

Associate Director, Clinical Processes & Solutions

Job ID
REQ-10022689
Oct 14, 2024
Ireland

About the Role

Your responsibilities will include;

- Drive the update of clinical document templates such as Clinical Trial Protocol, Investigator Brochure, Clinical Data Review, and Clinical Development Plan according to clinical guidance
- Participate and represent Clinical Development on important strategic cross-functional projects as defined by Clinical Development Leadership Team.
- Drive cross Clinical Development and Global Line Function alignment of processes as part of the deliverables of Clinical Development and drive implementation at the Unit level.
- Lead QA/SOP activities within Clinical Development, which includes coordinating Subject Matter Experts (SME) identification; applying clinical applicability; performing collegial reviews of SOPs, templates and processes
- Can serve as a Lead SME or as an SME for clinical process-related work such as protocol deviations
- Drive best practices by identifying clinical training needs and development opportunities. Identify cross-functional issues, gaps and lead global process improvement work streams as applicable
- In collaboration with QA, responsible to implement quality initiatives as needed: inspection readiness, records tracking, support audits preparation and follow up.
- Drive efficiency and track performance against metrics
- From a people standpoint, work with the Clinical Development to make sure that Clinical Development Leadership is informed at all points about key issues and has access to information when needed

Minimum requirements

- Advanced degree in life sciences/ healthcare (or clinically relevant degree) is required. Master, PharmD, or PhD strongly preferred
- Strong understanding of Pharmaceutical Development processes
- ≥5 years technical and operational experience in planning, executing, reporting and publishing clinical studies in industry or Academia
- Thorough knowledge of Good Clinical Practice
- Strong scientific background in basic and clinical research
- Strong skills in leading and managing cross-functional projects with significant business impact.
- Excellent interpersonal and communication skills with influencing, negotiation and conflict resolution skills
- Excellent analytical, process-oriented and data driven mind-set.
- Act as change agent and actively generate and foster creativity and innovation in CD
- Strong project management skills
- Leadership presence with the ability to present and interact with senior management

Why Novartis? Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to

become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <https://www.novartis.com/careers/benefits-rewards> 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.

Role Requirements

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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Division

Development

Business Unit

Innovative Medicines

Location

Ireland

Site

Dublin (NOCC)

Company / Legal Entity

IE02 (FCRS = IE002) Novartis Ireland Ltd

Functional Area

Research & Development

Job Type

Full time

Employment Type

CDI

Shift Work

No

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