

Technical Steward

Job ID REQ-10053848 Jun 10, 2025 USA

Summary

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 Maintenance & Calibration professionals to help us reach our ambitious goals.

Location: Onsite

Provides to the Site the specialist knowledge and expertise, as Subject Matter Expert (SME), of specific pharmaceutical processes or process technologies (e.g. Technical Steward for galenics, for film coating, biologics –upstream or downstream, etc). Oversees processes and standards to maintain and improve existing and to implement new innovative manufacturing technologies.

About the Role

Major accountabilities:

Stewardship - for technology assigned:

- Act as the SPOC for the interface with global MS&T network and with technical development organization, for the corresponding global activities, to define and implement new technical standards for existing and new technologies and equipment.
- Owns the knowledge of specific pharmaceutical manufacturing process technologies, locally, including any pilot scale, scale up or down, and Design of Experiments (DoE).
- Participate in the definition and selection of pharmaceutical equipment, through providing input to User Requirements.
- Collaborate with technical development, other sites and global MS&T network to facilitate transfer of technical knowledge.
- Assure that the necessary benchmark is done internally in Novartis, and externally in the scientific and academic environment, in order to stimulate and to extend the knowledge, increasing the know-how of the associates and expanding it to the rest of the organization.
- Be a recognized scientific expert internally and externally by reporting and presenting scientific/technical work at internal/external meetings/conferences and publish in peer reviewed international scientific journals including patents. Maintain their work in inspection readiness level.
- Support Product Stewards in creation of Quality Risk Assessments.
- Support creation of SOPs for Process Unit.
- Provide technical expertise to Engineering for design activities in Capex projects around technologies within area of responsibility.
- Provide technical expertise for equipment qualification around technologies within area of responsibility.

Validation:

- Approve validation reports under their area of responsibility (as needed) e.g. packaging validation.
- Provide technical expertise for validation activities around technologies within area of responsibility.

Launch & Transfer:

- SME for specific Technology Platform or pharmaceutical processes following process product/process transfer or handover from launch to commercial production. Manufacturing Excellence—for the technology(ies) assigned: Harmonize and optimize technical processes across the site.
- Benchmark new technologies and equipment relevant for site.
- Designs and controls optimization projects.
- Provide SME expertise to perform process characterization of the related pharmaceutical processes to increase robustness and sustainability.
- Support Product Stewards / Process Experts in trouble shooting / root cause investigation by providing second level of specialist expertise as SME and by harmonizing and optimizing related technical processes across the units.
- Perform technical feasibility trials related to process improvement and implementation of new manufacturing technologies.

Training:

- Own the Training Curriculum for own Job Profile and direct reports.
- Provide technical trainings and education programs for Process Experts and production operators.
 Novartis Manufacturing Manual:
- Support implementation of Novartis Manufacturing Manual principle 3.
- Provide SME input to Novartis Manufacturing Manual principle 4.
- Represent site in technical stewardship network.

The salary for this position is expected to range between \$114.100 and \$211,900 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:

- BSc. in Pharmacy, Pharmaceutical Technology, Chemistry or equivalent scientific degree. Master's Degree preferred.
- 8+ years of relevant experience in a GMP environment.
- Proven process understanding (Pharma, GMP, Regulatory aspects).
- · Excellent communication skills.

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 <u>us.reasonableaccommodations@novartis.com</u> 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.

Division

Operations

Business Unit

Innovative Medicines

Location

USA

State

Indiana

Site

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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REQ-10053848

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