NOVARTIS

Global Quality Management Systems (QMS) Manager

Job ID
REQ-10014085
Sep 03, 2024
Spain

Summary

~ Responsable de garantizar el cumplimiento y el desarrollo, soporte, mantenimiento y revisión constante de los Sistemas de Calidad y soporte para proyectos, así como la presentación de informes de los indicadores de rendimiento (KPI) e indicadores de calidad (KQI) necesarios. Apoyar la implementación de procesos efectivos y eficientes que cumplan con los requisitos y expectativas reglamentarios de manera sostenible para la cartera global de productos de Novartis.

About the Role

Key responsibilities

- 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.
- Align with other Business functions within the GCP, GLP and GVP areas e.g. Clinical Development and acquired companies, on QMS related activities.
- Represent global QMS at various boards/ meetings in the GCP, GLP and GVP areas on one hand and ensure the feedback from his / her network is taken into account in global initiatives or projects on the other hand.
- Function as the key point of contact for GDD, TRD, PV, GMA, NIBR associates on all topics re-quiring global QMS involvement, as well as act as a QMS representative and liaison partner in other initiatives, boards, meetings as necessary.
- 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, such as GxP Regulatory Assessment process.
- 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.
- Participate in benchmarking activities as applicable and keep up to date with industry standards.
- Maintain knowledge of current industry trends and Health Authority expectations.

Obligatory requirements:

- Education: University degree in Pharmacy, Chemistry, Engineering or equivalent related discipline preferably in Quality Systems.
- 6+ years' experience in Pharmaceutical, Chemical or Biological Operations with focus on QA processes and underlying regulatory requirements and industry standards/best practices.
- **Specific practical experience and expertise in both Clinical Operations and Regulatory Affairs**
- Good understanding of Novartis QMS principles.
- Senior expert level understanding of GxP regulations and guidelines, and solid understanding of health authority expectations and industry trends.
- 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
- Solid communication skills
- English fluent, written and spoken. Other languages are a plus.

Why consider Novartis?
236 million. That's how many lives our products touched in 2022. And while we're proud of that fact, in this world of digital and technological transformation, we must also ask ourselves this: how can we continue to improve and extend even more people's lives?

We believe the answers are found when curious, courageous and collaborative people like you are brought together in an inspiring environment. Where you're given opportunities to explore the power of digital and data. Where you're empowered to risk failure by taking smart risks, and where you're surrounded by people who share your determination to tackle the world's toughest medical challenges.

Imagine what you could do at Novartis!

Commitment to Diversity & Inclusion:
Novartis embraces diversity, equal opportunity and inclusion. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration, and empowers our people to unleash their full potential.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to learn more about Novartis and our 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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Division
Development
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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