Head Compliance CQA

Job ID
REQ-10013109
Sep 03, 2024
Spanien

Summary

Head, Compliance Clinical Quality Assurance.

Our Development Team is guided by our purpose: to reimagine medicine to improve and extend people's lives.

To do this, we are optimizing and strengthening our processes and ways of working. We are investing in new technologies and building specific therapeutic areas and platform depth and capabilities – all to bring our medicines to patients even faster.

We are seeking key talent, like you, to join us and help give people with disease and their families a brighter future to look forward to.

Apply today – we will thrive together!

About the Role

Job Purpose:

Are you ready to become the Head, Compliance Clinical QA? As primary quality contact for Business Process Owners (BPOs) in Development is responsible for end-to-end quality oversight of clinical processes, ensuring compliance with Health Authorities requirements and internal standards. The individual will a deep thinker and data focused. This will mean extracting information from different data sources, summarizing in a way that is actionable and what behaviours are we wanting to drive? You will be synergizing many elements; highest risk, what the data highlights, how many and where audits take place, time constraints, fixes any risks ahead of time for Novartis in the clinical space.

Key requirements:

- **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**

- **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 Manager(s) 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.**
- **Proactively address potential gaps and risks, while identifying valuable opportunities for continuous improvement. Drive continuous improvement through data-generated insights for the respective clinical processes, fostering a culture of excellence.**

Your Experience:

- **Master's degree in life sciences / healthcare, M.D, Ph.D or MBA is desired.**
- **At least 10 years of involvement in regulated activities (GCP/PH), clinical development and/or QA position in the 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.**
- **Proficient English language skills.**

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

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

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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

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Division

Global Drug Development
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Innovative Medicines
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Site
Barcelona Gran Vía
Company / Legal Entity
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Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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