NOVARTIS

Document Quality Manager

Job ID
390029BR
May 19, 2024
India

Summary

-Ensures a controlled documentation system, record retention, and information services including electronic records retention processes in accordance with regulatory requirements. Ensures compliance to the requirements from regulatory agencies. Maintains the technical and non-technical documentation change system. Assures procedures are in place to classify and maintain records. Interprets and enforces all documentation formatting, standards, policies, and operating procedure requirements. May identify submission components, communicate documentation standards and coordinate assembly of regulatory dossiers. May analyze and evaluate data, extract pertinent information, prepare information abstracts and executive summaries of material searched. May maintain extensive knowledge of product information and continuous contacts with local, regional, and divisional customers.

About the Role

Perform assessment, quality control and publishing of NIBR scientific documents to ensure consistency and to achieve the technical quality to comply with internal and external guidelines. Oversee external service providers as related to areas of responsibility. Collaborate to support timely compilation of high-quality submissions for Global Health Authorities.

• Perform technical (Novstyle) quality control (QC) of NIBR submission documents (simple to medium complexity) to ensure both content and format fulfil requirements. Collaborate with globally located NIBR scientific personnel to ensure finalization of the documents, according to timelines and quality requirements.
• May compile, integrate and publish applicable NIBR documents with state-of-the-art word processing, electronic publishing and document management systems in collaboration with the responsible author(s).
• Provide advice on template requirements of NIBR submission documents, to effectively guide the authors on document content. Work with external consultants (vendors) to coordinate outsourced activities related to the processed tasks.
• Manage the NIBR TM preparation activities in support of the NDA annual reports to the FDA, ensuring timely delivery in compliance with the internal SOP and health authority requirements.
• Resolve technical document or workflow issues as applicable on the documents being processed. Maintain support of IT systems/trackers (e.g., Trackwise, Sharepoint) to ensure accuracy of information by liaising with stakeholders.
• Advise authors, newcomers and vendors on requirements, technical formatting processes and the use of Novartis' document management systems.
• Generate ideas on areas for optimization and innovation and assist in process improvement activities related to document quality management and submission management in NIBR.
• Remain abreast of current processes, regulatory guidelines and legal requirements, as relevant.
• Assist in the testing for implementation, enhancement and maintenance of regulatory document systems.

• Provide input as required to content on S&D intranet sites and training materials. Represent S&D on local and/or global teams to provide technical, document or workflow-related expertise as required. Collaborate to provide metrics, KQIs and KPIs.

• Relevant work experience with electronic document management systems and document review.
• Basic understanding of clinical and nonclinical information contained in a submission dossier.
• Demonstrated ability to work successfully within a matrix environment and influence cross functional teams.
• Flexible and detail-oriented approach to documentation management, as appropriate.
• Experience with and ability to understand compliance practices which include GxPs and Standard Operating Procedures.
• Strong oral and written communication skills and customer service mindset.
• Proficient in Microsoft office programs (e.g. MS Word).
• Self-starter with a proven ability to prioritize work, multitask, display customer centricity and manage time appropriately, in a fast paced/high volume environment.

WHY NOVARTIS

769 million lives were touched by Novartis medicines in 2020, and while we're proud of this, we know there is so much more we could do to help improve and extend people's lives.
We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.
We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world's toughest medical challenges. Because the greatest risk in life, is the risk of never trying! Imagine what you could do here at Novartis!
Commitment to Diversity & Inclusion:
Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.
Join our Novartis Network : If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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

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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Division
Biomedical Research
Business Unit
Pharma Research
Location

India
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 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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