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Manager, Clinical Operations (Regulatory Affairs)

CCS Associates, Inc. - San Jose, CA

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Manager, Clinical Operations (Regulatory Affairs)

CCS Associates, Inc (CCSA) is a small, woman-owned company providing leading-edge scientific services in drug discovery and development to government agencies as well as to pharmaceutical and biotech industries. CCSA employs technology to create innovative solutions and high-quality products. Our expert professional, technical, scientific, library, and administrative staff brings wide-ranging experience in providing services to our government and industry clients (www.ccsainc.com).

Essential Duties and Responsibilities:

- Manage overall essential site document management operations; propose and implement practices to improve efficiency.
- Manage and supervise activities of Clinical Operations (Regulatory Affairs) staff.
- Serve as DSMB Administrator for the I-SPY 2 TRIAL;
- Provide specialized expertise in essential site documents and tracking (e.g., NCI's Registration and Credential Repository), human subject protections, research ethics, and IRBs.
- Ensure that all activities are conducted in compliance with Good Clinical Practice, relevant SOPs, and regulatory requirements, and meet appropriate quality standards.
- Prepare and deliver effective presentations for external and internal audiences.
- Represent the company to clients such as National Cancer Institute, Division of Cancer

Qualifications and Experience:

- Five years of Clinical Research Associate/pharmaceutical/biotechnology industry experience. Relevant clinical, regulatory and document management, including eTMF systems experience, preferred.
- Solid knowledge of applicable regulations; experience in interpretation of regulations, guidelines, policy statements, etc.
- Ability to work both independently with minimal direction and within project teams and committees and foster effective, positive interactions with other functional areas, clients, and partners.
- Demonstrated excellent leadership and communication skills, and strong organizational and project management skills.
- Ability to represent the department in project teams, committees and external meetings.
- Strong interpersonal skills and the ability to deal effectively with a variety of personnel, including medical and scientific staff.
- Experience in managing and supervising direct reports.
- Well organized, detail oriented, effective written and oral communication skills.

Education:

Company Info

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Bachelor's degree required, Masters or PhD in Biology/Chemistry, Life Sciences, or Drug Development preferred.

CCS Associates offers a full benefits package (medical, dental, vision, long-term health), AD&D, life insurance, and 401k plan.

We seek talented, qualified employees in all our operations. CCSA is an Equal Employment Opportunity Employer.

Job Type: Full-time

Required education:

- Bachelor's

Required experience:

- management/supervisory: 1 year
- pharmaceutical/biotechnology: 5 years
- Regulatory Affairs: 5 years
- clinical, regulatory, document management, eTMF: 5 years

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