Technology and Innovation QA Lead

Job ID
REQ-10062447

9月 25, 2025

Switzerland

摘要

The Technology and Innovation QA Lead role will collaborate with research, IT, technical and clinical operations teams to provide expert quality knowledge for emerging technologies such as mobile apps, medical devices, Digital Health Technology (DHT), imaging, sensors, artificial Intelligence (AI), and new therapeutic modalities. The role will work closely with research and clinical business partners and other stakeholders (Internal & External) to bridge from research to early development activities. The role will also be responsible for the QA activities to assure that Biomedical Research (BR) GxP processes & applications comply with Novartis Computer System Validation (CSV) and Health Authority requirements, assure systems remain compliant throughout their life-cycle in alignment with e-compliance, AI and data integrity standards and support the development of IT related compliance procedures (e.g. Standard Operating Procedures, templates, and training materials).

The role is also responsible for supporting the quality digital & innovation transformation initiatives and BR internal and external audit program

About the Role

Major accountabilities:

- Provide Quality support for innovation projects and emerging technology. This includes business partnering, applying scientific and Quality knowledge to innovation projects, and bridging the needs of the project with the appropriate resource within the Quality team.
- Serve as a functional representative reviewing current regulatory landscape in this space and ensuring it is embedded into the QMS landscape.
- Participate and provide quality input for data governance and processes including partnership with Research Informatics (RX) and Development IT.
- Provide QA oversight and support to assure computerized systems are in compliance with applicable regulations and the Novartis eCompliance requirements.
- Provide knowledge & support training program for Data Integrity and eCompliance requirements for technologies and processing of related data including health authority expectations.
- Participate in Health Authority inspections.
- Collaborate with stakeholders to implement new technologies, next generation technology and/or AI within Biomedical Research.
- Support quality due diligence activities for collaborations with external providers and BD&L deals. Identify, monitor, report and escalate compliance risks. Support integration activities for post-close BD&L deals
- Evaluate potential vendors and collaboration partners and provide advice on selected technology capabilities and ensure they are fit for purpose for the use case as well as further lifecycle requirements. Potential to perform audits and other assessments in the technology space.

Requirements:

- M. Sc. IT/Engineering/Scientific discipline and/or Ph.D. in a Scientific and/or Engineering discipline preferred. BS/BA with relevant experience also considered.
- Fluency in English (oral and written); German skills (B2 and above) preferred
- 5+ years' of practical experience in pharmaceutical/Biotech industry
- Broad knowledge of IT/Software/Medical Device regulations including practical experience. Experience in Digitalization clinical projects is considered a plus.
- Good knowledge of the System Development Life Cycle
- Demonstrated ability to partake in interdisciplinary projects with a wide range of business functions and successfully work in global cross-functional matrix.
- Knowledge of Industry Quality Standards (GLP, ICH, FDA 21 CFR Part 11, ISO 13485
- Knowledge of analytical methods and software
- Good working knowledge of GLP /GCLP/GCP, Scientific areas and relevant IT systems.
- Good knowledge of the System Development Life Cycle
- Ability to grasp new technologies quickly - high learning agility
- Stakeholder management & leadership including collaboration, and influencing skills
- Demonstrated ability to partake in interdisciplinary projects with a wide range of business functions and successfully work in global cross-functional matrix.

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.

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

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

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

部门
Biomedical Research

Business Unit
Pharma Research

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

Apply to Job

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

Job ID
REQ-10062447

Technology and Innovation QA Lead

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10062447-technology-and-innovation-qa-lead

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://www.novartis.com/about/strategy/people-and-culture
5. https://talentnetwork.novartis.com/network
6. https://www.novartis.com/careers/benefits-rewards

7. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Basel-City/Technology-and-Innovation-QA-LeadREQ-10062447
8. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Basel-City/Technology-and-Innovation-QA-LeadREQ-10062447