Expert Regulatory Writer

Job ID
REQ-10056707
Jul 04, 2025
India

Summary

To write, review and manage the production of high quality clinical and safety documentation for submission to regulatory authorities in support of To write, review and/or manage the production of high quality clinical and safety
documentation for submission to regulatory authorities in support of marketing applications. To provide authoritative documentation-related consultancy to other line functions. To coach/mentor and/or train less experienced writers.

About the Role

Major accountabilities:

- To author, review and/or independently manage high quality clinical and safety documents: complex Clinical Study Reports (CSR), Risk Management Plans (RMP), complex CTD submission documents (clinical overviews, summaries of clinical efficacy and safety, summaries of clinical pharmacology and biopharmaceutics), other documents for health authorities (e.g., Briefing Books, answers to questions).
- Lead writing team for complex submissions, actively contributing to key messaging and pooling strategy, providing expert content guidance for clinical portions of the CTD, and ensuring compliance of documentation to internal company standards and external regulatory guidelines.
- Ad-hoc member of Clinical Trial Team (CTT) / extended member of Safety Management Team (SMT). Core member of multiple Clinical Submission Teams (CST). Extended member of Global Clinical Teams (GCT).
- Input into planning of data analyses and presentation (statistical analysis plan review and meetings) used in CSRs, submission documents and/or answers to questions.
- Documentation expert in GCTs and CSTs to ensure compliance to internal company standards and external regulatory guidelines. Provide content and strategic expertise for clinical portions of the CTD.
- Program Writer for large and/or complex programs ensuring adequate medical writing resources are available for assigned program and consistency between documents.
- Lead process improvement in RWS and cross-functional initiatives and/or activities.
- Can identify training needs to foster high level of performance within RWS. Coach and/or mentor less experienced writers.
- Leader in cross-functional communication to optimize feedback and input towards high quality documents.
- Maintain audit, SOP and training compliance.

Key performance indicators:

- Delivery of high quality clinical and safety documents in time and in compliance with internal and external

standards, according to RWS metrics.
- Completion of an adequate volume of work (taking into account complexity) per year in accordance with the Key Performance Indicators.

Minimum Requirements:
Work Experience:

- ≥ 6 years medical writing experience or other relevant pharma industry experience combined with scientific and regulatory knowledge, plus expert knowledge of medical writing processes.
- Expert knowledge of and repeat experience in global regulatory environment and process (key regulatory bodies, key documents, approval processes, safety reporting requirements).
- Expert knowledge, extensive experience, and demonstrated record of accomplishment in global registering of drugs.
- Excellent communication skills (written, verbal, presentations) • Expert knowledge of biostatistics principles.
- Proven ability to prioritize and manage multiple demands and projects.
- Demonstrated ability to define and solve complex problems (“Problem-solver”)
- Broad knowledge and future oriented perspective
- Proven ability to drive and manage organizational and team performance across cultures.
- Proven track record in matrix environment
- Repeat experience in managing global, cross-functional teams or complex global projects.
- Demonstrated ability to motivate and coach people.

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

Division
Development
Business Unit
Innovative Medicines
Location
India
Site
Mumbai (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Alternative Location 1
Hyderabad (Office), India
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 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.

Job ID
REQ-10056707

Expert Regulatory Writer

Apply to Job

Source URL: *https://prod1.id.novartis.com/id-en/careers/career-search/job/details/req-10056707-expert-regulatory-writer*

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/Mumbai-Office/Expert-Regulatory-Writer_REQ-10056707
5. mailto:diversityandincl.india@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Mumbai-Office/Expert-Regulatory-Writer_REQ-10056707