Site Equipment & CQV Lead

Job ID
REQ-10000472
Sep 03, 2024
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 (RLT) to cancer patients.

Responsible for leading the equipment and CQV engineering team at a GMP Radioligand Therapies Isotope Production Facility. Act as Equipment & CQV Workstream Lead on a major site capital project with responsibility for commissioning, qualification and start-up of the GMP production equipment through to operational readiness. Support operational readiness and continuing manufacturing processes.

Location: Onsite

About the Role

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- Team lead of GMP equipment asset owners, managing complete GMP lifecycle from URS through to CQV and placing into operational use.
- Manage team of CQV/CSV and Equipment Engineers to maintain equipment reliability and ensuring compliance with all applicable quality and HSE regulations and requirements, both internal & external, for GMP Equipment.
- Promotes a strong quality & compliance mindset supporting timely closure of Equipment Engineering & CQV related cGMP deficiencies including audit observations, CAPA's and deviations. Drives pro-active site inspection readiness programs.
- Manage capital projects involving equipment upgrades. Manage planning, execution and documentation (URS, FRS, Specifications)
- Provide timely reporting to management on progress, priorities, timelines and sharing of necessary information.
- Contracts and manages outside vendors and contractors to fulfill business needs.
- Authors and/or manages authoring of CQV plans, qualification protocols, qualification summary reports and requirement trace matrices.

- Drive continuous improvement to meet world class standards using operational excellence principles while developing best practices.
- Oversee recruitment, training and manage qualified professionals. Coaches, develops, and grows talent of team.
- Manages complete CQV & CSV program; from site VMP, compliance with all qualification standards and through to periodic review and ensure validated state is maintained. Develops risk-based qualification approach and strategy (FMEA, Risk Assessments, PHA, etc)
- Subject matter expert (SME) at site to support internal and/or external inspections.
- Capable of managing capital project capex and qualification team budgets and supports site cost improvement initiatives.
- Supports development of CQV & CSV policies and procedures to maintain compliance with site, corporate and regulatory standards.
- Support 24x7 site-based operations after startup.
- Other related duties as assigned.

Minimum Requirements:

- Bachelor’s degree in engineering, computer science, automation, or related field is required.
- 5+ years of releengineering experience in Chemical or Pharmaceutical industry is required.
- Experience hiring, managing, and developing technical resources in an operating GMP environment is required.
- In-depth knowledge of FDA regulations and particularly 21 CFR part 11, GAMP5 and GMP systems.
- Excellent oral and written communication skills.
- 5-10% travel

The pay range for this position at commencement of employment is expected to be between $124,000 and $186,000 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.

Why Novartis?

766 million lives were touched by Novartis medicines in 2021, and while we’re proud of this, we know there is so much more we could do to help improve and extend people’s lives.

We believe new insights, perspectives and ground-breaking 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 is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

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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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