

Title: Associate Director, Regulatory Affairs

Job Summary:

Reporting to the VP Regulatory Affairs & QA the Associate Director will help develop the regulatory strategy for Concert's clinical-stage development programs and will direct the day-to-day regulatory activities. This position, as a key member of a small team, requires both strategic and operational capabilities and offers the opportunity to work on several divergent development projects.

Responsibilities:

- Works with the VP Regulatory Affairs & QA in developing regulatory strategy for development programs. Scope of submissions range from Pre-IND meetings through marketing authorization and post-approval requirements.
- Executes regulatory plans by coordinating regulatory workflow, leading submission teams and tracking and managing timelines to achieve program goals.
- Writing and/or review of regulatory documentation and serving as a resource for other document owners regarding regulatory content.
- Interfaces directly with regulatory agencies and CROs.
- Serves as the Regulatory Affairs representative on program teams and cross-functional sub-teams.
- Oversight of electronic submission publishing activities conducted by an external vendor.
- Responsible for establishing and maintaining the regulatory submission archive.

Qualifications:

- Bachelor's degree required, preferably in life / health sciences field.
- 8-10 years of increasing global regulatory affairs experience.
- Direct hands-on experience with a variety of regulatory submissions from all phases of clinical development, INDs, CTAs, NDAs etc.
- Strong experience of FDA interactions. Experience with Canada and the EU would be a plus.
- Regulatory operations/publishing experience would be a plus.
- Demonstrated ability to manage multiple assignments, appropriately identify and resolve regulatory issues, and communicate as needed to management.
- Demonstrated ability to work both independently and within cross-functional teams.
- Strong written and oral communication skills.

If you would like to be considered for a job on the Concert team, send your resume in the body text of an e-mail (no attachments please) to: careers@concertpharma.com.

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