Position:

Director/ Sr Director Clinical Sciences

About the Company:

Dren Bio (the "Company") is a privately held, clinical stage biopharmaceutical company focused on developing therapeutic antibodies for the treatment of cancer, autoimmune and other serious diseases. The Company's management team and scientific advisors have profound expertise covering the discovery and development of engineered antibodies designed to selectively target and deplete pathological cells. Dren Bio's pipeline is currently comprised of two distinct drug discovery programs. The Company's first program surrounds DR-01, its lead product candidate, which induces antibody-mediated killing of a cell type that is responsible for a multitude of hematologic malignancies and plays a key role in various autoimmune diseases. The Company's second program surrounds its Targeted Myeloid Engager and Phagocytosis Platform, a proprietary bispecific antibody-based technology that provides a novel mechanism of action to selectively engage myeloid cells for (1) targeted depletion of pathologic cells and other disease-inducing agents and (2) inducing localized immunostimulation. The engagement of antigen presenting cells has the potential to elicit a sustained, durable response.

Function:

Clinical

Level:

Director/ Sr. Director

Location:

Foster City, CA

Reporting Manager:

Chief Medical Officer

About the Opportunity:

Reporting to the Chief Medical Officer (CMO), we seek an experienced Clinical Scientist looking for the opportunity to play a pivotal role in further growing the Clinical Development function at Dren Bio and leading and contributing to the unique science of first-in-class and unique MOA biologics. This role will offer you a high level of influence and impact on novel therapies by partnering externally with some of the world's leading clinicians in the field of Oncology and Immunology while collaboratively partnering with our Clinical Development Organization at Dren Bio. This position is designed to establish the Clinical Science function at Dren Bio and eventually build out the team of clinical scientists consistently delivering outstanding input and analysis on clinical development programs. The position allows to partake in the definition of cell depleting and myeloid cell engaging therapies with curative approaches.

Role and Responsibilities:

Global Clinical Development (CD) Planning:

- Leads and/or participates in meetings, reviews, discussions and other interactions regarding early development/Phase I studies to provide clinical science input and guidance. Includes contributing to and reviewing of clinical protocols
- Develops the CD plan in collaboration the Clinical Development Physician for selected indication(s)
- Gathers, analyzes and summarized data and information necessary to create the CD plan. May also delegate such research and analysis to less experienced Clinical Scientists
- Leads and/or supports preparation for HA meetings. Participates in HA meetings as required. Ethically, effectively and professionally represents the interests of Dren Bio and patients involved in studies
- Stays abreast of internal and external data and developments, trends and other dynamics relevant to the work of CD to maintain, at all times, a fully current view and perspective of internal/external influences and/or implications for the assigned therapeutic and disease area(s)
- Maintains scientific and clinical knowledge in the specific therapeutic and disease area(s) of assignment and participates in competitive intelligence assessments as documented in
- Represent Clinical development in collaboration with Research and Translational Sciences for alignment on biomarker strategy and pharmacological assessments

Clinical Development Plan Implementation:

- Develops innovative clinical study designs in collaboration with Clinical Development Physicians
- Reviews and/or writes additional clinical science documentation and/or clinical science input into other documentation managed by Dren Bio (e.g., protocol summaries, safety monitoring plans, process documents, investigator brochures, etc.)
- Leads the response generation in alignment with Clinical Development Physicians in responding to HA inquiries
- Supports with completion and submission of regulatory filings and other regulatory documentation
- Delivers key presentations, both internally and externally, to convey the CD perspective and provide updates on strategies, plans and other activities. Includes presenting at advisory boards and other relevant external forums representing CRISPR Therapeutics.
- Collaborates with clinical operations, other groups and Medical Directors/Clinical Development Physicians to develop consistent language and criteria for the Informed Consent Form (ICF), protocol eligibility, protocol dose modification, protocol safety, Case Report Forms (CRFs), CRF instructions, etc.
- Collaborates under the leadership of clinical operations to develop and implement the overall data quality plan
- Oversees the review, analysis and reporting of clinical data in collaboration with biometrics and data management to enable clinical decision making and regulatory filings
- Develops and provides input for clinical presentation slides and other materials for internal/external meetings
- Helps to coordinate the successful completion of documents with other groups
- As needed/appropriate, collaborates with others in the review of safety narratives and other safety-related guidelines and documentation
- Participates in safety meetings and tracks, analyzes and reports any potential safety events
- Provides clinical and scientific support with site training, as needed, or requested
- Where assigned, acts as the primary CD liaison/point-of-contact from the team for inquiries from clinical operations, clinical research organizations (CROs), etc.
- Responds to questions from other internal and external parties regarding assigned studies and programs
- Works closely with Clinical Development Physicians, clinical operations and other groups to close-out clinical studies, secure data and complete study reporting
- Participates in the development and implementation of communications strategies to support existing and concluded studies.

- Leads to writing or if applicable writes and/or reviews abstracts, posters, content for scientific meetings, conferences, other events and presentations, and other publicly distributed materials and coordinates further reviews with internal partners and stakeholders. Coordinates submissions to scientific meetings and/or other appropriate venues or groups

Management/Leadership:

- Participates in the relevant Clinical Teams
- Represents CD in sub-teams relevant to assigned therapies)/indication(s). May act as the lead CD representative on sub-teams
- Identifies, recruits and manages new clinical science team members and ensures ongoing training and development of Clinical Science personal in conjunction with Development physicians
- Lead relevant sub-teams in assigning and training new team members (with or without direct reporting responsibility)
- Lead aspects of the ongoing enhancements/development of team processes, structures, systems, tools and other resources to ensure sustainable growth and nimbleness
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Education, Experience and Qualification Requirements:

- Advanced scientific or clinical degree (e.g. PhD, PharmD, MPH, etc).
- 10+ years of relevant clinical trial experience (must demonstrate a minimum of 5 years of high-level clinical trial experience in pharma/biotech industry). Filing experience highly desired. Title to be commensurate with experience and achievement.

Core Competencies, Knowledge and Skill Requirements:

- Data listing review experience and familiarity with standard clinical and regulatory references such as CTCAE, MedRa, WHO etc.
- Experience in the principles and techniques of data analysis, interpretation with a solid fundament of statistical principles
- Experience authoring experimental protocols and/or study results and conclusions.
- Relevant therapeutic area experience in hematology or oncology. Experience in immunology is highly beneficial
- In-depth understanding of Phase I (and beyond) drug development.
- Sound knowledge of medical aspects of GCP (Good Clinical Practice), ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use), FDA, EMEA, and other relevant guidelines and regulations.
- Proven abilities to perform Clinical Scientist responsibilities with increasing expertise and independence.
- Track record of working well with other scientists and clinicians and ability to influences without formal reporting relationship across hierarchies and functions
- Ability to travel (30%) domestically and internationally

Salaries, Benefits and Other Employee Perks:

Dren Bio strongly believes in investing in, and rewarding, its employees. This philosophy is embodied in the Company's total rewards program, which includes competitive cash compensation, equity incentive awards, and employer sponsored benefit offerings. The base pay range for this position at commencement of employment is expected to be between $185,000 and $225,000 per year. However exact base pay offered will be determined based on multiple individualized factors, including job-related knowledge, skills and experience and market location.

Employment Practices:

Dren Bio is an equal opportunity employer. Employment decisions are based on merit and business needs. Dren Bio will not discriminate against any job applicant because of race, color, national origin, ancestry, gender, sexual orientation, age, religion, creed, physical or mental disability, gender identity, medical condition, pregnancy, marital status, veteran status, or any other characteristic protected by federal, state or local law.