NOVARTIS

Product Quality Lead

Job ID
REQ-10033359
Dec 12, 2024
Spain

Summary

The Product Quality Lead is responsible for the holistic product quality stewardship of assigned Novartis biologics (NBE) and ATMP (Advance Therapy Medicinal Products) across multiple sites (or platforms, DS and DP sites, including CMOs) throughout the product lifecycle, from late phase development to discontinuation.

About the Role

Major accountabilities:

- Accountable for end-to-end quality stewardship (DS and DP) of assigned Novartis biologics product(s) (NBE's and biosimilars) from late phase development to discontinuation.
- Accountable for the end-to-end product quality strategy (DS and DP) across the global network and drive continual improvement through product and process lifecycle management, represent QBT&A in cross-functional project life cycle team.
- Provide expert quality guidance, technical support and quality leadership for implementation of quality guidelines, regulations, standards, processes, and strategy for assigned product(s) throughout the product and process lifecycle.
- Maintain global Quality oversight, oversee global regulatory filing activities including product registration and variation management, of assigned Novartis biologics product(s) (NBE's and biosimilars)
- Act as global quality lead in product related Q escalations, recalls and BPDR handling for product specific quality and compliance challenges. Provide clear direction and drive efficient decision making for global Quality issues related to assigned products.
- Involved in major product relevant investigations, in particular multi-sites deviations and recurring deviations, by leading / supporting global investigations / Task Force at the sites.
- Support global site readiness for product pre-approval inspections across the BT&A platform / network.
- Bridge between clinical, development and technical operation teams and engages at multiple interface(s) between the organizations to functionally lead and drive robust execution of the defined Product related Quality Program.
- Actively drive platform wide Q strategy harmonization and promote product Quality as competitive advantage.

Minimum Requirements:
Work Experience:

- 5+ years of experience in an operational GxP area in a Manufacturing/Development or Quality;
- Solid knowledge in biology/chemistry, pharmacy and biotechnology, medical devices/combination products;
- Thorough knowledge and expertise in cGMP and applicable guidelines

- Sound scientific, technical and regulatory knowledge, ideally in Biotechnology; expertise in validation (process and cleaning) a plus;
- Excellent and proven ability to analyze and evaluate cGMP compliance;
- Proven ability to influence people and communicate in a process-oriented organization;
- Fluent English, written and spoken. Any additional language is a plus.

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 trusted 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

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Benefits and rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: 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.

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Division
Operations
Business Unit
Innovative Medicines
Location
Spain
Site
Barcelona Gran Vía
Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Functional Area
Quality
Job Type
Full time
Employment Type

Regular
Shift Work
No
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