



Executive Director, Global Clinical Research & Development

Corporate Profile: Hana Biosciences, Inc. (NASDAQ: HNAB) is a South San Francisco, CA-based biopharmaceutical company focused on acquiring, developing, and commercializing innovative products to advance cancer care. The company is committed to creating value by building a world-class team, accelerating the development of lead product candidates, expanding its pipeline by being the alliance partner of choice, and nurturing a unique company culture. Additional information on Hana Biosciences can be found at www.hanabiosciences.com.

Job Functions:

Reporting to the Chief Medical Officer, the Executive Director, Global Clinical Research & Development will be responsible for the design and execution of clinical trials across Hana's portfolio of compounds in Oncology. In conjunction with the CMO, Regulatory & Biostatistics, he/she develops the long term strategy for the clinical drug development programs:

- Write protocols, author clinical development plan, integrate PD & PK onto overall development plan, map out regulatory pathways, give scientific presentations, conduct DSMBs and IDMCs.
- Oversees process development and participates in site selection, monitors patient enrollment and retention.
- Fosters strong relationships with clinical trial investigators.
- Oversees the implementation of processes relating to the use of contract resource organizations and ensures adequate quality of outsourced trials.
- Ensure studies are completed on time within budget and in compliance with SOPs, FDA regulations and ICH/GCP guidelines.
- Manage timely completion and analysis of ongoing leading Phase 2 program in second relapsed leukemia to support a US accelerated approval. Plan for EU registration.
- Responsible for selection and implementation of confirmatory trial.
- Preparation of study reports for regulatory filing including responsibility for overseeing and authoring results of lead trial.
- Works in conjunction with Product Safety to monitor for safety signals, conduct quarterly safety meetings, and ensure appropriate reporting to regulatory authorities.
- Conduct Clinical/Scientific Advisory Board meetings – both core and therapeutic area-based.
- Collaborate with key investigators and Clinical Operations on writing and submission of clinical abstracts, posters, scientific presentations, and manuscripts.
- Working in conjunction with Clinical Operations to solicit and prioritize external clinical research collaboration opportunities and oversee all external clinical investigator sponsored trials (ISTs).

- Work with the Senior Director, Clinical Pharmacology and Translational Research and the Senior Director, Global and Strategic Project Management to integrate preclinical research collaborations with external parties such as the NCI, thought leaders, investigators and key academic institutions with the clinical development program.
- Act as clinical scientist on cross-functional teams interfacing with in a matrix environment with Regulatory Affairs, Global Clinical Operations, Project Management, and Pharmacology/Translational Research for devising and executing strategic clinical plans.
- Interact with opinion leaders and regulatory agencies in U.S and EMEA.
- Work with Vice President, Regulatory, and the CMO in pursuit of regulatory distinctions for product candidates such as Pediatric Written Request, Fast Track, Orphan Drug, etc.
- Working with BD and the CMO and CEO to develop the publication strategy and manage the publication and presentation timelines for conferences and medical publications.
- Be a contributing member of Operations Committee; a biweekly leadership meeting conducted by the CEO.
- Assist CMO, CEO and BD in partnering efforts as needed.
- Monitor the competitive environment to sustain expertise in therapeutic area treatment management and new therapies and therapeutic area competition to update the executive management team on specific initiatives.

Qualifications:

- Advanced degree required: (M.D. or MD/Ph.D.), with a minimum of 5 years managing clinical trials/drug development experience in a pharmaceutical and/or biotechnology company demonstrating a broad background in Oncology.
- Early stage to late stage clinical trial experience required; NDA experience a plus.
- Thorough knowledge of FDA regulatory requirements and ICH/GCP guidelines essential.
- Demonstrated proficiency in the implementation, monitoring and management of clinical trials, Phase 3 and international experience strongly preferred.
- Knowledge of clinical research concepts, practices and FDA regulations regarding clinical research trials, familiarity with data processing methods, and general knowledge of clinical medicine, oncology.
- Broad knowledge and cross functional understanding of clinical trial methodology. Scientific expertise in oncology required.
- He or she will have excellent leadership, performance management and strong organizational skills.
- He or she must be able to inspire others, creating a dynamic environment that fosters transparency, collaboration and innovative thinking.
- Requires the ability to author clinical documents; good writing skills required.
- Excellent interpersonal and communication skills.
- Excellent verbal and oral presentation skills.
- Demonstrated management and/or supervisory skills.
- Must be able to develop people.

- Negotiate skillfully in tough situations with both internal and external groups. Ability to manage the needs of multiple internal and external partners and deploy resources to meet those needs. Able to solve problems effectively.
- Integrate rapidly into a very open, matrix-oriented culture to bridge internal and external activities, primarily but not exclusively in the clinical oncology arena.

To apply for this position please submit your resume to info@hanabiosciences.com.