NOVARTIS

Regulatory Affairs Associate

Job ID
REQ-10083967
июл 22, 2026
Индия
Available in: English | Deutsch | Español | Français | Italiano | 日本語 | Nederlands | Русский | Slovenščina | Türk | 中文

Сводка

-Provides effective operational and regulatory support to Novartis as well as to regional/global organizations for assigned regulatory submission and maintenance activities, including preparation and submission of regulatory dossiers, maintenance of regulatory databases and archives and artwork-related activities.

About the Role

Major accountabilities:

- Coordinates and prepares high quality submissions of regulatory dossiers for assigned products -Achieve the CTA/NDA submission on the targeted date; -Achieve the approval of CTA, NDA and other related supplementary application on the targeted date; -Ensure license renewal Submission and approval on time; -Ensure CMC/BPI/PSUR/RMP in line with NMPA regulation and Novartis internal policies; -Ensure registration master file update -Assist to coordinate f2f meeting with CFDA/CDE for new project discussion -Communicate the questions referred by HAs timely and smoothly; -Timely update and communicate the registration status to the line manager -Timely order and tracking the registration sample, dossier, certificates…; -Start to establish good communication and relationship with key stake holders.
- Get familiar and with company and department SOP and working procedures -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:

- Timely accomplishment of assigned tasks in required quality.
- Compliance with regulations and internal procedures -Relevant databases and archives up -to -date.

Minimum Requirements:
Work Experience:

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

Skills:

- Clinical Trials.
- Collaboration.
- Databases.
- Detail Oriented.
- Lifesciences.
- Project Planning.
- Regulatory Compliance.

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Development
Business Unit
Development
Место
Индия
Сайт
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

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.

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