Document Quality Manager

Job ID
387596BR
Mai 21, 2024
Inde

Résumé

-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. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

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

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

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Emplacement
Inde
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Hyderabad (Office)
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IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Recherche & Développement
Job Type
Full time
Employment Type
Regular
Shift Work
No
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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 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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