

Document Quality Manager

Job ID

387596BR

May 21, 2024

India

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.
- .
- 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.

Role Requirements

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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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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