Validation Engineer II

Job ID
REQ-10066420

11月 05, 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 to cancer patients. We are looking for experienced Manufacturing professionals to help us reach our ambitious goals.

The Validation Engineer will execute and manage process, primary packaging, and cleaning 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 expections.

About the Role

Responsibilities:

- Supports the development of Validation/Qualification documents including drafting risk

assessments, qualification protocols, deviations, and reports. Supports the execution of validation/qualification activities for the site (including manufacturing equipment, QC lab equipment, utilities).
- Reviews, evaluates and analyzes validation data for accuracy and adequacy.
- Supports the validation execution strategy and timeline for sustained commercial and clinical operations within a validation GMP environment.
- Assists with change management validation impact assessments.
- Supports the site validation periodic re-evaluation program including periodic reviews and requalifications.
- Assists with Validation lifecycle documents.
- Manages workload to ensure timely approval of validation testing and documentation.
- Supports the validation department during inspections or audits.
- Other related duties as assigned.

The salary for this position is expected to range between $63,600 and $118,200 per 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.

Minimum Requirements:

- BS/MS degree in Chemical, Industrial, Mechanical, or other related engineering/science discipline with a minimum of 2 years of relevant engineering experience in the pharmaceutical or Biopharmaceutical industry.
- Familiarity with good engineering practices, validation tools and processes, risk management, GAMP 5 applications and practices (including environmental mapping and use of Thermal Mapping equipment is preferred).
- Experience in cGMP environment (IQ, OQ, PQ).
- Familiar with current industry best practices, including ASTM e2500 to plan efficient/risk-based validation projects.
- Strong technical writing and verbal communication skills.
- Proficient in Microsoft Word, Excel, PowerPoint, and Project.

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: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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部门
Operations

Business Unit
Production / Manufacturing

地点
USA

状态

Indiana

站点
Indianapolis

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

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Job ID
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