Meissa Vaccines

1100 Island Drive Suite 202
Redwood City, CA 94065

Senior Manager, Quality Assurance

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 private Biotech company developing novel live viral vaccines for the prevention of severe respiratory illness caused by Respiratory Syncytial Virus (RSV), human metapneumovirus (hMPV) and human parainfluenza virus type 3 (hPIV3), which represents the largest unmet respiratory medical need in pediatrics. Our lead live attenuated RSV vaccine (MV-012-968), licensed from Emory University, was generated by synthetic biology using codon deoptimization of virulence genes. MV-012-968 is currently in Phase 1 clinical trials. Additionally, Meissa launched a vaccine development program for SARS-CoV-2 leveraging our platform technology. The cofounders, Dr. Martin Moore and Dr. Roderick Tang, are supported by a team with extensive experience in conducting preclinical research and vaccine clinical development.

Job description

Meissa is seeking a full-time Senior Manager in Quality Assurance responsible for developing and maintaining phase appropriate quality systems related to oversight of the manufacture cGMP supply of vaccines, as well as applicable GCP and GLP study sites. This individual will contribute to the quality assurance of the lead RSV clinical candidate, as well as additional pipeline programs. Depending on the product phase, the Sr. Manager provides both guidance and active development and management of quality systems in Phase 1 through BLA in preparation for commercial production. This will include development of quality systems covering, but not limited to, coordinating external audits and vendor assurance with contract development and manufacturing organizations (CDMOs), contract test labs (CTLs) and other external suppliers. In addition to this external oversight, this position will require the routine management of GXP quality systems internally. The candidate should be passionate about our company mission of improving global public health by developing innovative and safe vaccines against important respiratory viruses.

Candidate Profile

Candidates should have a high level of integrity and the ability to take on different roles as required in a small company, lead projects independently, and be a team player that shares the founders' passion in bringing these vaccines to patients. Preference will be given to local San Francisco Bay Area candidates.

- A minimum of 10 years in vaccine or biopharmaceutical QA management. Degree in biology, biochemistry, chemistry or similar is preferred.
- Proven experience in QA processes and systems to support vaccine or biopharmaceutical development.
- Experience in working with external vendors is required, including leading GXP audits.
- Experience in leading the Quality function for a vaccine or biopharmaceutical company and familiarity with GxP standards.
- Experience with electronic filing and database management abilities.
- Experience with documentation systems and with document review and auditing.

- Excellent interpersonal, organizational, negotiations and communication skills; team member than can work collaboratively with colleagues across all functions.
- Demonstrates strong organizational skills, including the ability to prioritize personal workload.
- Proven supervisory experience and ability to guide, train, supervise and prioritize workload of direct reports.
- Ability to work well in a deadline-driven environment.
- Capable of supporting multiple projects simultaneously.

Principal Duties and Responsibilities

- Develops QA function and actively manages GMP oversight of vaccine products produced at contract manufacturing sites.
- Develops applicable QA functions and actively manages GCP and GLP oversight both clinical and nonclinical study sites.
- Ensures Phase appropriate compliance with quality systems, quality procedures, and quality policies
- Develops, implements, and maintains programs/processes to ensure high quality products and compliance with cGMP.
- Responsibilities include the final release of cGMP intermediates and vaccine products
- Represents company as host of regulatory inspections at applicable contract sites and supports inspections at CMO facilities.
- Provide authoritative representation of Meissa's interests to partner organizations and the ability to harmonize communication and procedures across multiple partner organizations.
- Works with Process Development and Manufacturing during technology transfer of new and existing processes, establishing key checkpoints for new products and processes, and managing change control
- Works with appropriate team members to develop processes to support Meissa's nonclinical safety (GLP) program.
- Works with appropriate team members to develop processes to support Meissa's clinical (GCP) program.
- Develops and implements a departmental budget that meets all corporate and quality assurance goals and requirements.
- Directs all GXP compliance audits as required.
- Reviews, approves, and directs implementation of changes to controlled documents and processes (e.g., SOPs, Specifications, Methods, etc.), both internally and externally, as needed.

For consideration, please send a resume and cover letter expressing interest 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/long term disability, holiday pay, sick time, and generous paid vacation.

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.

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.