Product Quality Lead

Job ID
REQ-10033359

12月 12, 2024

Spain

摘要

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 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:
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.

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部门
Operations

Business Unit
Innovative Medicines

地点
Spain

站点
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Functional Area

Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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