Regulatory Operations Associate

Being Here Matters!

Are you ready to make a real difference in the lives of patients?

We at Gilead are passionate about advancing therapeutics and improving lives. At Gilead you are a part of a rapidly growing science-driven organization, working together to revolutionize healthcare by bringing innovative, urgently needed medicines to patients living with life-threatening diseases. We are energetic leaders and strategic entrepreneurs going above and beyond for patients, inspired by the opportunity to address unmet medical needs.

This is a contract opportunity as a ***Regulatory Operations Associate*** in Mississauga, Canada. Reporting to the Senior Regulatory Operations Associate, you will be a core member of a game changing team that challenges risks by its critical thinking and passion for deep diving. Our diversity of thought and in culture will broaden your skills and expand your outreach in several therapeutic areas making a real difference in the lives of patients.

Job Overview/ Summary

Publishing:

- Our North American publishing team is seeking a new team member to join our highly engaged and close working team.
- As a member of the Regulatory Operations team, this person will contribute to routine daily submission compilation and publishing activities associated electronic submissions.
- This member will publish and validate routine submissions with supervision and involvement of more experienced associates.

Document Processing:

- As a member of Regulatory Operations, this person will also help and advise the Regulatory Affairs (RA) team with routine document processing needs in both Word and Adobe PDF.

Job Responsibilities

Publishing:

- Prepares a variety of routine submissions including utilization of publishing tools for electronic submission generation.
- Performs filing and data retrieval functions as directed, or in conjunction with departmental SOPs.
- Supports current routine electronic initiatives in moving the company forward with electronic submissions and electronic archives.

- Performs workflows and procedures regarding document tracking, indexing, retrieving and disseminating of regulatory agency submissions as defined by Regulatory Operations management.
- Carries out project tasks under the direction of senior colleagues. Provides the status of their ongoing projects and submissions to the manager when required.

Document Processing:

- Helps RA with a variety of routine Word and PDF formatting including utilization of Document Processing supporting tools for submission-ready documentation.

Knowledge and Skills

Publishing:

- Demonstrates proficiency in routine submissions, with high-quality work output that requires limited supervision.
- Demonstrates an understanding of eCTD.
- A consistent demonstration of attention to detail, timeliness, and accuracy is critical.
- An understanding or an ability to learn publishing and other eCTD related software

Document Processing:

- Demonstrates knowledge in routine Word and PDF formatting, with high-quality work output that requires limited supervision.
- Technical knowledge of current systems (Word, Acrobat, document management system, Document Processing supporting tools).

Education and Experience

- 2+ years of relevant experience and a BA or BS.
- 1+ years of relevant experience and an MS.
- Relevant experience includes electronic document management systems, global regulatory submissions, or other experience directly related to Regulatory Operations.

Please e-mail all resumes to: brian.benitez@gilead.com