Clinical Quality Assurance - Program Lead

Job ID
REQ-10061585

9月 12, 2025

United Kingdom

摘要

LOCATION: London, UK, Dublin, Rep of Ireland or Barcelona, Spain
ROLE TYPE: Hybrid Working, #LI-Hybrid

As an Associate Director level, Clinical Quality Assurance - Program Lead within Clinical Quality Assurance, you will provide Quality oversight for the end-to-end clinical process for the clinical trials under responsibility to ensure compliance with the Health Authorities requirements, the internal standards and a full adherence to patients ' safety, rights and well-being.

About the Role

Key Responsibilities:

- Proactively provide QA leadership to the business strategy for assigned programs/trials by ensuring considerable organization awareness (e.g. Interrelationship of departments and

business priorities),
- Drive implementation of quality strategy within Global Clinical Team (GCT)/ Clinical Trial Team (CTT) under responsibility
- Regularly monitor the implementation of the annual Quality Plan pertaining to the assigned programs/studies
- Ensure adequate oversight of proactive quality risk management process in the overseen areas including quality risk assessments and submission/inspection readiness activities and ensure that Clinical Trial Process (CTP) are in control
- Provide robust and clear quality oversight in the following areas of clinical development:
    - Support/collaborate with key stakeholders (e.g., Country Development Quality (CDQ), Development Units (DUs), GCT and/or CTT members) to ensure that risks are detected and remediated.
    - Support core governance for quality incident management for critical and major deviations pertinent to the programs being assigned and ensure timely escalation when required.
    - Provide Good Clinical Practice (GCP) guidance to day-to-day questions arising from Clinical trials deliverables.
    - Collaborate with Country Development QA and External Service Providers (ESP) QA to drive initiatives relevant to internal monitoring and outsourced activities Quality oversight.
    - Support inspections preparation and facilitation in collaboration with other QA groups within Research & Development Quality (RDQ).
    - Support audits and inspections follow-up activities including Corrective & preventative Actions (CAPA) preparation.
- Actively leverage audit/inspection outcomes/trends to sustain improvement in clinical trials conduct.
- Active participation in continuous improvement initiatives (including Work streams) and ensure that areas identified as weaknesses are properly being addressed and executed for sustainability
- Be QA point of contact for the defined trials and attend the meetings and ensure quality is embedded in the decision taking processes.

Essential Requirements:

- Bachelor ' s degree in life science or healthcare field required. Advanced degree or equivalent education/degree in life sciences/healthcare preferred (PhD/MD/ PharmD/ Masters).
- 7 years of involvement in regulated activities (GCP/ Pharmacovigilance (PV)), clinical development and/or QA positions.
- Broad understanding of global expectations of Health Authorities in the area of Clinical Development and profound understanding of the science of product
- development.
- Ability to work independently and in a global/matrix environment.
- 3 or more years ' experience in managing projects.
- Strong skills in GCP, quality and/or clinical development

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
Development

Business Unit
Innovative Medicines

地点

United Kingdom

站点
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

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-10061585

Clinical Quality Assurance - Program Lead

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10061585-clinical-quality-

assurance-program-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/London-The-Westworks/Clinical-Quality-Assurance---Program-LeadREQ-10061585-1
8. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/London-The-Westworks/Clinical-Quality-Assurance---Program-LeadREQ-10061585-1