Job Title: Associate Director/Director, Preclinical Development (Part-Time)

Reports to: Vice President, Preclinical Development

Responsibilities Overview:
Lead the design and execution of studies in support of preclinical drug development efforts. Provide technical and strategic input regarding the advancement of drug candidates from the pre-IND stage through phase III clinical trials and eventual NDA filings.

Primary Duties and Responsibilities:
- Develop and manage innovative pharmacology, ADME, and toxicology studies in support of preclinical drug development efforts.
- Provide analysis and evaluation of data results; communicate results to internal project teams, and provide recommendations/strategic direction on appropriate next steps.
- Maintain knowledge of current ADME and toxicology study designs and guidelines for submissions to regulatory agencies, particularly related to IND and NDA applications.
- Assist with preparation of Regulatory submissions, including drafting of preclinical sections, and review toxicology and pharmacology documents as required.
- Perform other tasks as assigned.

Background Requirements:
- PhD in Pharmacology, Toxicology or similar
- Experience in the areas of immunology and/or hepatology
- 10+ years hands-on drug development experience in the biopharmaceutical industry
- Extensive experience drafting preclinical-related sections of IND and NDA submissions
- Extensive experience with set-up and execution of preclinical studies
- Experience working with CROs and consultants
- Proficiency with office equipment, computer systems and software (including Microsoft Office and Outlook) required
- Highly developed organizational skills and attention to detail are mandatory