

Global Regulatory Publishing Associate

Job ID
REQ-10027047
Nov 13, 2024
Ireland

About the Role

This role offers hybrid working, requiring 3 days per week in person in our Dublin, Ireland office. Ad-hoc working hours to overlap the US as required.

Major accountabilities:

- Accountable for electronically preparing, publishing, quality reviews, validation, dispatch & archiving activities related to clinical deliverables and global regulatory submissions.
- Produce high quality, clinical deliverables, and global submission outputs per agreed timelines and in compliance with worldwide HA requirements, internal working practices and guidelines.
- Act in a global capacity, and partner with various cross-functional stakeholders (e.g., Regulatory Affair Managers, Regulatory CMC Managers, Clinical Trial Leads, Nonclinical Managers, Safety and Quality associates as well as with Clinical Submission Managers, RA Operations Submission Managers and a publishing team located in multiple regions (e.g., US, EU, UK and India).
- Support the implementation of new technology, tools, and processes, contribute to ongoing initiatives and training, and help identify continuous improvement opportunities.
- Support submission resource planning activities, as required.

Essential Requirements:

- Bachelor's degree in life sciences or relevant discipline.
- Fluency in English
- Clinical Report and Global Submission dossier publishing/compilation experience in the pharmaceutical or related industry.
- Experience with electronic clinical document publishing standards/formats, electronic and global regulatory submission publishing standards/formats (e.g. eCTD, EU CTR).
- Working knowledge of publishing tools (e.g., DXC, eCTD Xpress, Veeva), global submission validation tools, Document Management systems, Toolbox, HA electronic submission gateways, IRIS, CTIS, MS Office tools
- Familiarity with global Clinical and Regulatory HA requirements (e.g., FDA, ICH, EMA, MENA region, CH, MHRA)
- Strong interpersonal and project management skills, and experience working in a complex, global cross functional organization.
- Highly motivated, organized, and detailed oriented team player
- Analytical thinker with excellent problem-solving skills and the ability to adapt to changing priorities and deadlines.

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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 & Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>

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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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>

Division

Development

Business Unit

Innovative Medicines

Location

Ireland

Site

Dublin (NOCC)

Company / Legal Entity

IE02 (FCRS = IE002) Novartis Ireland Ltd

Alternative Location 1

Ireland

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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