NOVARTIS

QA Operations Specialist

Job ID
REQ-10071235
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США

Сводка

About this role:

Help reimagine cancer care by shaping how our Radioligand Therapies (RLT) reach more patients—safely, reliably, and faster. At Novartis, we're pioneering the future of treatment through the fusion of nuclear medicine and precision oncology.

Our QA Operations Specialist manages Quality aspects and projects within area of responsibility as well as ensuring and supporting overall GxP conformity and Compliance with the Novartis Quality Management Systems for the Indianapolis manufacturing site.

Location: Carlsbad, CA #LI-Onsite

Shift: This position involves shift work which will be defined through site start up and commercialization readiness. 12-hour shifts and weekends will be required.

About the Role

Key Responsibilities:

- Provide QA support of production, QC, engineering, and supply chain operations through review/approval of test records for batch release, SOPs, CAPAs, Deviations, OOX investigations, Quality Risk Assessments, Quality Plans/Events, protocols, and change controls. Additionally, provide shop floor oversight with QA/compliance guidance to support decision-making throughout these processes.
    - Manufacturing support includes live batch record review and execution of AQL inspections.
- Support continuous quality improvement initiatives for manufacturing operations by collaborating with production, QC, engineering, and supply chain teams to implement and optimize processes that enhance efficiency.
- Support all regulatory inspections by assisting with preparedness initiatives and executing inspection activities, while also continuously performing/supporting any tasks necessary to ensure product quality and maintain site cGMP compliance as needed.
- Provide cGMP and associated OJT training to any other quality members and other operational areas as needed.

Cross Train Expectations:

QA Batch Release:

- Perform Master Batch Record approvals and issuance of batch records and labels
- Perform Raw Materials release, updating statuses of materials in the ERP system.
- Reviewing and approving raw material documentation and supplier CoAs to ensure quality and compliance of raw materials to be used in manufacturing processes.
- Perform Final Batch Record Review and Final Product Release
- Perform a comprehensive review of all executed batch records and associated documentation to ensure compliance with specifications and regulatory requirements before product release.

QA Compliance

- Support the following programs as needed: Change Control Management, Customer Complaint Management, Document Control Management, Training Program Management, Supplier Qualification Program, Audit/Self-Inspection Program, Annual Product Quality Review (APQR), Logbook Issuance

Essential Requirements

- Education: Bachelors' Degree, preferably in Life Sciences, Chemistry or related relevant degree strongly preferred.
- 3+ years of experience in a GxP (Bio)pharmaceutical or API manufacturing operations
- 2+ years of experience in a quality assurance role
- Collaborating across boundaries
- Functional Breadth
- QA and/or QC experience in pharmaceutical industry with environmental monitoring & cleanliness zones
- Knowledge of FDA and EU regulations and experience in US and international regulatory agency inspections.

The salary for this position is expected to range between $89,600 and $166,400/year. The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors. Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.

Read our handbook (PDF 30 MB)

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Дивизион
Operations
Business Unit
Production / Manufacturing
Место
США
Состояние
California
Сайт
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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