

Document Quality Manager

Job ID

387596BR

May 21, 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 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.
- Write, edit and /or manage the production of high quality clinical documentation (e.g. Clinical Study Reports & Summary Documents) for submission to regulatory authorities in support of marketing applications.
- Developing professional expertise, applies company policies & procedures to resolve a variety of issues.
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- 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.
- Refers to established policies & procedures for guidance.
- Contributes to some cost center goals & objectives -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 & stakeholder feedback

Minimum Requirements:

Work Experience:

- Cross Cultural Experience.
- Operations Management and Execution.
- Project Management.
- Functional Breadth.
- Collaborating across boundaries.

Skills:

- NA.

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.

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<https://www.novartis.com/about/strategy/people-and-culture>

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Division

Biomedical Research

Business Unit

Pharma Research

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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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 diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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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