NOVARTIS

Associate Director, External Service Provider Quality

Job ID
REQ-10019461
Ago 16, 2024
Reino Unido

Resumen

Primary Location: London Westworks, United Kingdom Alternate Location(s): Dublin, Ireland / Barcelona, Spain / Madrid, Spain Working model: All locations have a hybrid working model (12 days per month in the office) Note: Novartis is not able to offer relocation for this role. Please only apply if the location is accessible for you and you have the right to work in the country you are applying to. About this role: 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 across GxP areas in Global R&D Quality, ensuring that our partners meet the highest standards of excellence.

About the Role

Major accountabilities:

- Provide QA expertise and guidance to ensure compliance with requirement of the quality system are met, including implementation of quality risk-based and GxP-relevant process. Review and approval of External Service Providers (ESP) qualifications. Responsible for adequate Quality Assurance Agreements (QAA) / quality terms with ESPs are in place.
- Lead and manage a quality oversight and collaborate with business partners and other quality groups to ensure health authority and regulatory requirements are fully met. Translate functional QA strategy into applicable operational/compliance activities and support a risk-based implementation and execution of processes.
- 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.
- Ensure quality and compliance gaps are addressed and executed for sustainability and implement strategic process improvement, including review of procedural updates, quality issues, effectiveness checks, etc. Monitor implementation of the Quality Plan and support inspection readiness activities, including participation in regulatory inspection preparation, management, and follow-up. Support Audit team for audit planning and timely completion of audit CAPA.
- Support clinical trial team for oversight/management of external service providers and IT systems supporting research and development activities and drive facilitation and follow-up of audits and inspections, and ensure development, implementation and completion of appropriate corrective and preventive measures for findings. Ensure timely escalation of deviation/incidents and provide quality

oversight for deviations/incidents, including robust investigations, root cause analysis and corrective actions implementation.
- Collaboration with business partners and other 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.
- Contribute towards lessons learned based on audits, inspections, incidents, regulatory intelligence, effectiveness checks on process implementations and metrics and support a culture of proactive, risk-based behavior -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

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 an 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: 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

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

División
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Business Unit
Innovative Medicines
Ubicación
Reino Unido
Sitio
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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