NOVARTIS

RA GRSSC Interns

Job ID
REQ-10085036

8月 03, 2026

India

Available in: English

摘要

-To be used only for Intern or Student positions. Please enter specific details in the Additional Specifications Details field

About the Role

Major accountabilities:

- **Major Accountabilities** (Describe the main results of the role to be achieved)1. Provide operational support to Health Authority submissions including Annual Reports, DSUR, New Protocol Submissions, Protocol Amendment , and New Investigator Submissions to ensure timely submissions in accordance with the FDA regulations2. Conduct monthly reconciliation to ensure timely submissions are in accordance with FDA regulations as well as

meeting all Novartis requirements for submission-related activities (Eg. TOOs, VDRs, drug shipment ticket review (US)).3. Support regulatory compliance activities, including timely review and updates to product specific information as provided by program team representative into a compliance database (DRAGON), when applicable4. Assist regulatory managers to support compilation and release of submissions to regulatory agencies as well as submission-related activities for regulatory responses to health authorities5. In collaboration with the clinical/regulatory teams, compile, integrate and publish clinical/regulatory documents with word processing, electronic publishing using publishing software and archive in the document management systems.6. Maintain basic knowledge of current electronic publishing standards, regulatory guidelines, and legal requirements.7. Support regulatory compliance activities, including entering product specific attributes as provided by program team representative into Regulatory Information Management System (RIM) (e.g. DRAGON).8. Provide support as needed for routine Health Authority (HA) submissions including Periodic Reports, Renewal, Portfolio transformation (PT) Submissions (non-EU countries), New Product Planning (NPP) (non EU countries) etc. and procurement of registration samples and certificates, to ensure accurate and timely submissions to HAs.

Key performance indicators:

- 1. Timely tracking and reconciliation of routine submissions performed.
- 2. Timely completion of compliance activities and tracking.
- 3. Timely completion of Drug Shipping Process (US).
- 4. Timely completion of FDA forms and cover letters for CTD Module #1for maintenance submissions
- 5. Timely approval of Clinical Supplies/Labels.6. Completion of all assigned trainings

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)

部门
Development

Business Unit

Development

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Others

Job Type
Full time

Employment Type
Early Career (Fixed Term)

Shift Work
No

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Apply to Job

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