

# BR Submission Management, Specialist

Job ID

REQ-10022909

19. September 2024

Indien

## Summary

Lead the BR cross-functional submission sub-teams ensuring that our regulatory dossiers are prepared in a timely manner and in compliance with Regulatory Authority regulations, guidance, SOPs, working practices and quality standards.

## About the Role

- Manage activities associated with the preparation of Investigator Brochure (IB) annual updates within Biomedical Research (BR) in compliance with internal SOP and health authority requirements.
- Organizing and chairing the kick-off meeting to establish the level of update and contributors across Biomedical Research Translational Medicine and Development.
- Leads subsequent IB planning discussions, creating, and maintaining a comprehensive project plan, identifying key interdependencies/rate limiting steps, capturing actions and key activities, target governance board review, content delivery timelines, and finalization date for IB, executing this plan according to agreed timelines.
- Manage stakeholder engagement, and ensure that any issues, risks, or impact due to changes in strategy and/or timelines are assessed quickly and remediated.
- Timely escalation (as per agreed process) if the IB will not be finalized within the annual update period.
- Collaboration with Document Quality Management (DQM) team and other key stakeholders e.g. Regulatory Operations, to ensure strategic resource planning of downstream activities allowing IB to be finalized in accordance with targeted timelines. Completion of all internal documentation and distribution of the final IB package in accordance with SOP and internal guidance.
- Timely update of all internal tracking systems.
- Manage submission related activities associated with the preparation of Clinical Trial Application/IND submissions following internal working practice, guidance, and SOPs to ensure the delivery of high-quality submission documents to regulatory operations.
- Including creation of requisite templates, drafting of timelines, ensuring documents are finalized according to internal process via source data verification and formatting checks in accordance with agreed timelines, in addition to the oversight of the preparation/delivery of supportive documentation and stakeholder management.
- May manage the preparation of Biomedical Research components (preclinical and early phase clinical) of supplementary submissions.
- May distribute workload to and collaborate with external vendor on documentation specific activities.
- Regularly maintain supporting IT systems/trackers to ensure accuracy of information by liaising with stakeholders.

## Education / Background:

Undergraduate degree, preferably in a scientific discipline or life science background or equivalent work experience

## Years of Experience:

Minimum of 1-2 years' experience working in a regulated, life science environment (pharmaceutical, biotechnology)

## Key Competencies:

- Comprehensive understanding of relevant technical requirements for electronic registration submissions (eCTD) e.g. Bookmarking, hyperlinking, cross referencing etc.
- Demonstrated ability to work successfully within a matrix environment and influence cross functional teams.
- Experience with and ability to understand compliance practices which include GxPs and Standard Operating Procedures
- Proficient in Microsoft Office suite in addition to SharePoint.
- Strong oral and written communication skills and customer service skills and organizational skills.
- Self-starter with a proven ability to prioritize work, multitask, display customer centricity, and manage time appropriately, in a fast paced/high volume environment.
- Demonstrated organizational skills.

## Languages:

Fluent oral and written 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>

**Join our Novartis Network:** Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

<https://talentnetwork.novartis.com/network>

**Benefits and Rewards:** Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

Aufteilung

Biomedical Research

Location

Indien

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

[Apply to Job](#)

## 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](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.

iframe{ width: 100%; margin-top: 3rem; } @media screen and (max-width: 767px){ iframe{ height: 30vh !important; } } @media screen and (min-width: 768px){ iframe{ height: 34vh !important; } }

Job ID

REQ-10022909

## BR Submission Management, Specialist

[Apply to Job](#)

---

**Source URL:** <https://www.novartis.com/ch-de/careers/career-search/job/details/req-10022909-br-submission-management-specialist>

### List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://talentnetwork.novartis.com/network>
3. <https://www.novartis.com/careers/benefits-rewards>
4. [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis\\_Careers/job/Hyderabad-Office/BR-Submission-Management--Specialist\\_REQ-10022909](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/BR-Submission-Management--Specialist_REQ-10022909)
5. <mailto:diversityandincl.india@novartis.com>
6. [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis\\_Careers/job/Hyderabad-Office/BR-Submission-Management--Specialist\\_REQ-10022909](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/BR-Submission-Management--Specialist_REQ-10022909)