NOVARTIS

Product Quality Lead

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REQ-10078711
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Испания

Сводка

The Product Quality Lead plays a crucial role in ensuring the quality and consistency of our products throughout their lifecycle. This role encompasses a wide range of responsibilities that bridges clinical, development, and technical operations, providing expert guidance and leadership to ensure the highest quality standards for our products.

The PQL collaborates with various teams during different phases of product development, from preclinical to postapproval changes. The PQL works closely with Quality Control (QC), Analytical Science & Technology (AS&T), Manufacturing Science & Technology (MS&T) and ESO QA teams to ensure product quality.

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 devia-tions, 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 ad-vantage.

Minimum Requirements:

- 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

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.

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.

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)

Дивизион
Operations
Business Unit
Quality
Место

Испания
Сайт
Barcelona Gran Vía
Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Alternative Location 1
Ljubljana, Словения
Alternative Location 2
Mengeš, Словения
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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