Global Regulatory Submission Manager

Job ID
REQ-10011623
Nov 04, 2024
Regno Unito

Sommario

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!

About 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.

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.

Essential Requirements:

- 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.
- 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.
- Demonstrated negotiation skills and a positive attitude.
- 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.

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 & 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**

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

Divisione
Development
Business Unit
Innovative Medicines
Posizione

Regno Unito
Sito
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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