



Senior Clinical Research Associate / Clinical Research Associate

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 strengthen the foundation of cancer care. The company is committed to creating value by building a best in-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.

Job Functions: The Clinical Research Associate will be an active member and team player in the Clinical Operations group. His/her responsibility will include the following:

- Partnering with the medical monitor, clinical staff, and other departments, he/she will ensure the clinical trials are conducted in accordance with corporate SOPs and Guidelines, Good Clinical Practices, ICH Guidelines and applicable federal and national regulations.
 - Draft and participate in the development of relevant documents for Phase I through III studies including protocols, informed consents, CRFs, monitoring plans, data management plans, abstracts, presentations, and manuscripts and clinical study reports.
 - Assist in the preparation and finalization of corporate SOPs.
 - Assist in the preparation of safety, interim and final study reports and resolving data discrepancies.
 - Assist in compilation of investigator brochures, under close supervision.
- Monitor (able to perform site visits for data collections, source data verification, and review of regulatory documents/files, if applicable) or Co-monitor with CROs, regional monitors as required. Travel 25%.
 - Assist in site selection, study implementation and ongoing management of study sites either directly or via vendor/CROs, if applicable.
 - Participate in evaluating study drug supply requirements and managing logistics.
 - Manage CRO/Vendor relationships.
 - Coordinate and/or participate in Investigator meetings.
 - Interact with investigators in protocol development, presentations and publications.
 - Train study coordinators, vendors and investigators regarding GCP and Hana Biosciences processes.
 - Participate in the development of best practices for Phase I through III study management.
 - Requires minimal direction to determine methods and procedures on new assignments.

Qualifications: A Bachelor of Science/Bachelor of Arts degree in a relevant scientific discipline or equivalent. Candidates for this position should have a minimum of 1-3 years of relevant clinical or life science experience in the pharmaceutical industry or equivalent.

Oncology experience is a plus. Candidates must possess knowledge of GCP and/or ICH guidelines, regulatory requirements and quality assurance procedures. In addition, candidates should have strong written communication and presentation skills including the use of appropriate medical/scientific terminology, strong attention to detail and meticulous with follow-through, ability to work in a fast paced environment, and excellent computer skills which include MS Word, MS PowerPoint, MS Excel, MS Outlook.

To apply for this position please submit your resume to info@hanabiosciences.com or contact Sue Hirabayashi, Director, Clinical Operations at (650) 228-5036 or sue.hirabayashi@hanabiosciences.com.