Job Description
Associate Director Regulatory Operations

Summary

The primary responsibilities of an Associate Director include, but are not limited to, management of the Regulatory Operations group, representation on client project teams, process development, interactions with software developers/vendors, and participation in business development activities/meetings. As appropriate, an Associate Director also may provide support on other project activities.

Major Responsibilities

1. Develop and implement processes and procedures to ensure that all regulatory reports and documents are published and submitted according to ICH, eCTD, and other applicable electronic publishing standards.
2. Manage the Regulatory Operations group.
3. Support the hiring, training, evaluation, and retention of employees within assigned area.
4. Train and mentor new employees.
5. Represent Regulatory Operations in client project teams to support submission planning and ensure coordination of system development activities
6. Liaise with software developers/vendors to procure and implement electronic submission, document control, and other applicable software/systems.
7. Participate in business development activities (ie, respond to RFPs, prepare proposals, work orders).
8. Represent the department during business development meetings and bid defenses as required.
9. Adhere to the requirements of regulatory authorities, ICH GCP, and Impact and client SOPs and guidance documents, as applicable.
10. Establish and maintain good working relationships with client representatives and Impact co-workers.
11. Author or review internal work instructions and standard operating procedures (SOPs) pertaining to submission preparation, QC, and document management.
12. Perform other duties as assigned.

Skills Required

1. Proficient with U.S. and EU submission requirements and associated guidance including but not limited to compiling and publishing eCTD INDs, NDAs/BLAs, and MAAs.
2. Excellent organizational skills, sufficient to multi-task and manage project timelines in an extremely fast-paced environment with changing priorities.
3. Extensive experience using eCTD publishing software and electronic document management systems.
4. Knowledge expert regarding global regulatory submission standards, software validation concepts, and publishing best practices.
5. Proficiency in MS Word, Excel, PowerPoint, Project, Adobe Acrobat, and ISI Toolbox.
6. Independently motivated, detail oriented and good problem solving ability.
7. Ability to learn and interpret Impact policies and procedures.

8. Ability to learn and follow all relevant SOPs (Impact and Sponsor).
9. Knowledge and understanding of relevant country- and region-specific regulations and guidelines.
10. Strong planning and organization skills.
11. Previous experience managing others.
12. Excellent time management skills and ability to meet deadlines.

Working Conditions

Usual office conditions
Travel: Up to 5%
Keyboarding: 50-75%

Education or Equivalent Experience

A Bachelor's Degree or higher with a minimum of 10 years of experience in a pharmaceutical company, contract research organization, (CRO), or comparable environment with a minimum of 5 years in a Regulatory Operations capacity. Regulatory Affairs Certification (RAC) is a plus.