



Position: Regulatory Affairs Specialist

Job Description:

The Regulatory Affairs Specialist is responsible for ensuring that work undertaken by GMCS meets the requirements of government Regulatory Authorities in China, which necessitates the submission of appropriate documentation to Regulatory Authorities prior to the performance of clinical trials and again prior to marketing of a new pharmaceutical, biotech, or medical device product for registration in China, as well as any maintenance tasks associated.

Responsibilities Include:

- Responsible for timely preparation/coordination of regulatory submissions for clinical trials and market registrations for pharmaceutical, biotech, or medical device projects.
- Works to high standards (governmental, Sponsor and GMCS) with minimal supervision.
- Maintains awareness of current regulatory legislation, Guidance, and practice standards related to drug and device submissions and clinical research.
- Responsible for providing regulatory consultancy to client companies and/ or the GMCS project team.
- Participates in project team planning, proposes registration plans, and ensures the implementation of these plans.
- Serves as liaison between the client and Regulatory Authorities and proactively interacts with internal GMCS teams
- Evaluates the impact of clinical/regulatory changes on assigned projects as well as GMCS business operations
- Reviews and approves deliverables prior to submission to clients and/or Regulatory Authorities to ensure the compliance of deliverables to applicable regulations, guidance requirements and client requests
- Develops and maintains documented regulatory procedures (SOPs) as required to assure consistent and compliant regulatory activities
- Other relevant duties assigned for which the incumbent is qualified

Requirements

- Bachelors degree, preferably in life sciences, with two years of experience in Pharmaceutical or Medical Device industry or equivalent education and experience
- A strong understanding of China and/or international Drug, Biologics or Device guidelines and regulations
- Effective communication, planning, and organizational skills
- Ability to work in a team environment and be an independent self-starter, as required
- Must be able to meet deadlines and be detail oriented
- Proficiency in Microsoft Office (Word, Excel or Access, PowerPoint)
- Good command of English language and communication skills.

Reporting Requirements

The Regulatory Affairs Specialist reports directly to the General Manager.