NOVARTIS

Document Quality Management, Associate Director

Job ID
REQ-10073841
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Индия

Сводка

Provide business leadership on a specific area of expertise, guidance on solving complex system- and document-issues and drive compliance and efficiency. Support group head in overseeing workload and assignments; supervise associates as assigned and oversee external services providers as related to areas of expertise. Perform and oversee processes and systems to enable contributors to provide timely and accurate input for Biomedical Research (BR) submissions to Regulatory Affairs

About the Role

Major accountabilities:

1. Provide business leadership and oversight over a broad area of expertise (focus area) on projects related to public facing or submission documents and/or systems and tools and work with TM personnel cross-functionally to ensure adherence to processes, quality requirements and timelines.

2. Lead qualification, procurement and quality oversight of external service providers, such as health literacy writers, medical writers, QC reviewers, document publishers and/or data managers and assume responsibility for risk mitigation planning

3. Troubleshoot and identify solutions to complex technical, document and (document management) system-related issues at the request of customers and collaborators which may include the processing of tickets.

4. May serve as Line Function Applicability Representative as assigned, thereby administering the training standards for SOPs and Working Practices relevant to the roles within S&D.

5. Provide DQM-leadership on BR and Global Merger & Acquisition projects by managing and coordinating the activities for the migration and integration of nonclinical documents to Novartis document management systems. Collaborate with key business stakeholders to ensure all aspects of the process are efficient and provide quality documents ready for submissions.

6. Advise on submission documentation and/or document management aspects of asset divestitures and collaborate with Regulatory Affairs, Legal and other business stakeholders as required.

7. Act as data steward for due diligence, data retention etc, as required.

8. Represent the Document Quality Management department in audits and inspections.

9. Identify, explore and implement new systems and tools that prove to be suitable for the benefit of S&D by increasing efficiency and/or accuracy.

10. Lead Subject Matter Expert (SME) in broad area of expertise, provide training and guidance to team members as well as collaborators throughout TM and liaise with stakeholders across one Novartis.

11. Lead initiatives for the evaluation of DQM and/or S&D processes for opportunities to outsource routine activities, increase efficiencies and implement scope expansion that adds value and benefits the business and ensure compliance to new and evolving regulatory requirements.

12. Oversee as content owner departmental training materials and coordinate SME input to ensure accuracy and maintenance of materials

13. Supervise associates as assigned or project-based staff as required; deputize for next level manager or department head on request

14. Maintain expert knowledge of current processes, health literacy and clinical transparency principles, regulatory guidelines and legal requirements, as relevant.

15. Represent S&D, TM or BR on global workstreams and initiatives to provide system, submission or process-related expertise as required.

16. Participate in hiring process, ensuring S&D is able to access and attract top talent as required

17. Collate and perform analysis on group metrics, KQIs and KPIs to support the management of the group’s deliverables and workload.

QUALIFICATION & KEY COMPETENCIES

Education / Background:

Undergraduate degree preferably in a scientific discipline or equivalent work experience

Years of Experience:

5+ years in relevant discipline

Key Competencies:

• Expert level relevant job experience with electronic document management systems and document review.

• Advanced understanding of clinical and nonclinical information contained in a submission dossier.

• Proven leadership skills and strong ability to manage/ lead projects

• Demonstrated ability to work successfully within a matrix environment and influence cross functional teams in a global setting.

• Ability to provide advanced level support for electronic document management and publishing systems.

• Experience with and strong ability to understand compliance practices which include GxPs and Standard Operating Procedures.

• Excellent written and verbal communication skills with superb presentation capabilities.

• Highly proficient in Microsoft office programs (e.g. MS Word).

• Demonstrated ability to prioritize competing business priorities, build cross functional alliances, display customer centricity, effectively manage projects and resources, in a fast paced/high volume environment.

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
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Дивизион
Biomedical Research
Business Unit
Research
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

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

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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