CoNCERT Pharmaceuticals Inc.®

## Title: Manager/Senior Manager, Regulatory Affairs

### Job Summary:

Concert is seeking an experienced and detail-oriented individual to manage and complete regulatory projects consistent with company goals. Reporting to the Assoc. Director, Regulatory Affairs, the Manager/Senior Manager, Regulatory Affairs will be responsible for timely planning and coordination of regulatory submissions, providing guidance to cross-functional teams on regulatory tactics, and maintaining regulatory archives. The individual will coordinate the compilation of information and documentation into IND & NDA submissions to FDA and CTA submissions to Health Canada and global regulatory authorities and ethics committees.

### Responsibilities:

- Independently manage the planning and preparation, including writing as necessary, assembly, review, and timely submission of regulatory dossiers for investigational products in the US and abroad.
- Manage the preparation, review, and submission of all components of regulatory submissions for NDAs, INDs/CTAs and amendments.
- Ensure regulatory submissions are prepared in compliance with applicable regulatory requirements.
- Support and manage preparation of all submission types including meeting requests, briefing documents, SPAs, annual reports, Investigator's Brochures, clinical study protocols, and informed consent forms.
- Participate on project teams and provide expertise on regulatory matters.
- Manage registration and maintenance of clinical study protocol records in ClinicalTrials.gov.
- Assist in management of electronic submission documents with an outside submissions vendor.
- Review Site Essential Document packages for compliance with FDA regulations, ICH Guidelines, and internal requirements for initiation of North American and European clinical sites.
- Maintain various regulatory files databases/archives, correspondence chronologies, and tracking systems in good order.
- Maintain knowledge of current regulations, guidance documents, ICH standards, regulatory intelligence/precedence, and competitive landscape. Advise management of significant developments.
- Work in close collaboration with external consultants and/or CROs, as needed, to ensure that regulatory milestones are achieved.
- Support non-project activities as needed, for example, SOPs and organizational initiatives.

### Qualifications:

- Bachelor's degree, preferably in life sciences or related field.
- 5+ years of pharmaceutical regulatory affairs experience.
- Hands-on experience with preparation of INDs, CTAs, (required) and NDAs (highly desired), as well as supportive amendments and supplements (nonclinical, clinical, CMC).
- Experience with eCTD required. Experience with publishing documents in Adobe Acrobat Professional is a plus.
- Working knowledge of FDA regulations and ICH Guidelines.
- Understanding of FDA structure and function. Experience with Health Canada, EMA and national EU regulatory authorities is desirable.
- Comprehensive knowledge of GMP, GLP, and GCP regulations, as well as an understanding of the full drug development process and pharmaceutical product lifecycle.
- Strong verbal and written communication skills.
- Detail-oriented, meticulous, and comfortable with broad responsibilities in a fast-paced, small company environment.
- Ability to independently build networks with internal and external cross-functional team members.

- Excellent operational competencies, including planning, organizing, and ability to proactively lead cross-functional teams.
- Ability to work autonomously, effectively manage time, and deliver results on time.
- Excellent organizational skills, with ability to manage multiple tasks simultaneously.
- Proficiency with Microsoft Word, Excel, and PowerPoint.
- Ability to work flexibly within tight timelines.

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If you would like to be considered for a job on the Concert team, send your resume to: careers@concertpharma.com.

*Concert provides equal employment opportunities to all employees and applicants for employment and prohibits discrimination and harassment of any type without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws.*