Process Expert - Comecer Lines

Job ID
REQ-10025733
Ott 11, 2024
USA

Sommario

#LI-Onsite

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

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 provides direct front line support to production activities using technical understanding and knowledge of cGMPS, SOPs, and process steps. This individual is accountable to support process issues, protocol generation, general documentation support, deviation investigations, and continuous improvement of the process.

About the Role

Major accountabilities:

- Responsibilities include but not are limited to:
- Support a culture of safety, quality, diversity, and inclusion.
- Provide front line support to manufacturing shifts to ensure safe, quality, and timely completion of product batches.
- Manage and maintain manufacturing documentation including Master Batch Record, applicable SOPs, risk assessments, protocols, and other documentation as needed.
- Track and trend critical process parameters and in process checks as part of ongoing process verification (OPV) and identify CAPAs to address any trends.
- Identify, assess, and own technical changes through GMP change control processes.
- Investigate deviations and determine root causes and identify CAPA.
- Act as Subject Matter Expert (SME) for process flow and support data gathering for Annual Product Review.
- Ensure processes are inspection ready at all times.
- Support continuous improvement through identification of opportunities, technologies, and owning changes to implement improvements.
- Support on going self learning and ensuring training is up to date.
- Provide support to production team through training and knowledge sharing.

Minimum Requirements:

- Bachelor’s degree in Engineering, Pharmacy, Pharmaceutical Technology, Chemistry or other science related fields or equivalent experience.
- 1+ years of experience in a manufacturing environment, preferably in pharmaceutical manufacturing
- Direct experience in a GMP or aseptic/sterile environment is highly desired.
- Radio pharma experience is a plus
- Word, Excel, Powerpoint, and Teams Experience
- Ability to work in a cross functional team
- Technical writing experience preferred
- Excellent communication skills
- English fluently, verbally and in writing

Commitment to Diversity & Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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

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EEO Statement:

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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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