Global QMS Manager

Job ID
REQ-10047333

Jun 02, 2025

Spain

Summary

The Global QMS Manager ensures maintenance and continuous improvement of designated Quality processes and respective tools to drive standardisation and harmonization further and meet compliance requirements. Leads the QMS Networks across Novartis with all relevant Novartis Functions and Entities for all QMS topics. Leads/participates in key QMS projects or initiatives and maintains knowledge with current industry trends, Health Authority expectations.

About the Role

Major accountabilities:

- Establish and run the QMS network for GCP (Good Clinical Practices), GLP (Good Laboratory Practices) and GVP (Good Vigilance Practices) areas and drive interactions with GDD, TRD, Country, GMA, NIBR, and Regulatory Affairs Functions through the defined governance model.

- Establish and run the QMS network for GMP (Good Manufacturing Practice) and GDP (Good Distribution Practice) and drive interactions with the Operations functions, including TechOps, through the defined governance model.
- Act as Process Owner for the GxP Regulatory Assessment process and manage this process, including the Emerging Regulations, and the associated governance meetings.
- Act as a subject matter expert for selected Quality processes and collaborate with the respective QSO/Process owner to ensure GxP compliance of the processes and tools within own remit.
- Act as Process Owner for designated processes to drive process lifecycle management from development to archiving of related IT systems.
- Author/review respective QMS documentation.
- Lead and/or participate in key QMS projects or initiatives ensuring that: defined quality elements and compliance requirements are addressed, all required activities for successful and timely execution are completed, the roll-out to impacted local entities across Novartis is achieved.
- Establish and maintain community/network of Subject Matter Experts or Single Points of Contact and drive interactions with corresponding Functions.
- Establish strong partnership with key stakeholders.
- Create synergies and opportunities by leveraging lessons learned and communicating them to the SMEs and stakeholders as applicable.
- Act as a QMS representative and liaison partner in other initiatives, boards, meetings as necessary.
- Participate in benchmarking activities as applicable and keep up to date with industry standards.
- Maintain knowledge of current industry trends and Health Authority expectations.

Minimum Requirements:

- Education: University degree in Pharmacy, Chemistry, Engineering or equivalent related discipline.
- Broad experience in QA processes and underlying regulatory requirements and industry standards/best practices
- Good understanding of Novartis QMS principles
- Leadership and Project Management skills to ensure successful implementation of projects or initiatives.
- Curiosity and agility to be able to adapt to fast moving environment
- Fluent English written and spoken as a minimum, other languages an advantage.

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部門
Operations

部門
Innovative Medicines

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Spain

勤務地
Barcelona Gran V í a

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

Functional Area
Quality

職種
Full time

雇用形態
Regular

Shift Work
No

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