NOVARTIS

Associate Director, Global Regulatory Submission Management

Job ID
REQ-10011620
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 to 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.

The Associate Director, Global Regulatory Submissions Manager is a expert level position in Regulatory Affairs Operations - accountable for independently managing the delivery of global cross functional HA submission documentation and format, oversee, guide and direct publishing activities and dispatch of compliant, complex worldwide regulatory submissions in support of NVS global product portfolios.

About the Role

Major accountabilities:

- Manages multiple, large and complex global regulatory submission projects in eCTD and non-eCTD [e.g., NDA/BLA/INDs, MAAs (CP, MRP, Nees), HA AtoQ, Compliance submissions, etc.] efficiently, accurately and simultaneously.
- Key contributor and decision driver in submission management activities related to acquisitions, partnerships and divestitures, point of contact for regulatory agency inspections, and other miscellaneous regulatory operational activities.

- Provides expert guidance to project teams related to worldwide HA submission structure/format/requirements, submission filing strategy, eCTD document lifecycle management and submission compilation workflows.
- Lead, coach and mentor peers and colleagues.
- Develops and authors training materials and leads efforts to implement training to ensure optimal use of templates, processes, and tools critical related to regulatory submission activities.
- Expert advisor in evaluation, selection, and implementation of technologies and processes related to submission planning, publishing, assembly, and archiving (as needed).
- Submission Management Expert on key internal initiatives, Health Authority meetings and various industry forums/conferences, as required.
- Excellent ability to troubleshoot and assess technical/quality issues relating to compilation, validation, and dispatch of global submission outputs with accuracy.

Your Experience:

- Bachelor's degree in Life Sciences or a relevant discipline. Master's degree preferred.
- Extensive experience and knowledge of the Regulatory Affairs environment, regulatory submission format and worldwide HA requirements and publishing principles.
- Extensive knowledge of drug development process
- In depth 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
- Strong interpersonal and negotiation skills, excellent communicator, and presenter.
- Expert level project management skills and experience leading meetings, cross functional teams and driving change.
- Must be able to innovate, analyze and solve problems effectively, accurately, and independently.
- Fluent in English (both written & oral). Additional language an asset.

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.

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

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Innovative Medicines
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State
London
Site
London (The Westworks)

Company / Legal Entity
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Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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List of links present in page

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2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/about/strategy/people-and-culture
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7. https://www.novartis.com/about/strategy/people-and-culture

8. https://talentnetwork.novartis.com/network
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