Consultant/Sr. Consultant

Dark Horse Consulting Group Inc.
Location: Remote

Position Description:

The candidate will serve as a team member providing technical consulting services to clients of Dark Horse Consulting Group (DHC). The candidate should be experienced in preclinical development of cell and gene therapy products and possess deep knowledge of the design and execution of *in vitro* and *in vivo* pharmacology and safety/toxicology studies. The candidate will serve as a Subject Matter Expert (SME) as well as a resource to other consultants in support of company efforts to provide technical and strategic preclinical consulting services in the cell and gene therapy fields.

Responsibilities:

- The individual will be responsible for supporting DHC projects and must be comfortable being a preclinical SME for a wide range of gene therapy products, including viral vector products and gene-modified cell therapy products
- The individual may be asked to perform business development to bring in new clients, help enhance the internal knowledge base and operational efficiencies, and mentor to staff
- Personnel and project management may be required
- This position will require client visits, on site person in plant at CMOs and contract vendor audits on a global basis. Therefore, the ability to travel up to 20% of the time (including internationally) is a pre-requisite and should be expected

Qualifications

- BS in cell biology, molecular biology, vector biology or related biological sciences field required (MS or PhD preferred)
- Minimum of 5 years' experience in the biotechnology or pharma industry with a primary focus on preclinical development for AAV, Lentiviral, Retroviral and Adenoviral vectors; plasmids; and/or gene-modified cell therapies
- Strong technical writing skills, including experience with preparing nonclinical sections of regulatory filings (e.g. INTERACT, Scientific Advice, pre-IND, CTA, IND amendments, BLA, MAA)
- Ability to operate in a fast-paced, multi-disciplinary industrial environment
- Strong presentation and oral communication skills
- The ideal candidate will possess the following competencies:
  - Familiarity with overall preclinical development strategy, including the progression from pilot to clinical-enabling studies
  - Familiarity with common *in vitro* and animal model systems used for efficacy and safety testing
  - Familiarity with regulatory standards and guidances for preclinical safety and efficacy testing of gene therapy products
  - Experience designing and executing pilot and clinical-enabling preclinical studies for gene therapy products
  - Familiarity with the interplay between preclinical studies and analytical development
  - Experienced in writing and reviewing protocols and reports for a range of preclinical studies
  - Familiarity with conduct of GLP studies and experience in oversight of GLP studies
  - Experience with vendor selection and management of suppliers and preclinical CROs