Associate Director ESP Quality (m/f/d)

Job ID
REQ-10039485
Feb 13, 2025
Alemania

Resumen

As our Associate Director External Service Provider QA, you'll have the thrilling opportunity to oversee the implementation of top-notch quality standards, cutting-edge processes, and innovative tools and systems.

You will play a pivotal role in managing external service providers supporting Novartis Global Clinical Trials in R&D Quality, ensuring that our partners meet the highest standards of excellence.

About the Role

Key Responsibilities:

- Responsible for review and approval of External Service Providers (ESP) qualification for global clinical trials.
- Responsible for negotiation and execution Quality Assurance Agreements (QAA) / quality terms with ESPs.
- Review and approval of external service provider Quality Risk Assessments (QRAs) to enable identification and evaluation of various metrics, risks, trends, and potential quality and performance issues with the ESP in a proactive manner. Ensure communication and support mitigation of actions for potential risks.
- Responsible for review and approval of quality issues related to ESPs and ensure appropriate escalation of major and critical issues. Support assessment of serious breach and reporting to health authorities.
- Collaboration with business partners such as, Vendor Partnership and Governance, Global Medical Affairs, other applicable Vendor Business Offices and Procurement to ensure their involvement in the risk evaluation and timely communication to the business and follow-up on required actions.
- Review quality metrics, monitoring and reporting including follow-up with line functions and escalation.
- Ensure inspection readiness of ESP related activities and support for internal and external audits and health authority (HA) inspections pertaining ESP management.
- Ensure compliance with regulatory requirements (GCP, GLP, GVP, GMP) and continuous improvement of quality relevant processes within area of responsibility.

Role Requirements:

Experience:

- 12+ years' experience in pharmaceutical development and excellent knowledge of the quality management system, clinical operations processes and vendor management related activities is preferred.

Education:

- Minimum a bachelor's degree in Life Sciences, Pharmacy or Medicine, or other related discipline required

Languages:

- Fluent English (both spoken & written)

Skills & Expertise:

- Good knowledge of GCP/GLP, GMP, GVP.
- Demonstrated leadership in implementing robust processes and quality systems, and setting global quality standards in a regulated area, including controlled documentation for the pharmaceutical development area.
- Experience in managing External Service Providers and knowledge of quality standards and regulatory requirements. Experience in interactive response technology (IRT), eCOA and Imaging services is added advantage.
- Thorough technical understanding of quality system, clinical trial process collecting, analyzing, and monitoring of Third-party Key Quality Indicators
- Experience in data analysis and trending using available tools
- Demonstrated effective management and establishment of successful international and cross-divisional collaborations.
- Demonstrated root cause analysis skills, Stakeholder engagement and critical thinking

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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Company / Legal Entity
DE61 (FCRS = DE061) Novartis Business Services GmbH
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Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve. Hiring decisions are only based on the qualification for the position, regardless of gender, ethnicity, religion, sexual orientation, age and disability. The law provides for severely disabled / equal applicants the opportunity to involve the local representative body for disabled employees (SBV) in the application process. If you would like to request this, please let us know in advance as a note on your CV.

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