multidiscipline is responsible for support in execution of engineering processes/activities within an aseptic environment (design, implementation, maintenance, etc.) by providing a technical area of expertise while using reliable and cost-effective technical solutions, ensuring technical quality to enable the overall site / project objectives in accordance with the law, internal regulations. Responsible for reliable, efficient and sustained operation of the facility and all equipment. Additionally supports current project operations and site goal objectives and ensures compliance with regulatory, corporate, and site requirements related to their functional area.

About the Role

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 Supply Chain professionals to help us reach our ambitious goals.

Location: Onsite

Your responsibilities include, but are not limited to:

- 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.
- Provides hands-on support and oversight of installation, maintenance, troubleshooting, and repair of assets and systems which support the manufacturing facility.
- Creates, reviews, and approves critical documentation such as operational procedures, maintenance plans, engineering drawings, and equipment specifications.
- Manage technical / engineering changes: originate Change Request, approve Change Request, close Change Request.
- Assist with preparation of estimates for bids and proposals.
- Perform GMP risk assessments (incl. Sensors SRA).
- Independently leads and/or provide SME-level support on all phases of projects, from identification to close out.
- Ensures new equipment is appropriately designed/commissioned/qualified and existing processes run in a compliant manner throughout the equipment lifecycle.
- Support internal and external audits.
- 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.
- Supply information and technical data for securing spare parts.
- Provide responsive customer support with emphasis on customer satisfaction.
- Perform startup and commissioning & qualification 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
- Leads small teams to advance facility and equipment changes in line with 5- and 10-year strategic plans.
- Complete and provide accurate documentation, as required in cGMP operations.
- Actively monitors equipment performance in compliance with site reliability and maintenance strategies.
- Collaborates with operations and manufacturing sciences to evaluate new product introductions and facility fit evaluations.
- 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 \$92,800 and \$139,200 per year; however, base pay offered may vary depending on multiple individualized factors, including market location, job-related knowledge, skills, and experience. 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 or Mechanical Engineering, or related technical field, with 3+ years’ experience providing maintenance, automation, engineering, or equivalent support within the pharmaceutical, biotechnology, or related industry OR Associates Degree/Diploma/Certification in Engineering Technology or Related Skilled Technical Field, with 5+ years’ work experience providing maintenance, automation, engineering, or equivalent support within the pharmaceutical, biotechnology, or related industry.
- Having wide-ranging experience, uses professional concepts and company objectives to resolve complex issues in creative and effective ways.
- Excels in a team environment, with excellent communication and organizational skills. Promotes information sharing, facilitates groups to ensure open discussion.
- Exercises independent judgment in methods, techniques and evaluation criteria for obtaining results.
- Strong project management skill set with ability to manage projects from start-to-end.
- Applied knowledge of root cause analysis, equipment troubleshooting, automated building management systems, and industrial PLCs.
- Must be able to adhere to all applicable procedures, cGMPs, company policies and any other quality or regulatory requirements. (For example: OSHA, DEA, FDA, EMEA, ANVISA, HS&E, etc.).
- Proficient computer skills. Experience using a Computerized Maintenance Management System (CMMS)

like Blue Mountain Ram or SAP.

- Ability to climb ladders and lift up to 50 lbs.
- Aseptic Filling line, packaging operation experience is preferred.
- Training in radiochemistry or radio pharmacy 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!

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>

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Division

Operations

Business Unit

Innovative Medicines

Location

USA

Site

Remote Position (USA)

Company / Legal Entity

U469 (FCRS = US469) AAA USA Inc.

Alternative Location 1

Carlsbad, USA

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

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