Senior Quality Assurance Engineer Lead

Job ID
REQ-10017895
Aug 02, 2024
USA

Summary

Location: Carlsbad, California (on-site)

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. We are looking for an experienced pharmaceutical industry professional with Manufacturing and Quality experience to join the team at our new Carlsbad site.

As the Senior Quality Assurance Engineer Lead, you will be responsible for the design, construction, validation, maintenance and overall compliance of facilities, systems and processes at the Carlsbad RLT manufacturing site.

About the Role

Key Responsibilities:

- Ensure Quality and Compliance aspects of design and work in collaboration with Engineering, technical functions, Manufacturing Operations and outside consultants and contractors to ensure that the facility is:
  - Compliant with all Novartis QMS and appropriate regulations (e.g. FDA, EMEA and other major health authorities) for GMP manufacturing.
  - Capable of manufacturing products that are safe, effective and that meet all applied controls and specifications.
  - Capable to meet intended design goals of output volume, turnaround time and operating and product costs.
- Provide strategic quality input on the translation of commercial product requirements into technical solutions that are capable of meeting defined CQAs (product Critical Quality Attributes) and CPPs (Critical Process Parameters).
- Provides oversight of the Computerized System Validation Lifecycle efforts to ensure compliance with 21 CFR Part 11, EudraLex Annex 11, and applicable FDA/EMA Guidance's on electronic data integrity Contributes to design of facility, utilities and process equipment from a Quality and Compliance perspective.
- Participate in development and implementation of validation strategies, policies, and other documentation for CSV systems and IT applications. Provide Quality oversight, review, and approve Validation Documentation including but not limited to: Validation Master Plan, User Requirements, Functional Requirements, Installation Qualification, Operational Qualification, Performance Qualification, Trace Matrix, Validation Summary Reports, and Change Controls.
- Support cross-functional team risk assessments to evaluate and mitigate risks associated with equipment

and facilities as appropriate using tools such as Failure Modes Effects and Analysis (FMEA), Fault Tree Analysis (FTA) or other available risk management tools.
- Review and approve periodic review documentation for qualified equipment/systems (audit trails, user groups, system administration). Review and approve change controls, SOPs, Deviations, and CAPAs associated with qualification/validation execution to ensure effectiveness of actions.
- Ensure that vendor assessments, audits and quality agreements (if required) of suppliers of GxP computer software are in place
- Lead and support internal self-inspections.
- Ensure all quality personnel, including contractors, consultants and temporary employees have the proper qualifications, skill sets, education, and training to perform their job in accordance with applicable procedures and regulations

Essential Requirements

- B.S. degree and 6+ years of experience in a GxP pharmaceutical manufacturing operations, including at least 2+ years of experience in a quality assurance role
- Strong knowledge and application of the CFR's and cGMP's and have been involved in regulatory inspections.
- Comprehensive knowledge of FDA and EU regulations and experience in US and international regulatory agency inspections. Experience leading internal audits, identify findings, drive resolution and provide closure report is desired.
- Direct experience with commissioning, qualification and validation to meet FDA and other health authority requirements.
- Experience with deviations, CAPAs, and Change Controls.
- Direct experience reviewing and/or authoring standard operating procedures and partnering with operations on product related investigations and deviations.
- Experience leading people. Excellent oral and written communication skills with strong technical writing experience required.
- Demonstrated ability to perform long-term project planning, team building, budgeting and operational excellence.

Desirable Requirements

- B.S. in Engineering, Chemistry or Biochemistry
- Sterile manufacturing experience preferred

The pay range for this position at commencement of employment is expected to be between $112,800 and $169,200 per year; however, while salary ranges are effective from 1/1/24 through 12/31/24 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.

Benefits and rewards: Read our handbook to learn about all the ways we'll help you thrive personally and

professionally: Thrive Together (novartis.com).

Commitment to Diversity and Inclusion:
Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

#LI-Onsite

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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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
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Major Accountabilities ~ Steigern Sie Ihr wettbewerbsfähiges Umsatzwachstum ~ Identifizierung und Priorisierung von Kunden mit hohem Potenzial durch Datenanalyse (HCPs und Stakeholder), die Verschreibungsentscheidungen beeinflussen ~ Steigern Sie die Vertriebsleistung durch die geschickte Orchestrierung positiver Kundenerlebnisse ~ Engagieren und Beziehungen aufbauen ~ Führen Sie wertorientierte Gespräche (persönlich und virtuell), um kritische Kundenherausforderungen, Entscheidungstreiber, Schwachstellen und Chancen zu verstehen ~ Personalisieren und orchestrieren Sie Customer Engagement Journeys für HCPs,

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