Interested Parties Should Contact:
Keith Ryan 508 359 4120
kryan@geneousbiomedical.com

Position: Associate Director/ Director, Regulatory Affairs

Location: Cambridge, MA

Position Profile

This new position has emerged as a result of a decision to bring US regulatory affairs expertise in-house following the expansion of clinical trials to the US and the IND maintenance activities associated with this, including planned interactions with FDA relating to the development of therapeutic compounds. Responsible for a broad range of regulatory activities, the role involves interacting with a multidisciplinary team, both in-house and outsourced, as well as navigating successful relationships with FDA.

KEY RESPONSIBILITIES

- Providing regulatory support to cross functional development project team; presenting project status updates and strategy approaches
- Managing the US regulatory activities associated with project team plans
- Management, preparation, co-ordination and submission of the documentation supporting regulatory submissions to the U.S, and, if required, international regulatory authorities, in support of e.g. INDs, NDAs, amendments, CTAs, safety reports and annual updates
- Responsible for interactions and contact with FDA (including FDA meetings), and if required, international regulatory agencies.
- Representing Regulatory Affairs on the global CMC sub-team. Responsible for the CMC regulatory documentation submitted globally to regulatory authorities, with support from the QA and CMC departments.
- Performing regulatory review of clinical trial labelling and CMC documents for regulatory compliance
- Maintaining a working knowledge of regulatory requirements and guidelines, in particular within the US, and for communicating changes in regulatory information to project teams
- Contributing to the development of procedures and working practices commensurate with the requirements of a growing company

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- Maintaining a regulatory archive of all submissions and tracking of all correspondence, and ensure compliance with regulatory feedback and that commitments are met

ESSENTIAL CRITERIA

- Excellent knowledge of US regulatory requirements and extensive experience with maintaining US INDs
- Experience in representing Regulatory Affairs on cross functional development teams
- Experience in working in a Chemistry, Manufacturing and Control (CMC) Regulatory, Quality or drug development environment
- A good understanding of global development regulations and guidelines
- Experience in preparing for and conducting FDA meetings

DESIRABLE CRITERIA

- Experience in supporting global clinical studies
- Experience of interacting with European and / or other international regulatory authorities
- Experience of managing, preparing, submitting NDAs/MAAs
- Experience of working with orphan drugs

PROFILE

- Minimum of 8 years' experience in drug development, with a minimum of 5 of these years within US Regulatory Affairs
- Educated to degree level or equivalent in a relevant scientific field
- Ability to work independently
- Happy to be in a hands-on role
- Detail oriented with excellent organisational and interpersonal skills
- Strong written and verbal communication skills (English)

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