Regulatory Publishing Associate

Job ID
REQ-10048407

4月 23, 2025

United Kingdom

摘要

Ensures a controlled documentation system, record retention, and information services including electronic records retention processes in accordance with regulatory requirements. Ensures compliance to the requirements from regulatory agencies. Maintains the technical and non-technical documentation change system. Assures procedures are in place to classify and maintain records. Interprets & enforces all documentation formatting, standards, policies, and operating procedure requirements. May identify submission components, communicate documentation standards and coordinate assembly of regulatory dossiers. May analyze and evaluate data, extract pertinent information, prepare information abstracts and executive summaries of material searched. May maintain extensive knowledge of product information and continuous contacts with local, regional, and divisional customers.

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:

- Manages medium to small level global regulatory submission projects.
- Provide submission and contribute to the technical related regulatory strategy, intelligence and knowledge required to develop, register, and maintain global products.
- Contribute to strategic and technical input /support to drive implementation of global systems, tools and processes to support global development projects and/or marketed products.
- Frequent internal company and external contacts.
- Represents organization on specific projects -Works on problems of moderate scope where analysis of situations or data requires a review of a variety of factors.
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Minimum 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.

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.

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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

部门
Development

Business Unit
Universal Hierarchy Node

地点
United Kingdom

站点
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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