# Associate Director Medical QA

Job ID
REQ-10036985
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Irlanda

## Resumen

Our Development Team is guided by our purpose: to reimagine medicine to improve and extend people's lives.

To do this, we are optimizing and strengthening our processes and ways of working. We are investing in new technologies and building specific therapeutic areas and platform depth and capabilities – all to bring our medicines to patients even faster.

We are seeking key talent, like you, to join us and help give people with disease and their families a brighter future to look forward to.

Apply today and we can thrive together!

This role will be based in Dublin, Ireland in a hybrid working approach.

## About the Role

Are you ready to become the Associate Director, Medical Quality Assurance? You will safeguard quality and compliance in the medical environment for key medical activities focusing on strategic and operational governance provided to Global Medical Affairs, Global Clinical Operations and Patient Safety & Pharmacovigilance. This means providing strategic quality oversight to ensure compliance with the Health Authorities requirements, the internal standards and a full adherence to patients' safety, rights and well-being. The incumbent will undertake risk analysis, take critical decisions together with internal stakeholders, ensuring clinical/medical trials have no delays whilst maintaining high quality level data. So, if taking full ownership of the quality aspects of the assigned clinical trials, leads the due diligence efforts for assigned programs and drive a culture of quality then this role sounds very suited to you.

**Major accountabilities but not limited to:**

- Ensure adequate quality oversight for all GxP and regulatory obligations for Interventional Studies (INT), Non-Interventional Studies (NIS), Managed Access Programs (MAPs), Investigator Initiated Trials (IITs) and Research Collaborations (RCs). Strong business collaboration, paying specific attention to the interfaces with GMA and PS&PV.
- Provide quality support and oversight for supported activities by e.g. actively participating in respective governance or other boards as appropriate.
- Contribute quality advice and input to the development and implementation of the annual Quality Plan related to supported activities.

- Contribute quality expertise to processes, systems and standards related to supported activities to ensure compliance to Novartis requirements and to sustain compliance excellence.
- Support inspection and audit activities in covered areas as assigned.  Assist with support of Health Authority inspections.
- Provide quality and compliance support and guidance during the development and execution of corrective and preventive actions (CAPA), as follow-up to inspection and audit findings or any other activities identifying quality and compliance gaps to current or future regulatory requirements and Novartis standards.
- Provide quality expertise to the management of quality issues, deviations and escalations in the supported areas including investigation and root cause analysis. Review and approve the content of quality issues, deviations and escalations with relevant actions and approve action closure.

**Key performance indicators:**

- Quality processes, systems and standards for business partner activities are supported.
- Quality and compliance support is adequately provided for business partners' governance activities.

## Your Experience:

- Degree in Life Sciences or related scientific discipline. Higher degree desirable.
- Excellent written and verbal English communication skills
- At least 8 years QA / PV / clinical / regulatory affairs / pharmaceutical industry / Health Authority experience.
- GCP/PV auditing or inspection experience and Heath Authority interactions a plus.
- Experience in QA governance a plus.
- Ability to travel to support inspections.
- Ability to independently manage and objectively evaluate complex compliance issues with minimal supervision; excellent problem solving, decision making and prioritization skills.
- Quality mindset and excellent quality and compliance leadership and facilitation skills.
- Extensive knowledge of GCP, GPP and PV regulations, guidelines and policies.
- Ability to lead teams and operate successfully in various team capacities and diverse cultural environments.
- Ability to deputize for the Global Head Medical QA as needed.

**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

## Commitment to Diversity & Inclusion:

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

## 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

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**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
Development
Business Unit
Innovative Medicines
Ubicación
Irlanda
Sitio
Dublin (NOCC)
Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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