Process Expert

Job ID
REQ-10039811
Feb 07, 2025
Estados Unidos

Resumen

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 Process Expert will represent production management to the team members and promote Novartis values within the team. Engage and motivate the team and delivers strong results with an empowered team. The Process Expert will provide front line expert support for all process-specific issues to production. Act as Subject Matter Expert (SME) for the product and process and lead investigations.

This role is located on-site in Millburn, NJ. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

The shift for this role is Wednesday through Saturday (1pm - 11pm)

About the Role

Major accountabilities:

Shop Floor Support:

- Provide front line technical and procedural support to manufacturing, working with the cell processing team, focusing on manufacturing each batch safely, on time, in compliance with the batch record and quality requirements.
- Provides latest information regarding best practices, investigation findings, CAPAs, MST/TRD experiences to manufacturing SMEs.
- Perform data analysis and identifies potential process shifts/trends and escalate as necessary.

Deviations, Investigations, and CAPAs:

- Author investigations for product and non-product deviations.
- Conduct manufacturing investigations for Out Of Expectation (OOE), Out Of Specification (OOS), Out of Tolerance (OOT) results.
- Work cross-functionally to assess deviation impact and identify root causes.
- Work with Scheduling and QA to ensure that batches of are released on time through the closure of robust investigations and impact/risk assessments.

- Use process knowledge and root cause investigation tools to analyze data and to identify and root causes of product and process failures.
- Initiate CAPAs and CAPA effectiveness checks to eliminate/mitigate deviations.
- Support the process of escalation of deviations when appropriate according to escalation guidelines. Present escalation events and provide deviations details clearly and on-time (root cause and CAPAs).

Business Process & Improvements:

- Identifies opportunities for process, operational, and quality improvements in conjunction with Manufacturing Team (PU) and Operational Excellence Team (OpEx).
- Execute process technical batches to generate sufficient process knowledge by thoroughly testing critical variables.
- Evaluates manufacturing pre-production technical planning, review of technical data of incoming apheresis materials, to ensure timely and required batch pathway processing by the manufacturing team.
- Provide timely updates to management on status of manufacturing performance. Escalate potential performance issues to 3rd parties.

Technology Transfer:

- Provide timely support for process technology transfer activities from clients/3rd parties.

Training:

- Develop and provide training (as immediate response to unexpected events, for technical document execution, and new products/processes) to the Cell Processing team, as required.
- Owns the Training Curriculum for this Job Profile and provides the necessary training and support to new associates joining the Process Expert position.
- Coach new investigators as part of the Investigator Certification Program.

Audit Support:

- Maintain their processes at inspection readiness level and to provide the necessary support in any internal or external audit.
- Support Regulatory Authority inspections.

The pay range for this position at commencement of employment is expected to be between $77,000 to $143,000 a 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.

Minimum Requirements:

- Bachelors Degree is required. Scientific focus is preferred.
- 3+ years of previous GMP experience is required.

- Previous experience in pharmaceutical industry is required.
- Previous experience leading investigations is required.
- Previous radiopharmacy experience is preferred.

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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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