Senior Quality Manager - TRD QA

Job ID
REQ-10062676

9月 24, 2025

Switzerland

摘要

Location: Basel, Switzerland #onsite

Role Purpose:
Provide quality assurance expertise, guidance and support to operational activities in development and research organizations to ensure compliance with applicable regulatory requirements and Novartis procedures and quality standards. Manage projects, including Quality Plan initiatives, and processes that support quality objectives to assure their compliance with GxP regulations.

About the Role

Major accountabilities:

- Support maintenance of the regulatory-required files for health authority inspections and assist with health authority inspection management -Support generation of Quality Plans (and

review other plans for quality/safety aspects) for clinical programs -Support initiatives to maintain or improve quality performance and compliance of operational activities including risk management, health authority reporting, IT systems -Support initiatives focused on quality, process and compliance improvement, including identification of opportunities and develop strategies aimed at improving quality while ensuring compliance with regulatory requirements -Ensure information gained during quality and compliance initiatives, as well as audit and assessment results, are evaluated to identify any regulatory, compliance and QA training needs -Aid in the identification of quality issues and assist with root cause investigations and Support the development of corrective and preventative action plans (CAPA), including monitoring status to Ensure issues are addressed, completed and documented.

- Provide assistance in the remediation of deviations, Ensure follow up and monitoring of associated corrective and preventive actions.
- Manage and Support quality aspects of projects and activities, including those related to third parties, analytical instruments, manufacturing equipment, quality plans, training, IT validations, etc. -Review and approve quality deliverables to ensure compliance (including procedures, records, third party work, contractors, clinical trial material, components, gap assessments) -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Minimum Requirements:
Work Experience:

- Functional Breadth.
- Critical Negotiations.
- Project Management.
- Collaborating across boundaries.

Skills:

- Knowledge Of Capa.
- Qa (Quality Assurance).
- Quality Management.
- Risk Management.
- Root Cause Analysis (Rca).
- Self Awareness.
- Six Sigma.
- Sop (Standard Operating Procedure).
- Technological Expertise.

Languages :

- English.

Accessibility and accommodation
Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of

the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to inclusion.switzerland@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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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部门
Development

Business Unit
Innovative Medicines

地点
Switzerland

站点
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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