Global Regulatory Submission Manager

Job ID
REQ-10018585
Aug 12, 2024
India

Summary

-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 and 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

Major accountabilities:

- Manages multiple, large and complex global regulatory submission projects.
- Develop and 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.
- A seasoned, experienced professional with a full understanding of area of specialization; resolves a wide range of issues in creative ways.
- This job is the fully qualified, career-oriented, journey-level position .
- Works on problems of diverse scope where analysis of data requires evaluation of identifiable factors.
- Demonstrates good judgment in selecting methods and techniques for obtaining solutions.
- Networks with senior internal and external personnel in own area of expertise.
- Contributes to many cost center goals and objectives; may contribute to service line goals -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Adherence to Novartis policy and guidelines -Project and stakeholder feedback

Minimum Requirements:
Work Experience:

- Cross Cultural Experience.

- Managing Crises.
- Functional Breadth.
- Project Management.
- Collaborating across boundaries.
- Operations Management and Execution.

Skills:

- Data Analysis.
- Documentation Management.
- Lifesciences.
- Project Management.
- Regulatory Compliance.

Languages :

- English.

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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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

Division
Development
Business Unit
Innovative Medicines
Location
India
Site
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
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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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