SURGE Therapeutics – The Intraoperative Immunotherapy Company

SURGE FOCUSED. IMMUNOTHERAPY. DELIVERED.

Senior Clinical Project Manager (Sr. CPM)

SURGE Therapeutics seeks to change the standard of care for cancer patients by transforming how, when, and where cancer immunotherapy is deployed in order to dramatically improve survival outcomes. We are reimagining surgical oncology from being only a physical intervention to being a therapeutic intervention as well; creating a world where nobody grieves the loss of a loved one due to preventable post-surgical cancer recurrence.

To strengthen our team, we are looking for an experienced Senior Clinical Project Manager.

The **Senior Clinical Project Manager** will be a key member of the SURGE Clinical Operations team. They will report to and work closely with the Senior Vice President of Clinical Operations. Providing operational expertise and leadership to project teams under the guidance of the SVP of Clinical Operations, the successful candidate will be a key interface with clinical sites involved in our clinical trials. The Sr. CPM will lead clinical trial implementation teams and have oversight of assigned Contract Research Organizations, laboratory vendors, and assigned clinical trial service providers. The successful candidate will be goal oriented, flexible, adaptable, and willing to "roll-up one's sleeves." This leader will think strategically, have strong communication skills, function across departments, and drive initiatives with unquestionable integrity, ethics, and moral character. SURGE employees must be self-confident, results-oriented, independent, and team players with a patient-focused passion.

Your Responsibilities:

The Senior Clinical Project Manager plans and manages overall clinical operations for assigned clinical trials and programs; including timelines, budgets, resources, investigational sites, vendors, and key project deliverables. This role will ensure compliance with SOPs, regulatory requirements, and ICH/GCP guidelines, while maintaining alignment with assigned strategies and goals. This includes strong coordination and communication to oversee clinical program activities with other functions, including next-stage and long-term planning.

Clinical Trials: Plan, Manage, and Conduct

- Lead and manage a multidisciplinary clinical trial team to ensure all trial deliverables are met according to timelines, budget, quality standards, and operational best practices
- Maintain a high level of professional expertise through familiarity with clinical protocols and projects
- Triage CRO and clinical site questions
- Manage selection of study vendors for assigned studies and throughout the life of assigned clinical trials
- Select investigational sites with input from internal stakeholders and vendors
- Review and refine clinical operation plans, including monitoring project plans
- Work with clinical supplies and CMC to determine IP requirements
- Work with operations to oversee investigative sites' adherence to pertinent regulations through review of monitoring reports and audit reports as well as communications with investigators, study site personnel, & CRAs
- Providing input and contributing to study-related documents
- Work with clinical team to establish budget and timelines for the study
- Review clinical regulatory documentation for study submission, including but not limited to CTA modules, IB, IMPD, EC, safety reports, and labels
- Develop the Clinical Study Report as needed to support the project team
- Identify and provide solutions to clinical trial issues and/or risk management
- Provide input together with the Clinical Project Team on responses to questions from Health Authorities, Ethics Committees, or IRBs
- Providing or facilitating training to clinical study teams on protocol-specific topics
- Participate in internal and external audits
- Manage communication of study status and guidance to internal stakeholders

Subcontractors: Oversight and Management

- Participating in the selection of our CRO; reviewing the CRO contract, including scope of services

- Supervise adherence to scope of work within timelines and budget
- Oversee and drive the preparation and updates of Investigational Drug Brochures (IBs) and annual reports (AR/DSUR)

Quality and Process: Assure adherence to standards, process, and best-practice
- Contribute to and initiate process improvement initiatives
- Manage the development of in-house operations SOP's, guidelines, and systems
- Collaborate with other department members to promote and assure compliance and alignment of all processes and procedures
- Participate in document quality control

Budget and Planning: Establish and manage budgets and timelines
- Oversee the preparation and management of clinical trial site budgets; establishing project milestones, budgets, and timelines for study conduct together with the study team; establishing a detailed project plan
- Build initial, follow-up, and close-out study budgets
- Monitor the recruitment rate of the study and taking appropriate and timely corrective actions, as needed
- Track all aspects of the clinical trial, providing regular progress reports
- Update management team with project milestones, costs, and projections for future activity (providing various strategic scenarios and proposals with proactive or corrective action when needed)

Project Team Representation: Key advocate for planning, troubleshooting, and managing project team requirements
- Participate in the overall project planning, optimization, and consolidation with the project team
- Working closely with medical experts and other cross-functional leads for the design of clinical trials within the project
- Report progress on deliverables to the project team, identifying variances, and presenting solutions
- Manage operational aspects of the clinical project in terms of timelines, costs, and resources
- Proactively evaluating risks at operational level and building contingency plans for discussion within the project team
- Serve as a Subject Matter Expert and mentor to the project team
- Special projects as requested

Qualifications
- University degree, preferably in a biologic/scientific discipline
- Minimum of 7-10 years of R&D experience in biotech, pharmaceutical, or relevant clinical CRO experience, including 5+ years in clinical trial management
- Experience in executing multiple phase I-III global clinical trials (oncology preferred)
- Secondary experience in surgical oncology/device trials is a plus
- Must have knowledge of FDA regulatory requirements
- Must exhibit ability to solve problems and work independently as well as work well in a team
- Must have demonstrated multi-tasking ability, managing multiple conflicting priorities effectively
- Strong interpersonal skills, reflecting confidence, responsiveness, flexibility, and diplomacy
- Exceptional leadership skills, including ability to lead, influence, and manage conflict, change, and teams
- Excellent written and verbal communication skills
- Strong computer skills (Excel, Word, Power Point, MS Project) and presentation skills
- Ability to travel (likely minimally but potentially up to 30%); this position is otherwise fully remote

We offer:
- Opportunity to contribute to the shift in the standard of care for cancer patients
- Opportunity to grow within an exceptional and experienced team
- An exciting scientific environment with a positive culture
- Excellent benefits; medical, dental and vision, including a 401k match and flexible time off

SURGE Therapeutics is an equal opportunity employer that is committed to diversity and inclusion in the workplace.