Job Title: Associate Director/Director of Clinical Operations

Field: Clinical Development

Company: Salubris Biotherapeutics, Inc.

Location: Gaithersburg, MD

Salubris Biotherapeutics, Inc. (hereafter referred to as SalubrisBio) is a science-driven biotechnology company dedicated to the discovery and development of novel antibody therapeutics for the treatment of cancer and cardiovascular diseases. Our mission is to translate innovative scientific concepts and technology into medicines which make a meaningful and impactful improvement in the health and lives of patients. SalubrisBio is seeking a self-motivated Associate Director/Director of Clinical Operations to coordinate with various external vendors and provide oversight and management of outsourced CRO activities. Candidates should be highly organized, self-motivated, and have exceptional written and oral communication skills in order to effectively work with external vendors as well as company personnel.

Responsibilities and Duties:

- Serve as primary point of contact for CROs conducting clinical studies, and other supporting external vendors;
- Review, evaluate, and advise on budget for CRO activities to identify and implement cost-saving changes in scope and allocation of responsibilities;
- Manage study budget on an ongoing basis;
- Lead coordination across external vendors including but not limited to: primary CRO, imaging and central overread vendors, regulatory affairs, QA personnel, and shipping and logistics vendors;
- Coordinate and monitor recruitment at and across sites;
- Oversee data collection and management;
- Support data safety committee (DRC) meeting logistics as needed;
- Interface with site investigators and other site personnel as needed;
- Assist in preparation for auditing, DUSR and annual reports, and other legal and regulatory filings.
- Author and implement vendor oversight SoPs
- Participate in internal and external conference calls;

Qualifications and Skills:

- BS/MS in a scientific field of study with 10+ years of relevant experience working in Clinical Operations in the pharmaceutical/biotech industry or a CRO;

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- Clinical trial experience in cardiovascular disease and/or oncology preferred;
- In-depth understanding of industry standards and applicable guidelines; FDA regulations and ICH GCP knowledge;
- Experience in developing clinical operations SOPs and metrics;
- Cross-collaboration proficiency with other functions such as Regulatory, CMC, Biostatistics/Data Management, Finance and Program Leadership;
- Proven leadership experience with the desire and ability to work in a fast-paced, matrixed, start-up environment;
- Strong collaboration and team-working, communication and organizational skills required;
- Strong problem solving and analytical skills necessary;
- Ability to prioritize activities appropriately and manage time
- Willing to travel domestically and internationally as needed.

Benefits:

SalubrisBio is an equal opportunity employer. The company offers competitive benefits including medical, dental, vision, short/long term disability and life insurance, as well as 401(k) match and paid time leave.

To apply for this job, please send your resume via **hiringclinicalops@salubrisbio.com**