Head Process Quality

Job ID
REQ-10022528
Oct 30, 2024
Spain

Summary

As the primary quality contact for Business Process Owners (BPOs) in Development, you are the guardian of excellence, ensuring seamless quality oversight of clinical processes. Your mission is to uphold the highest standards of compliance with Health Authorities' requirements and internal benchmarks.
In this dynamic role, you will forge powerful partnerships within CQA and RDQ, providing strategic and operational QA/GxP expertise. You will be the champion of a quality mindset, driving alignment with the broader goals of RDQ and Development. Your leadership will inspire a culture of excellence, ensuring that every step taken is a stride towards unparalleled quality and success.

About the Role

** 2 positions available **

Primary Location: Barcelona or Madrid, Spain

Alternate Location(s): London, England / Dublin, Ireland

Working model: All locations have a hybrid working model (12 days per month in the office)

Note: Novartis is not able to offer relocation support for this role. Please only apply if the location is accessible for you.

About this role:

As the primary quality contact for Business Process Owners (BPOs) in Development, you will ensure compliance with Health Authorities requirements and internal standards while driving continuous clinical process enhancements. You will lead quality initiatives, manage quality risks, and oversee quality issue management across Development Units and therapeutic areas. By partnering within CQA and RDQ, you will provide strategic QA/GxP expertise, ensuring exceptional quality, proactive compliance, and superior business satisfaction.

Key Responsibilities:

- Actively drive a culture of Quality and successfully embed a Quality mindset across Development by forging strong business partnerships, positively impacting business deliverables, and effectively implementing the strategy, mission, and purpose of RDQ.

- Act as primary quality contact for Business Process Owners (BPOs) and actively engage with relevant RDQ representatives to provide comprehensive guidance.
- Collaborate with BPOs to conduct regulatory requirements gap assessments and implement necessary actions to address any identified gaps.
- Monitor and evaluate changes in regulations, best practices, and internal process working groups, and promptly initiate changes to clinical processes as applicable.
- Guide Quality System Owners (QSOs) and BPOs in the development of a robust strategy for clinical process changes, considering interdependencies and guide respective risk business owners in all aspects of risk management.
- Collaborate closely with BPOs to prepare for audits, actively participate, support formulating robust CAPA plan, ensuring its comprehensive review and flawless implementation.
- Collaborate closely with the Head GCP Inspection Management and GCP Inspection Project Managers when a GCP Health Authority Inspection is announced, promptly identifying potential risk areas that may impact the process.
- Guide BPOs in preparing for specific presentations and deliverables requested during inspections.
- Ensure diligent oversight of process-specific Audit and Inspection CAPAs creation and implementation to drive continuous improvement.
- Establish and diligently manage comprehensive reviews of quality and compliance-related topics within the relevant clinical business process area.
- Proactively address potential gaps and risks relevant to Clinical Development and Clinical Operations processes, while identifying valuable opportunities for continuous improvement.
- Drive continuous improvement through data-generated insights for the respective clinical processes, fostering a culture of excellence.
- Provide expert input into RDQ strategic initiatives, including the Quality Plan, within the relevant clinical business process area.
- Support communications to RDQ and Development Line functions relevant to process-related CQA knowledge management, fostering effective information sharing, and delivering impactful CQA-specific communication to stakeholders.

Role Requirements:

- Master’s degree in Life Science/Pharm.D., M.D. or Ph.D. or MBA desired
- Fluent English both spoken and written
- At least 10 years of involvement in regulated activities (GCP/PV), clinical development and/or QA positions in pharmaceutical drug development.
- Broad understanding of global expectations of Health Authorities in the area of Clinical Development and profound understanding of the science of product development.
- High learning agility, mentally quick, comfortable with complexity and diversity, and highly interested in continuous improvement.
- Effectively collaborating with stakeholders at all levels of the organization with a possibility to inspire and motivate cross-functional teams to drive change and promote a culture of excellence.
- Ability to present to Novartis senior management, corporate functions and to local executive team members, as well as to external audiences, health authorities and government officials.
- Proven ability to build strong and effective relationships with internal and external partners.

Closing date for applications: 13 November 2024

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

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.

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

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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

Division
Development
Business Unit
Innovative Medicines
Location
Spain
Site
Barcelona Gran Vía
Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Alternative Location 1
Dublin (Novartis Corporate Center (NOCC)), Ireland
Alternative Location 2
London (The Westworks), United Kingdom
Alternative Location 3
Madrid Delegación, Spain
Functional Area
Quality

Job Type
Full time
Employment Type
Regular
Shift Work
No
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