

Director of Regulatory Affairs

Insmed is seeking candidates for the position of Director of Regulatory Affairs in its Boulder, CO facility.

Essential Duties and Responsibilities

- Develops and oversees regulatory strategies (including risk assessments) regarding submissions and compliance issues as they relate to the clinical and development of biologic products.
- Directs the organization and preparation of clear and effective submissions and presentations for external parties (e.g., FDA, corporate partners, other regulatory agencies, etc.) and internal personnel (e.g., executive management, project teams etc.);
- Monitors and evaluates FDA and international regulatory agency activities in the company's product areas and prepare periodic summaries;
- Participate in the scheduling and coordination of FDA meetings, and the preparation of the pre-meeting information package
- Provides guidance and advice to senior management and development staff to achieve goals and regulatory compliance related to drug development and commercialization, including regulatory time-lines, quality assurance, chemistry, clinical trials, GXP and product distribution.
- Participate in the preparation and submission of IND's, CTA's, NDA's, BLA's, Site Master Files, Annual Reports, supplements and amendments.

Qualifications

Education

- Degree in scientific discipline and at least 5 years of senior level experience in regulatory affairs. Advanced degree a plus.

Experience/Skills

- Previous biologics experience preferred.
- Established relationships with regulatory agencies, including the FDA and international regulatory agencies.
- Demonstrated experience working with orphan and recombinant DNA products.
- Experience dealing with world wide regulatory agencies, preferably by taking products from early stage clinical development and through marketing approval.
- Background in working in multi-disciplinary development teams and experience in all phases of human drug development.
- Strong technical education and training.
- Excellent written and oral communication and organization skills.
- Familiarity with Common Technical Document (CTD) a plus.

Please send resume and cover letter to:

Human Resources
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