Manufacturing Process Expert

Job ID
REQ-10030683
Nov. 29, 2024
USA

Zusammenfassung

Location: Carlsbad, CA #LI-Onsite

About this role:
The Manufacturing Process Expert provides direct front line support to production activities using technical understanding and knowledge of cGMP, SOPs, and process steps. This individual is accountable to support Manufacturing activities, develop training materials for production operators, training production staff, support process issues, protocol generation, general documentation support, deviation investigations, CAPA ownership, change record ownership, and continuous improvement of the process.

About the Role

Your responsibilities include, but are not 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 the lead for 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 the product and process knowledge and provide input to the 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 validation protocol generation and execution.
- Support on going self-learning and ensuring training is up to date.
- Provide guidance and support to production team through training and knowledge sharing.

- This position will involve wearing protective clothing and working in a Manufacturing Grade C clean room environment.
- This position may require shift work including weekends and off hours support.
- Strong interpersonal, written, communication skills along with problem solving and follow-up skills.
- Well organized, flexible and work with minimal supervision.

Essential Requirements:

- BS degree in life sciences, engineering, chemistry, biotechnology, or related field or equivalent relevant experience
- Training in radiochemistry or radio pharmacy is an preferred
- 4 or more years' experience in GMP operational roles with direct experience in pharmaceutical manufacturing, specifically low bioburden manufacturing preferred
- Involvement with quality regulatory inspections of facilities from major agencies such as FDA or EMA.
- Shows the appropriate sense of urgency around given tasks
- Strong change management skills, adaptability, and the ability to work under pressure.
- Proficient technical writing skills.
- Good understanding of manufacturing and validation requirements and activities.
- Radiation safety education (desired).
- Leverage new technologies and techniques to eliminate non-value adding activities and improve productivity / performance through new processes.

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

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EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. 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. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

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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