NOVARTIS

Commissioning & Qualification (C&Q) Engineering Lead (RLT, Carlsbad)

Job ID
REQ-10004943
Apr 30, 2024
USA

Summary

The C&Q Engineering Lead (RLT, Carlsbad) has responsibility for executing and managing equipment, facility, utility, process, primary packaging validation activities and change management activities to meet cGMP requirements on time and quality to ensure that site validation programs are compliant with global regulatory expectations. 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:

- Lead site C&Q planning by writing and maintaining master plans for projects and the site including equipment, facility, utilities, processes, packaging processes and ongoing verification for processes and cleaning (as applicable).
- Maintain the site process control strategy.
- Draft CQV and CSV activities for production and manufacturing equipment.
- Supporting on going qualification activities of VHP qualification, smoke studies, temperature mapping, room qualification, requalification.
- Design, execute and document experiments (formulation / analytical tests etc.) for products assigned in the context of process transfer, process improvement and process validation.
- Prepare and review appropriate GxP documentation including change requests.
- Identify improvement options of current processes, propose business cases.

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

- Bachelors degree is required; Masters Degree is preferred. Prefer concentration in Chemical or Mechanical Engineering.
- 5+ years’ experience of relevant experience in a GMP pharma environment is required.
- Experience in executing CQV, having led and managed validation projects is required.
- Direct experience in an aseptic manufacturing setting is highly preferred.
- Expert in reviewing and writing technical reports.

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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