Product Steward (Product Life Cycle Owner)

Job ID
REQ-10030811
May 14, 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 an experienced pharmaceutical professional to help us reach our ambitious goals.

As the Product Steward, you will be part of our Manufacturing Science and Technology (MSAT) team and own the process knowledge of products throughout the commercial lifecycle, maintain oversight of process capability, ensure processes are robust, in continued state of validation, and continuously improving. You will facilitate the seamless flow of knowledge and information across functions, and with other Sites, and provide second line technical/scientific process support.

About the Role

Stewardship:

- Maintain the process control strategy. Monitor all critical variables and key variables using statistical analysis and conducting regular product specific data trending. Review Annual Product Quality Review (APQR) to ensure products and processes are in a state of control.
- Create and maintain product Quality Risk Analysis (QRA). Assist in initiating the product monitoring of all critical In Process Controls (IPC) and release parameters in each laboratory.
- Maintain oversight and knowledge of the entire manufacturing process performed on site and throughout the entire commercial lifecycle, acting as the Single Point of Contact (SPOC)
- Track and evaluate product performance, detect issues, implement Corrective and Preventive Actions (CAPAs), and lead or support root cause investigations of process failures.
- Present product performance and status of product improvement projects in site Manufacturing Robustness Review Board (MRRB).
- Assess impact of technical changes, assess their technical feasibility and determine scope / design of technical batches, challenge technical risk and business benefit of technical changes proposed.
- Ensure creation of Master Batch Record and own change control. Support registration activities as needed.

Validation:

- Ensure the continued state of validation (process, cleaning, ongoing verification etc.). Support process validation lifecycle activities by ensuring a state of control is maintained through ongoing process verification (OPV).
- Ensure that the ongoing verification report (OPV) is established on time in alignment with the APQR.
- Support site validation planning by reviewing and approving validation protocol and report related to

technical changes for processes, cleaning, packaging processes and ongoing verification for processes and cleaning (as applicable).

Launch & Transfer:

- Work in close collaboration with development organization (or sending site) for technical transfers and new product launches to ensure that knowledge is transferred, control strategies are appropriate, risks are analyzed and controlled and to ensure that commercial processes are validation ready
- Participate in pre-validation activities and risk assessments to ensure the success of commercial process validation.
- Provide the necessary data for technical activities involved in transferring out a product, focusing on existing knowledge, through the appropriate documentation and support at the receiving site as needed.

Manufacturing Excellence:

- Design and manage optimization projects, provide SME expertise to perform process characterization of pharmaceutical processes to increase robustness and sustainability
- Collaborate with Operational Excellence (OPEX) for product and process improvements

Essential Requirements:

- BSc. in Chemistry, Pharmacy, Chemical Engineering or Pharmaceutical Technology and 5 years of experience in process support, manufacturing, manufacturing science and technology, technical development or quality.
- Proven process understanding - thorough understanding of manufacturing processes and related process equipment.
- Strong working knowledge of quality systems and regulatory requirements across multiple health authorities.
- Expert in reviewing and writing technical reports.
- Sound experience of data handling and applied statistics is a must.

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: novartis-life-handbook.pdf.

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

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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.

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