

Clinical Quality Assurance - Program Lead (Associate Director)

Job ID

REQ-10078182

May 29, 2026

LOC_IE

About the Role

Major Accountabilities:

- 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. Lead 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).
- Extensive experience of involvement in regulated activities (GCP/ Pharmacovigilance (PV)), clinical development and/or QA positions with strong understanding on clinical trials
- 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.
- Experience in managing projects.
- Strong skills in GCP, quality and/or clinical development

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Role Requirements

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Division

DIV_GD

Business Unit

Quality

Location

LOC_IE

Site

Dublin (NOCC)

Company / Legal Entity

IE02 (FCRS = IE002) Novartis Ireland Ltd

Functional Area

FCT_QA

Job Type

Full time

Employment Type

Regular

Shift Work

No

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