Global Regulatory Submission Manager

Job ID
REQ-10018934
Sep 03, 2024
Vereinigtes Königreich

Summary

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 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 and help give people with disease 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 India/US time zone as required. Please note we do not provide sponsorship or relocation support for this role.

As Global Regulatory Submission Manager you will be responsible for managing the delivery of cross functional submission documentation, overseeing submission publishing activities including the dispatch of HA compliant, worldwide regulatory submissions in support of Novartis global product portfolios.

About the Role

Major accountabilities:

- Lead and manage multiple and simultaneous global regulatory submissions in eCTD and non-eCTD formats components.
- Drives cross-functional teams focused on the planning, overseeing compilation activities, and dispatch of worldwide regulatory HA submissions, anticipating technical obstacles and developing solutions.
- Negotiate timelines, manage global stakeholder
expectations, publishing team and leadership communications.
- Provide guidance to global project teams on worldwide HA submission format/requirements, filing strategy, eCTD document lifecycle management and submission compilation workflows
- Plan, manage and track delivery of submission components, coordinate submission publishing activities with publishing team, organize submission review and approvals.

- Partner across multiple cross functional functions, troubleshoot submission technical / quality issues and manage the efficient use of global resources. Organize, lead and participate in both internal and external stakeholder meetings (including acquisitions, partnerships and divestiture efforts).
- Develops/implements solutions to create efficiencies and effectiveness.

- **Your Experience:**
- Bachelor's degree in life sciences or relevant discipline.
- Regulatory affairs or regulatory submissions related experience in global HA regulatory formats and submissions publishing activities.
- Familiarity with the drug development process, global HA regulations/ guidance e.g. FDA, ICH, EMA, MENA, CH.
- Proven enterprise mindset and quality driven
- Strong interpersonal/project/time management skills and experience managing through complexities in a fast-paced, global cross functional organization.
- Effectively works as part of a team environment or independently.
- Strong project management skills: Analytical thinker with excellent problem-solving skills and the ability to adapt to changing priorities and deadlines
- Decisive, solution-oriented, pragmatic, customer focused, readily adapts to changing priorities and composed under pressure.
- Working knowledge of publishing tools (e.g., DXC (eCTDxpress/Publisher),Veeva), global submission validation tools, Document Management systems, Toolbox, HA electronic submission gateways, IRIS, CTIS, MS Office tool
- Familiarity with submission publishing/compilation principles is ideal
- Fluency in English.

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

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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Functional Area
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Job Type
Full time
Employment Type
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Shift Work
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inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

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