Director, Regulatory Affairs

AmerisourceBergen is a publicly traded Fortune 11 global healthcare solutions company and is one of the world's largest pharmaceutical services companies. Innomar Strategies, a part of AmerisourceBergen, is Canada's leading patient support provider for specialty pharmaceuticals. Through our Integrated Service Model, we deliver customized solutions to improve product access, increase supply chain efficiency, and enhance patient care. Innomar is the trusted expert in specialty pharmaceuticals with an unwavering commitment to patients.

POSITION SUMMARY:

The Director, Regulatory Affairs reports directly into the Director/Senior Director, Regulatory Affairs. They act as a primary contact for clients responsible for maintaining client relationships, including work on and oversight of client projects and services, quoting, and invoice reconciliation. They are responsible for leading a number of regulatory initiatives and will interact cross-functionally to support Innomar teams. They will serve as the principal interface with health authorities and manage the strategies and execution of these interactions.

PRIMARY DUTIES AND RESPONSIBILITIES:

- Provides support to generate new business for TPIreg and broader Innomar team as applicable while maintaining assigned billable targets
- Participates in professional activities such as industry training, conference presentations, publications and webinars as applicable
- Builds and maintains a positive and productive liaison with internal and external contacts, including interfacing with clients/agencies/professional associations as applicable
- Acts as primary contact for clients with responsibility for maintaining client relationships, including quoting, invoice reconciliation and provision of client services
- Responsible for the overall management of key accounts to ensure compliance with client internal review processes and required external approvals
- Develops and maintains partnerships with senior decision-makers in all departments to effectively achieve business results
- Manages multiple simultaneous projects to ensure that they are on budget, meet timelines and client expectations
- Analyzes data, the regulatory environment and business objectives to recommend priorities
- Provides teams with direction on regulatory authority interactions while ensuring cross-functional perspectives and expertise are incorporated into regulatory plans
- Manages decision-making and conflict resolution surrounding regulatory issues within cross-functional teams
- Provides regulatory intelligence
- Engages in continuous learning activities in order to provide effective consulting services

- Develops, mentors and manages direct reports and other members of the team as applicable assigning work and guiding use of consulting resources to deliver a value service offering while supporting development of staff knowledge and skills
- Other related duties as assigned

EXPERIENCE AND EDUCATIONAL REQUIREMENTS:

- B.Sc. required (life sciences disciplines strongly preferred)
- Advanced Degree in related field is preferred
- 12+ years of relevant experience in regulatory affairs or related functions in pharmaceutical/biologic/medical device development/manufacturing
- Prior consulting experience preferred
- Regulatory Affairs Certification (RAC) and other certifications such as Quality or Clinical Research are an asset

MINIMUM SKILLS, KNOWLEDGE AND ABILITY REQUIREMENTS:

- Superior project and people management/mentorship skills to manage multiple concurrent projects within established timelines in a dynamic environment
- Demonstrated strategic planning and complex problem-solving skills to ensure service value offering
- Ability to drive results in a team environment
- Demonstrated senior leadership abilities in a cross-functional, multi-disciplinary team environment
- Direct experience with and working knowledge of a wide range of regulatory submission types
- Broad understanding of international regulations, processes and issues in drug/biologics/medical device development. Includes sound knowledge of ICH, Health Canada, FDA, EMA, and other relevant guidelines with focus in area of specialization such as biologics or pharmaceuticals.
- In depth experience of successfully managing Health Authorities interactions on a regional basis
- Effective organizational skills and attention to detail
- Ability to develop professional networks that will drive business development and regulatory intelligence
- Strong business and financial acumen
- Strong analytical and mathematical skills
- Ability to communicate effectively both orally and in writing
- Strong computer skills, including Microsoft Office Suite (Word, PowerPoint and Excel) and Adobe Acrobat

Please note: This role can be based out of our office in Oakville, ON or potentially remotely from home

TO APPLY:

Copy and paste the link below to submit your application:
https://abccareers.taleo.net/careersection/2/jobdetail.ftl?job=00001UAM&src=JB-10063