

# Regulatory Coordinator

Job ID  
REQ-10022239  
Sep 16, 2024  
Indien

## Zusammenfassung

-Contributes and support the development of submission of product registration, progress reports, supplements, amendments, and/or periodic experience reports. Supports all registration activities of the Department to ensure compliance with the requisites of the local pharmaceutical regulatory environment.

## About the Role

### Major accountabilities:

- Achieve the best product registration with commercially attractive labelling in accordance with registration plan -Maintain and secure product license in terms of CMC/CDS/safety update according to local regulations/law/guidelines, company strategy and global compliance -Ensure compliance with NP4, KRPIA code of conduct, relevant regulations and laws for related CPO activities (DRAGON update, RMP, packing materials, promotional materials/activities, PMS/drug safety reporting etc.) -Foster and maintain good relations with internal and external stakeholders -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:

- Project & stakeholder feedback -Product license update in terms of CMC in agreed timeline -Adherence to Novartis policy and guidelines

### Minimum Requirements:

#### Work Experience:

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

#### Skills:

- Analytical Skill.
- Clinical Trials.
- Collaboration.
- Detail Oriented.
- Lifesciences.
- Project Planning.

- Regulatory Compliance.

**Languages :**

- English.

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Abteilung

Development

Business Unit

Innovative Medicines

Ort

Indien

Website

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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[diversityandincl.india@novartis.com](mailto: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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