Document Quality Manager

Job ID
387596BR
Mai 21, 2024
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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.

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Institutes for BioMedical Research (NIBR)

Business Unit
Pharma Research
Standort
Indien
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Hyderabad (Office)
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Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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