Job Title: Principal Consultant, Regulatory Affairs, CMC
Location: Regional (US or EU) or head-office based
Type: Full time, permanent

The Position:
Reporting to the Divisional Principal, Regulatory CMC, the Principal Consultant, Regulatory CMC provides expert regulatory CMC advice/strategy and opinion to clients. The Director will lead and execute projects, managing regulatory submission documents for biologics and/or small molecules in adherence with applicable regulations and guidelines for submission to Canada, US, EU, and ROW.

Responsibilities:

Provide strategic technical and regulatory support to clients on chemistry manufacturing and control issues for biologic and/or small molecule products.

- Effectively manage/execute/oversee the preparation of CMC regulatory submission documents, including for clinical trial applications, marketing applications, post-market changes, and scientific advice in adherence with applicable regulations and guidelines for submission to health authorities.
- Review and/or create primary source documents including technical study reports and protocols.
- Author CMC submission documents/reports and/or review client-prepared documents for completeness, accuracy and compliance to regulations.
- Prepare technical assessments of CMC source documentation and responses to client technical questions on document content.
- Prepare or review gap analyses of client prepared regulatory documents detailing requirements for submission to different jurisdictions.
- Facilitate submission approvals and amendments through leading communications and negotiations with clients, health authorities, and project teams, building positive working relationships with clients and health authority contacts.
- Manage project workflow including prioritizing project objectives, and establishing timeframes for projects with clients. Oversee progress and completion of projects with project team members, ensuring timeframes and deadlines are met.
- Lead and participate in formal interactions (face-to-face meetings, teleconferences, etc.) with clients and health authorities.
- Develop new business and conduct quote preparation and new project /client consultations.
- Act as an internal resource and mentor for peers, advising on technical and regulatory CMC issues and strategies, based on a deep knowledge of applicable scientific concepts and governing legislation and guidelines.
- Present industry related training seminars or workshops at industry conferences.
- Participate in the planning and execution of the strategic direction for the regulatory CMC business.
- Other duties and responsibilities as assigned.

Requirements:

- Minimum Bachelor's degree in chemistry, chemical engineering, biochemistry, biology or life sciences, advance degree is an asset.
- Minimum 10 years regulatory CMC experience, with expert knowledge and understanding of pharmaceutical/biologics product and process, analytical or formulation development.
- Extensive knowledge of regulatory submission types across the product life cycle, specifically with Module 3 and 2.3 QOS requirements, with global dossier preparation experience.

- Experience of Regulatory CMC and product development in US and Europe. Experience in other regions is advantageous.
- Innovative strategic planning and excellent problem solving skills.
- Previous business development/senior consulting experience is an asset.
- Strong knowledge of a variety of computer programs including MS Office, Adobe Acrobat, eCTD compiling software, and electronic document management systems.
- Self-motivated and proactive, with excellent problem solving, negotiation, organizing and planning skills.
- Excellent written and oral communication skills, including scientific/technical writing experience.