

Process Expert

Job ID
REQ-10074285
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CLIA

Сводка

The Process Expert will provide front line support for all issues related to the manufacturing process, continuously improving in quality and efficiency, and in compliance to cGMPs, SOPs and applicable guidelines.

Location: Morrisville
Onsite
1st shift (Monday through Friday)

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.
- Authorities' inspections

The salary for this position is expected to range between \$81,200 and \$150,800 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:

- Bachelor's degree in Science, Engineering or Biology or related field or relevant experience in lieu of a degree.
- 2+ years of relevant experience in a GMP environment is required with degree; 7+ years of relevant experience in lieu of a degree.
- Previous GxP experience is required.

- Excellent communication and collaboration 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>

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally. [Read our handbook \(PDF 30 MB\)](#)

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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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