Meissa Vaccines
*1100 Island Drive Suite 202*
*Redwood City, CA 94065*
www.meissavaccines.com

**Senior Clinical Trial Manager/Program Manager**

**Are you ready to work for a small pioneering vaccine biotech? We are seeking a talented, ambitious team member who shares our passions for science and battling the burden of infectious diseases.**

**About Meissa Vaccines Inc.**

Meissa Vaccines is a biotech company focused on the advancement of vaccines for respiratory syncytial virus (RSV), which represents the largest unmet respiratory medical need in pediatrics. The company is also developing vaccines for 2019 novel coronavirus (COVID-19), human metapneumovirus, parainfluenza virus type 3, and other emerging respiratory viruses. The technology is sourced from Dr. Martin Moore's laboratory, when he was at Emory University. Dr. Moore, together with Dr. Roderick Tang, are cofounders of Meissa and supported by a team with extensive experience in conducting vaccine clinical trials.

**Candidate profile and job description**

Meissa Vaccines seeks a full-time Clinical Trial Manager (CTM)/Program Manager (CPM) to join our collaborative team in North Redwood City, California. This individual, reporting to the Senior Director of Clinical Development, will contribute to successful completion of multiple clinical studies across indications in support of our mission: improving global public health by discovering and developing innovative and safe vaccines against important respiratory viruses.

Qualified candidates must be legally authorized to work in the United States. Additionally, Meissa is not able to provide sponsorship for employment visa status for this position.

**Key responsibilities**

Contribute to the team's production of important study documents, ranging from training manuals to protocols to various study-specific plans. Perform systematic QC review and, where applicable, writing of designated or operational sections of these deliverables. Develop and update standard company procedures related to trial and clinical sample management.

Partner with contract research organizations (CROs) in identifying potential study sites and assessing feasibility. Oversee completion of site selection visits conducted by CROs by reviewing finalized reports and participating in evaluating them.

Take an operational leadership role in organizing site initiation visits (SIVs), investigator meetings (IMs), and other engagements, including preparation and/or delivery of presentations for sites, CROs, and other attending stakeholders.

Serve as primary point of sponsor contact for investigators, study coordinators, IRBs, ethics committees, CROs, site-facing vendors, and other stakeholders leading up to, during, and after closeout of studies.

Actively track overall study metrics and individual subject data (e.g., critical sample collections, visit adherence), providing status updates to the team. Monitor study timelines, working cross-functionally with Project Management in doing so.

Oversee CRO monitoring of study-related documentation and activities at sites, both remotely and via periodic in-person oversight visits conducted in parallel with scheduled site monitoring visits by CRO CRA, to ensure adherence to Good Clinical Practice (GCP) guidelines, protocols, monitoring plans, regulatory requirements, and relevant standard operating procedures (SOPs). Oversee and prepare corresponding reports to be provided to the team as requested.

Review incoming clinical trial data. Collaborate with Clinical Development and, if applicable, Clinical Data Management team members on resolving data queries with sites and CROs, followed by coordination of locking of the trial database.

Contribute to clinical study report preparation, including review of tables, figures, and listings for accuracy and completeness, in collaboration with team members from other functions.

Develop, maintain, and regularly evaluate company relationships with site-facing vendors, including central clinical laboratories, CROs, and carriers providing shipment of IP and supplies to sites.

Monitor and update study data on clinicaltrials.gov, EU Clinical Trials Register, and analogous electronic trial databases.

Compile and maintain trial master files (TMFs) for ongoing studies, in conjunction with on-site CRO team members.

Build rapport with and motivate sites to adhere to study timelines in achieving study milestones. Contribute to development and rollout of strategies to enhance study enrollment, where needed.

Be responsible for execution and tracking of confidentiality agreements with collaborators and other stakeholders.

Work closely with other functions (e.g., Regulatory, Clin. Develop.) on preparing documents for regulatory submissions.

Be available to assist, if needed, with tracking study contracts, invoicing, payments, and budgets across vendors and sites.

Take on additional responsibilities and grow into new roles that will evolve in parallel with ongoing clinical development.

**Requirements**

Education

At minimum, Bachelor's Degree (BS, BA) in life sciences, nursing or health-related field, or equivalent.

Certification from the Association of Clinical Research Professionals (ACRP) or the Society of Clinical Research Associates (SOCRA) (as CCRA® or CCRP, respectively), a plus.

Professional Experience

At least 5 years cumulative postgraduate experience as CRA, Senior CRA, and/or CTM/CPM monitoring/managing clinical trials at a CRO and/or within pharmaceutical/biotech industries. Experience in Clinical Operations spanning the full spectrum of study progress, from site selection to startup to closeout, is required. Preference is for a candidate with experience across the early and late phases of clinical development.

Solid understanding of GCP, U.S. FDA, and international/ICH guidelines pertaining to the drug development process and conduct of clinical studies. Proficiency applying these guidelines to ensure that internal and external (i.e., site-generated) trial documentation meets these standards.

Substantial experience conducting the duties listed under 'Key responsibilities' above.

Relevant Skills

Excellent interpersonal skills, including a track record of working successfully both as an individual and while on cross-functional teams.

Fluency in English with excellent written, verbal, and reading comprehension. Aptitude for communicating clearly and proactively during face-to-face meetings, in written communications, and in other venues including teleconferences.

Strong organizational and project management skills, with success working in a fast-paced environment. Self-starter, with ability to take initiative without continuous oversight.

Solid proficiency in MS Office (Word, PowerPoint, Excel).

Willingness to travel domestically and internationally (up to 20%, if/when deemed safe in light of the ongoing COVID-19 pandemic), including for clinical monitoring, investigator/site engagements, and other functions.

**For immediate consideration, please email your CV to:** careers@meissavaccines.com

Meissa Vaccines offers competitive salary and comprehensive benefits, including group medical, dental, and vision, as well as company paid life, AD&D, short and long term disability, holiday pay, and unlimited PTO.

Meissa Vaccines Inc. is an Equal Opportunity Employer. We celebrate diversity and are committed to creating an inclusive environment for all Team members. Meissa Vaccines, Inc. does not discriminate on the basis of race, religion, color, sex, gender identity, sexual orientation, age, non-disqualifying physical or mental disability, national origin, veteran status or any other basis covered by appropriate law. All employment is decided on the basis of qualifications, merit, and business need.