Cancer Research And Biostatistics
1505 Westlake Ave N, STE 750
Seattle, WA 98109-3050
Phone: (206) 652-9711
Fax: (206) 342-1689
http://www.crab.org

Regulatory Affairs Specialist — Position Number: RAS.1018

Cancer Research And Biostatistics (CRAB) is a non-profit organization whose purpose is to help conquer cancer and other diseases through the application of biostatistical principles and data management methods.

Position Summary:
The Regulatory Affairs Specialist provides regulatory compliance guidance to CRAB by establishing guidelines for creating, maintaining and enhancing administrative and regulatory systems associated with conducting clinical trials. This position is 50% FTE.

Primary Duties and Responsibilities:

- Responsible for ensuring compliance to all regulatory requirements for clinical trial services as deemed appropriate within the scope of the project
- Contributes to CRAB Standard Operating Procedures (SOPs) to confirm that applicable regulations are followed and training programs for regulatory procedures at CRAB are established, implemented and documented
- Provides regulatory support and feedback to clinical investigators and organization throughout the lifecycle of a clinical trial
- Prepares and administers regulatory submissions as required
- Reviews and maintains regulatory documents associated with the conduct of clinical trials, e.g. study TMFs and associated computerized systems
- Reviews research team documents and templates related to regulatory compliance, including Corrective and Preventive Action (CAPA) plans
- Provides regulatory oversight to clinical trial work performed by CRAB
- Identifies and reports general regulatory affairs issues to Quality Compliance
- Maintains knowledge of current regulations and trends to incorporate into CRAB quality and regulatory systems
- Assists in the implementation, testing, and administration of systems, including databases, documentation management systems, and publishing technologies for regulatory submissions
- Acts as a liaison between CRAB and participating study sites for Regulatory issues
- Processes Serious Adverse Events (SAE), prepares documentation, follows up for medical evaluation, and distributes to necessary parties
- Participates in internal, client and regulatory authority audits as required
- Performs other duties as assigned

Required Qualifications:

- Bachelor’s degree or equivalent years of related work experience
- Minimum three years of clinical trials research experience, preferably in drugs and biologics
- Two years of clinical regulatory affairs experience
- Working knowledge of FDA and GCP regulations and guidelines
- Knowledge of 21 Code of Federal Regulation Parts 11, 312 and 820
- Limited travel may be required

Desired Knowledge, Skills and Abilities:

- Certification in regulatory affairs or clinical trials research is preferred
- Experience in training others in regulatory guidelines and requirements
- Clinical quality assurance experience a plus
- Excellent written and verbal communication skills
- Experience with on-site and centralized monitoring
- Strong planning and organization skills
- Highly detail oriented
- Ability to work well as part of a team or work independently
- Spanish language skills a plus

This position is 50% FTE and is Non-Exempt from state and federal overtime regulations.
Employment authorization is required.
Travel/relocation expenses will not be provided for this position.
CRAB is an Equal Opportunity Employer.

In your cover letter, describe how your skills and experience match the qualifications for the position.

To apply, submit resume and cover letter with position number via mail, fax or email to:
Cancer Research And Biostatistics
Attn: Hiring Coordinator
1505 Westlake Ave N, Suite 750
Seattle, WA 98109-3050
Fax: (206) 342-1689
crabjobs@crab.org

Posting Date: October 25, 2018

Closing Date: Open until filled