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

**Position:** Director/Senior Medical Director – Gene Therapy

**Location** Cambridge, MA

The Director/Sr. Medical Director is responsible for assisting with the advancement of gene therapy late stage pre-clinical and clinical development programs. The Director/Sr. Medical Director will lead the strategic, clinical and regulatory aspects of assigned programs and serves as the Medical Monitor for clinical trials in ALS and A1ATD, ensuring compliance with ICH/GCP and federal regulations.

**Primary responsibilities include:**

- Provide medical and clinical development expertise and leadership to assigned gene therapy clinical development programs
- Assist in the design and drafting of clinical development plans, protocol synopses, clinical trial protocols and protocol amendments
- Provide medical oversight of multiple clinical studies and provide medical input and guidance on scientific, clinical and safety monitoring issues
- Provide leadership and direction to Director of Clinical Operations and consulting support team
- Establish and maintain positive relationships with clinical trial investigators/physicians, KOL's and clinical advisors through independent collaborations and scientific meetings
- Lead the IDMC/DSMB meetings when reviewing clinical data
- Provide clinical development support for regulatory agency engagements and documents including INDs and BLAs
- Provide strategic input on gene therapies in development and propose clinical development strategies
- Provide medical expertise as needed for business development initiatives
- Provide medical and scientific expertise to preclinical discovery groups for programs that are in preclinical development

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**Education and Skills Requirements:**

- MD required, subspecialty training in neurology or hepatology(liver)/pulmonary is preferred;
- 2-4 years of hands on pharmaceutical, biotech, or academic hospital experience in clinical development. Rare/orphan diseases preferred, but not required
- Strong immunology and/or gene therapy background is highly preferred
- Prior hands-on IND/CTA and/or NDA/MAA filing experience
- In depth knowledge of drug development process and oversight of clinical trials
- Working knowledge of biostatistics, regulatory, clinical pharmacology and pharmacokinetics
- Excellent interpersonal, written, verbal and visual communication skills
- Proven ability to successfully manage multiple tasks and prioritize accordingly
- Professional and pleasant demeanor
- Willingness to travel
- Recognized by former peers, colleagues, managers and direct reports for attributes congruent with company values

Candidates must be authorized to work in the U.S.