Associate Director, External Service Provider QA

Job ID
REQ-10050379

May 09, 2025

United Kingdom

Summary

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

Primary Location: London, United Kingdom

Secondary Location(s): Barcelona, Spain; Madrid, Spain or Dublin, Ireland

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

Key Responsibilities:

1. Responsible for review and approval of External Service Providers (ESP) qualification for global clinical trials.

2. Responsible for negotiation and execution Quality Assurance Agreements (QAA) / quality terms with ESPs.

3. 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.

4. 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.

5. Support evaluation and assessment of technology like Software as Medical Device (SaMD), Digital Health Technology (DHT), Software as Service (SaaS) provided by Third parties. Review relevant processes and documentation to ensure regulatory compliance.

6. Support the clinical trial team for trial specific assessment to ensure technology is fit for purpose based on specific study design.

5. Facilitate the 'Quality with Technology' discussions with Third Party management team other interested parties to promote greater understanding of quality challenges when working with tech enabled Third Parties and overcome them through improved collaboration and awareness.

8. Act as ESPQA representative for cross-functional Digital and IT related projects, managing the overall Third-Party Quality activities

9. Participate in the independent review of technology implementations ensuring inspection readiness and data integrity awareness.

10. Ensure inspection readiness of ESP related activities and support for internal and external audits and health authority (HA) inspections pertaining ESP management.

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 computer system validation and digital technology assessment
- 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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部門
Development

部門
Universal Hierarchy Node

国
United Kingdom

勤務地
London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Alternative Location 1
Barcelona Gran V í a, Spain

Alternative Location 2
Dublin (NOCC), Ireland

Functional Area
Quality

職種
Full time

雇用形態
Regular

Shift Work
No

Apply to Job.

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

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