Quality Assurance Manager

Job ID
REQ-10012511
juin 27, 2024
Espagne

Résumé

As Quality Manager you will assure that the product quality conforms with specifications and that production activity is compliant with Novartis quality policy and GxP requirements. You will ensure that relevant documentation is up-to-date and archived correctly and ensure “state of the art” GxP know-how and future trends in the field of GxP.

About the Role

Major accountabilities:

- Ensure that all aspects of the handling, manufacturing and distribution of biopharmaceutical / pharmaceutical products are in compliance with the Novartis Quality Manual, the effective Quality Agreement that they meet relevant GxP regulatory requirements and are conducted according to local SOPs.
- Prepare, review and check the batch documentation for correctness, completeness and safely archive the original documents for the prescribed period and plan, conduct and monitor self-Inspection schemes for all sections.
- Ensure that all drug products are released to the market in accordance with the registered specifications and with local/international regulations.
- Escalate any issues or instances of instability per the Novartis escalation policy, and initiate any market action that is required.
- Responsible for assessing quality trends and driving continuous improvement for processes and product quality performance and maintain access to regulatory and Pharmaceutical authorities in respect to up-dated GxP ovide latest know how in the field of GxP and other quality related fields.
- Establish and maintain cross-functional contacts with peer organization -Support launches of product in close collaboration with BD&L partner and/ or development organization.
- Ensure that Change requests are managed according to the Novartis SOPs from receipt, through to the implementation and closure.
- Archive relative documentations and manage/Approve critical quality issues (deviations, complaints, recalls, counterfeits and product tampering, stability failures, etc.) according to the Quality Agreement and the Novartis Quality Manual.

Obligatory requirements:

- Education: Pharmacy, Biotechnologist, or any other health care degree.
- 5+ years of experience in Quality Assurance, Quality Control and/or Manufacturing Operations,
- Solid knowledge of GMP regulations.
- Fluent English and Spanish, written and spoken.

Why Novartis:
Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and tru ste d medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people and culture

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits rewards

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

Join our Novartis Network:
If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis an d o ur career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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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