Interested Parties should contact:
Keith Ryan kryan@geneousbiomedical.com
508 359 4120

Position: Head of Clinical Development
Location: Cambridge, MA

Our client is a well-funded, clinical-stage biopharmaceutical company advancing novel peptide technology to develop a new class of therapeutics for cancers and other diseases. Their goal is to use their proprietary drug platform to create first-in-class therapeutics that may be able to address historically undruggable targets.

Based on their robust preclinical data and early clinical data showing strong anti-tumor activity, they feel that their lead program can be developed into an effective monotherapy or combination therapy for a wide variety of solid and liquid tumors.

We are working with them to identify an experienced executive for a Head of Clinical Development.

KEY RESPONSIBILITIES

- Leading the development of all clinical protocols
- Assisting in the identification of clinical investigators and coordinating their activities in conducting clinical trials and medical advisory board meetings
- Managing and maintaining strong, effective relationships with global vendors, consultants, investigators, and other external clinical trial participants to ensure that the primary goals of the clinical development programs are met
- Managing medical strategy, questions, and internal and external relationships that are related to clinical programs
- Monitoring/analyzing clinical trials for safety and, when appropriate, efficacy, and working in conjunction with external Drug Safety vendors to insure timely reporting of safety signals to regulatory authorities
- Providing medical review and author content for the Informed Consent Form template and subsequent drafts as necessary
- Reviewing clinical data and authoring its translation into the investigational brochure updates and DSUR
- Leading submission of essential documents to the TMF and Regulatory Department
- Managing and coordinating deliverables, per vendor and CRO contracts, to ensure project deliverables are met on time and within budget
- Reviewing and contributing the necessary templates and documentation (i.e., manuals, guides, communication plans) for each clinical study
- Assisting with the generation, analysis, and presentation of clinical data, including manuscripts, abstracts, and oral presentations (including authoring documents and slide preparation as appropriate)
- Communicating in a timely and effective manner with executive management and others, on clinical trial status and activities

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PROFESSIONAL EXPERIENCE/QUALIFICATIONS

- Ten or more years of experience leading or overseeing Oncology related pharmaceutical development projects to include managing such projects across multiple functional areas.
- Demonstrated ability to successfully execute development plans
- Phase 2/3 experience is preferred
- Significant experience with NDA/BLA preparation and submissions
- Experience with projects relating to Oncology
- Demonstrated ability to lead and influence experienced professionals
- Ability to lead in a fast-changing environment
- Broad knowledge and exposure across all R&D functions
- Deep understanding of pharmaceutical development
- Strategic thinker
- Strong execution skills
- MD or MD / PhD required.

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EDUCATION

- MD or MD/PhD

COMPENSATION

An attractive compensation package commensurate