Global Head Pharmacovigilance QA

Job ID
REQ-10027955
Nov 13, 2024
Svizzera

Sommario

Location: Basel, Switzerland (80-100%)

Working model: Hybrid working model (12 days per month in the office)

The Pharmacovigilance Quality Assurance (PVQA) organization within the Development Quality organization, supports Novartis Patient Safety & Pharmacovigilance Department.

In this role, you will provide comprehensive expertise and oversight of PV Quality, ensuring compliance with regulations and the Novartis Quality Management System. You will be the QA responsible for global end-to-end Pharmacovigilance and Device Vigilance Systems, as well as commercial and patient-focused activities across all Novartis Enterprises and countries.

About the Role

Major accountabilities:

• Align closely with global and local business partners to drive quality oversight and governance of patient-focused activities involving Patient Safety, Pharmacovigilance and Device Vigilance.
• Drive quality leadership, oversight, and governance of PV activities within and outside of Development. Ensure compliance with PV regulatory requirements and establish harmonized internal standards for global, regional, and local commercially oriented patient-focused activities.
• Ensure a high level of HA PV inspection readiness at the global and local level. Work closely with applicable Quality and business partners on preparation, management, facilitation, and follow-up for PV inspections, as well as for Clinical, GMP, and Device inspections with PV components. Drive the development of robust and sustainable inspection responses and corrective and preventive action plans.
• Contribute to fulfilment of NVS strategic objectives through support of Merger & Acquisition activities, including performance of Due Diligence and leading/managing PV/QMS transitions, integrations, and divestments.
• Maintain oversight of the structures, processes, and performance metrics of the Novartis Enterprise PV quality system and support ongoing updates of the Novartis PV System Master File (PSMF) to ensure timely release of updates that are in compliance with regulatory requirements, internal standards, and the protection of patients for the Novartis product portfolio and covering the full product life cycle.
• Ensure effective quality oversight, management, and support of global PV operational vendors. Drive vendor quality awareness and improvement measures.
• Serve as the PV Quality representative on the Portfolio Stewardship Board (PSB), responsible for preventing,

mitigating, and/or minimizing potential safety risks for patients, and reducing the risk of litigation and reputation damage to the company in relation to safety issues that cannot be solved at the level of the line function unit or other safety boards.
• Contribute to the quality management cycle including working with business partners to identify quality improvement opportunities and incorporate them into the annual Quality Plan.
• Drive quality performance of the Novartis PV and Device Vigilance Systems to ensure tasks and responsibilities required under global PV and Device Vigilance regulations are fulfilled regarding monitoring the safety of Novartis-authorized products and detecting changes to their risk-benefit balance.
• Develop appropriate measures to assure communication, management, and remediation of PV/Device Vigilance-related quality and compliance issues.

Role Requirements:

• Degree in Life Sciences or related scientific discipline. PhD or other higher degree desirable.
• At least 10 years of industry experience within a Big Pharma company.

• At least 5 years of PV, Quality Management and/or GXP Regulatory experience demonstrating increasing levels of responsibility.
• At least 3 years global team management experience or equivalent.
• Thorough and extensive knowledge of international Pharmacovigilance and Device Vigilance regulations, including FDA/EU PV, ICH, new drug regulations, other key HA guidance's, and current industry practice.
• Excellent leadership skills, experience managing associates across functional and geographical boundaries, and ability to lead and/or work successfully within cross-functional teams.
• Capability to drive and implement changes and agility, dynamic with excellent negotiation and communication skills.

Languages :

- Fluent English (both spoken and written) is essential.
- Additionnal languages are an advantage.

Skills:

- Agility.
- Business Acumen.
- Business Partnering.
- Business Strategy.
- Clinical.
- Clinical Trials.
- Continuous Learning.
- Dealing With Ambiguity.
- Decision Making Skills.
- Drug Development.
- Employee Performance Evaluations.
- Health Authorities.
- Influencing Skills.
- Inspection Preparedness.
- Knowledge Of GxP.
- Leadership.

- Organizational Savvy.
- People Management.
- Problem Solving Skill.
- QA (Quality Assurance).
- Quality Management.
- Research.
- Risk Management.
- Self Awareness.
- Smart Risk Taking.
- Stakeholder Management.
- Storytelling.
- Technological Expertise.

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

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits rewards

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

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

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

Divisione
Operations
Business Unit
Innovative Medicines
Posizione
Svizzera
Sito

Basel (City)
Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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