# Site Quality Head, Carlsbad (Associate Director)

Job ID
REQ-10049013

4月 24, 2025

USA

## 摘要

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 experience building teams in start-up environments to lead the Quality function at our new Carlsbad site.

As the Site Quality Head, you will provide quality assurance oversight and be accountable for supporting site start up and Quality operations at the Carlsbad site. You will provide technical and strategic leadership for the Manufacturing site for all quality-related matters and be part of the Site Senior Leadership Team.

## About the Role

**Key Responsibilities:**

- Support plant start up, expansions and product transfers. Create and maintain updated project plans to track progress, and support in informing senior management. Ensure proper preparation and consolidation of the budget for the Quality Unit.
- Provide leadership for strategic site initiatives and represent site SLT quality in local cross-functional and global projects teams as team member or team leader that represent site quality. Establish Quality as a valued business partner.
- Provide leadership, direction and support to the people within the Quality Assurance department and ensure that they are qualified, achieve a high level of competence, are motivated and carry out their duties in a safe manner.
- Work with internal and external personnel to create user requirements and specifications to be used for projects in compliance with company standards for equipment, process and facilities.
- Ensure all facilities, utilities and equipment are designed and installed to be operated in a safe and effective manner and are compliant with applicable standards
- Ensure that during project phase planning, construction, commissioning, qualification (IQ, OQ and PQ) including any other validation activity complies with cGMP
- Timely escalation of risks in meeting timelines and / or budget incorporating site master planning and the long-term strategic plan.
- Ensure adequate management of product critical quality issues (deviations, out of specifications). Ensure investigations are correctly executed and adequate CAPAs are defined, and proper follow up of CAPAs effectiveness. Review, provide guidance for, escalate where appropriate, and approve Health Authority notifications.
- Define, implement, monitor, consolidate and analyze Site Quality KPIs. Ensure Site Quality Committee is established, ensure relevant corrective and preventive actions are endorsed and implemented.
- Drive for Site management team accountability. Coordinate the generation and monitor the execution of the Site Quality Plans, DI Plan, Site Quality Risk Assessments and other relevant gap assessments.

**Essential Requirements:**

- BS in Life Sciences and/or related experience in lieu of degree. 10 years of experience in GMP Pharmaceutical Manufacturing (including laboratory operations and Aseptic experience), at least 3 years combined of relevant experience in Quality Control and/or Quality Assurance.

- Proven track record and practical experience in supporting a Quality Control operations unit and operating in full compliance with global cGMP requirements. Successfully managed inspections from major Health Authorities (e.g. US FDA, EMA)

- In-depth knowledge of cGMP, FDA regulations (21 CFR Parts 211, 212), and ICH regulations. Understanding of United States Pharmacopoeia (USP), European Pharmacopoeia (EP), American Chemical Society (ACS).

- Proven ability to manage multiple projects with moderate resource requirements, risk and/or complexity. Highly developed management and communication skills, with experience in working in a matrix organization.

- Experience in process improvement approaches (Lean Six Sigma, Total Quality

Management, 5S, etc.) Understands economic business impacts of decisions. Defining and implementing productivity improvement measures.

#LI-Onsite

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The pay range for this position at commencement of employment is expected to be between $ 138,000 and $ 257,400 per 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.

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Operations

Business Unit
Innovative Medicines

地点
USA

状态
California

站点
Carlsbad

Company / Legal Entity
U469 (FCRS = US469) AAA USA Inc.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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