Technical Transfer Lead (Ac-225 Focus)

Job ID
REQ-10049022

6月 16, 2025

USA

摘要

#LI-Onsite
Location: Indianapolis, Indiana

At Novartis, we are pioneering the future of cancer treatment through Radioligand Therapy (RLT) - a powerful fusion of nuclear medicine and precision oncology. As we expand our global RLT manufacturing footprint, we are seeking passionate, purpose-driven individuals to join our mission of delivering life-changing therapies to patients around the world.

As the Technical Transfer Lead, you will lead and execute technical activities for the actinium project at the site level (within, inbound and outbound), including any scale-up or other process adaptations, according to the project timeline. You will ensure process, technology and product are efficiently transferred to the site. You will also act as the go-to person for MS&T related activities within the project during transfer and implementation. You will lead the technical transfer project team at the site and liaise with other sites and all involved functions (e.g. Technical Development, Supply Chain, Production Unit, Quality Control, HSE).

About the Role

Key Responsibilities:

- Review and update Quality Risk Assessment (QRA) prior to transfer and prior to validation, adapt control strategy, if needed. Provide technical expertise, facilitate establishment of a product specific QRA.
- Review first APQR after transfer to ensure adequate product performance -Ensure that all relevant technical information and documentation for validation is available. Review subsequent APQRs and decide on state of control.
- Define and implement pre-validation / validation strategy including process, cleaning, packaging, ongoing verification and supportive studies (e.g., hold times). Overall responsibility for establishment, prioritization, execution and tracking of Validation Master Plan. Coordinate technical, regulatory and validation batches at site. Support Validation team in creation of validation protocol and report. Provide technical expertise for validation activities around technologies within area of responsibility.
- Maintain oversight and knowledge of the entire manufacturing process performed on site and throughout the entire commercial lifecycle, act as SPOC.
- Monitor all critical variables and key variables as appropriate using statistical analysis and conducting regular product specific data trending.
- Interface with global MS&T network and Technical Development organizations, for the corresponding global activities, to define and implement new technical standards for existing and new technologies and equipment. Own the knowledge of specific pharmaceutical manufacturing process technologies, locally, including any pilot scale, scale up or down, and Design of Experiments (DoE).
- Harmonize and optimize technical processes across the site.
- Support Product Steward in maintaining the process control strategy.
- Lead complex projects with deep understanding of development process requirements.

E**ssential Requirements:**

- BSc degree in Pharmacy, Pharmaceutical Technology, Chemistry, or related field, MSc. or equivalent relevant experience desirable.
- 8 years ' experience in the pharmaceutical industry, including 3+ years' experience in radiopharmaceuticals, especially isotope manufacturing.
- Comprehensive understanding of pharmaceutical technology and validation requirements and activities.
- Involvement with quality regulatory inspections of facilities from major agencies such FDA or EMA.
- Project management experience. Proven ability to plan and manage operational process to meet project timelines
- Excellent technical writing skills. Strong leadership skills

Desirable Requirements:

- Direct experience with low bioburden manufacturing

- Radiation safety education

The pay range for this position at commencement of employment is expected to be between $ 114,100 and $ 211,900 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.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

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.

部门
Operations

Business Unit
Innovative Medicines

地点
USA

状态
Indiana

站点
Indianapolis (Indiana)

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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