Global Regulatory Publishing Specialist

Job ID
REQ-10011625
Sep 02, 2024
Vereinigtes Königreich

Summary

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

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

We are seeking key talent, like you, to join us in evolving the future of Regulatory Operations and give our patients and their families a brighter future to look forward to.

Apply today and welcome to where we thrive together!

The Role:

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

As a Global Regulatory Publishing Specialist, you will be accountable for all clinical document/report and submission dossier publishing, verification, dispatch, and coordination of HA compliant, worldwide HA submissions in support of Novartis global product portfolios.

About the Role

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.

Your Experience:

- Bachelor's degree in life sciences or relevant discipline.
- 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.
- Ability to readily adjust to change in a fast-paced environment and multitask.
- Positive attitude and ability to effectively collaborate with peers, stakeholders, cross-functional colleagues in a global team environment.
- Strong technical skills
- Strong communication and business writing skills.
- Fluency in English

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.

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Job Type
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