



### Senior Clinical Research Associate (Sr. CRA) Part-time, non-travel (M-F)

We are looking for a part-time Senior CRA. You will be monitoring internal studies and data collecting for clinical trials and studies conducted at Machaon Diagnostics to assess all data documentation, reports and records for consistency with IRB-approved protocols, and determine if clinical trial/study documentation is within parameters of study goals, as well as to monitor clinical trial/study safety, in keeping with protocols, GCP, CLP, GCLP and regulatory requirements.

#### Tasks include:

1. Verifying that study data is well maintained, well organized and available for sponsor and regulatory agency audit.
2. Ensuring that source documentation is properly recorded and stored for future review and audit.
3. Provide oversight of and insights into trial activities (e.g., trends in protocol compliance, enrollment, monitoring deviations, data quality).
4. Report findings to laboratory directors and support staff, and study sponsor management.
5. Conduct and document staff training in GCP, GLP, CAPA, GDocP, cGMP and other regulatory areas.
6. Develop and deliver technical training on protocols, database, compliance, adverse event reporting, study investigation protocols, amendments, regulatory documentation requirements as well as training and proctoring new employees on trial and study related activities.
7. Contribute to the development of clinical protocols, informed consent forms, and case report forms.

#### Required Education/Skills:

1. Prior hands-on clinical research experience encompassing all aspects of the clinical process is required.
2. 4+ years working at the senior Clinical Research Associate level that includes clinical trial and study monitoring, ideally in the laboratory industry.
3. Candidates must have a life science degree (master degree preferred).
4. Clinical research Certification is strongly preferred (ACRP, SoCRA, other).
5. Ability to communicate and relate well with key opinion leaders and various clinical personnel.

Machaon Diagnostics Sr. CRA Job Posting

June 10, 2015



6. Excellent written and verbal communication skills, presentation, interpersonal and analytical skills required.
7. Substantial computer literacy
8. Solid understanding of the reference laboratory and CRO industries.

Please send your CV and a list references in PDF format when applying for this position.

Machaon Diagnostics is a 12-year old laboratory firm that is accredited by the College of American Pathologists (CAP), accredited by CLIA and licensed by the State of California. We are experts in hemostasis, thrombosis, immunology, special chemistry, platelet physiology/function, molecular diagnostics, and genetic assays.

The laboratory is located on a hospital campus in the sunny San Francisco East Bay, just 11 miles from downtown San Francisco.

