

Versartis, Inc.

Job Description

Job Title:	Director/Sr. Director, Clinical Pharmacology
Department:	Development
Reports To:	CEO
Type:	Regular
Work Schedule:	Full-Time
FLSA Status:	Exempt

Job Summary

The Director/Sr. Director of Clinical Pharmacology will, in partnership with senior management, design and execute translational research and early phase human clinical studies in alignment compound development strategy and long/ short term business plans. This position will work with other development team members and consultants to construct the clinical development plan for each product and ensure the successful, cost-effective, and timely execution of early clinical studies (including proof-of-concept study). Responsibilities will also include acting as a medical monitor and safety officer for clinical trials, as needed. It is expected that as head of Clinical Pharmacology, he/she will develop clinical protocols and conduct clinical trials that meet the business and product development goals of the Company.

Duties and Responsibilities -- Essential Functions

- Responsible for writing clinical synopses and protocols to support early clinical studies for Versartis products
- Responsible for writing the clinical sections of regulatory submissions, clinical study reports, and the Investigator's Brochure.
- Responsible for selection, oversight, and monitoring clinical programs at outside contract services (CROs) in collaboration with Regulatory Affairs and Program Management
- Facilitates the translation of preclinical data into overall development strategy to ensuring successful early phase (Phase 1/2) proof of concept for Versartis products
- Establishes policies and procedures for clinical trial conduct and monitoring in collaboration with Regulatory Affairs and Quality
- Develops pharmacovigilance systems as appropriate to support early phase trials

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- Interprets pharmacokinetic and pharmacodynamic results from human clinical trials to enable further clinical development
- Develop draft clinical development plans to support the target product profile
- Provide early clinical input to the Amunix research team to assist in research/non-clinical development plans of a target
- Works with senior managers and CEO to assess new product opportunities
- Manages external resources such as consultants or paid advisors
- Other duties and responsibilities as assigned
- Position requires some travel

Job Specification

- Demonstrated ability to design and execute early phase human clinical trials that provide proof of concept in patients and a foundation for further development
- MD or PharmD degree plus at least 8 years of experience in the biotechnology or pharmaceutical industry
- Minimum of 5 yrs experience in Clinical Pharmacology roles with more than 2 years as a senior manager or above (for Sr. Director, more than 5 years as Director) in a medical affairs function at a biotechnology or pharmaceutical company with direct involvement in early phase human clinical trials
- In-depth experience with drug development issues is required
- Experience in monitoring clinical programs (medical monitor) and interacting with clinical sites is preferred
- Experience writing clinical protocols and regulatory submissions is required
- Ability to translate preclinical safety and efficacy studies into design of human clinical trials
- Technical understanding of biologics drug development is required
- Experience in endocrinology and/or metabolic disease is preferred
- Ability to present technical and business aspects of projects
- Forward-thinking and creative with high ethical standards
- Team player with leadership skills
- Strategic visionary with sound technical skills, analytical ability, good judgment and strong operational focus
- Well organized and self-directed
- Strong interpersonal skills with an ability to communicate to people at all levels of an organization

Date Revised: December 17,2009