

Associate Director, Clinical Processes & Solutions

Job ID REQ-10022689

10月 14, 2024

Ireland

摘要

When we put our heads together, we can do brilliant work. And when we do brilliant work, we can achieve remarkable things for patients as we positively transform healthcare. We are looking for a Associate Director Clinical Processes & Solutions.

The Associate Director Clinical Processes & Solutions is responsible for leading and driving operational and scientific excellence through clinical process improvement across the portfolio. This includes but is not limited to actively driving updates of standard operating procedures, templates, guidance, and trainings. This position also serves as a clinical representative on cross-functional governance boards and development initiatives (including other line function initiatives).

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

About the Role

- 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

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部门 Development
Business Unit Innovative Medicines
地点 Ireland
站点 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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