U NOVARTIS

Regulatory Translation Coordinator

Job ID REQ-10042922

3月 18, 2025

India

摘要

Supports the provision of timely, high-quality regulatory translations essential for product registration, maintenance, and launches worldwide.

problem-solving, Office proficiency, organization, adaptability, commitment.

Project management, vendor management, proficiency in any additional language other than English (good to have)

-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

Administrative support

- Performs general coordination and administrative tasks to support the Regulatory Translation Hub functioning.
- Grants access to relevant CO associates to hub repository folders and keeps access information updated.
- Organizes and archives documentation in team repositories, including dispatch emails and surveys as required.
- Ensures renewal of licenses regarding translation-related software and indexing tools, including Trados Studio, Verifika, and dtSearch
- Updates team lists and trackers, e.g. general job list, invoicing tracker, QC tracker, quality incidents tracker, email contact lists, CO job list tracker.
- Assists team members with the preparation of reports and presentations.

PO creation and invoice management

- Manages invoices and creates POs on behalf of the Head of regulatory translations.
- Maintain invoice records.
- Addresses invoicing-related matters with vendors or service providers.

Operational support

- In the absence of Regulatory translations project managers or at their request, assigns urgent jobs to appropriate vendors, and performs quick format checks on outsourced translations before delivery.
- Provides support with uploading and downloading files from relevant databases as necessary.

SKILLS

Qualifications and experience

- Certified Administrative Professional (CAP) certification or an equivalent administrative degree.
- Fluency in English (both written and spoken). Proficiency in other languages (optional)
- At least 3 years of administrative experience, especially in Regulatory Affairs.

Skills required

- Strong problem-solving skills.
- Proficiency in Office tools (Excel a must).
- Excellent organizational skills.
- Adaptability.

- Commitment to quality.
- Good interpersonal skills.
- Highly committed and team oriented.

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部门 Development

Business Unit Innovative Medicines

地点 India

站点 Hyderabad (Office)

Company / Legal Entity IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area Research & Development Job Type Full time

Employment Type Regular

Shift Work No

Apply to Job

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to <u>diversityandincl.india@novartis.com</u> and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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