Meissa Vaccines

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JOB DESCRIPTION: Chemistry Manufacturing and Controls (CMC) Lead – Meissa Vaccines Inc. 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). Our lead live attenuated RSV vaccine (MV-012-968) licensed from Emory University was generated by synthetic biology using codon deoptimization of virulence genes. A first-in-human clinical trial of MV-012-968 is targeted for Q4 2019.

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The CMC lead will be responsible for CMC-related activities across the portfolio including manufacturing proof-of-concept, pre-formulation and stability studies. Managing contract manufacturing organizations and clinical trial material testing. The ideal candidate will be a highly motivated individual with experience and interest in working in a small, entrepreneurial environment with broad responsibilities and opportunities.

Principal Duties and Responsibilities

• Oversee drug substance and drug product activities from preclinical development through clinical supplies
• Management of cGMP manufacture and supply of Drug Substance (DS) and Drug Product (DP) in support of ongoing clinical programs
• Develop and implement strategy and DOE (design of experimentation) for optimizing and controlling quality of DS and DP using CROs and CMOs
• Work with external consultants and vendors on strategies for robust, scalable and cost-effective manufacturing routes and drug product formulations that meet or exceed the target clinical profile
• Develop realistic budgets for commercial production of DS and DP
• Management of supply chain and logistics in support of clinical studies
• In coordination with Quality Assurance, implement stage appropriate analytical methods and protocols and ensure that all CROs and CMOs are using systems and processes in compliance with all relevant regulatory standards
• Develop plans for the validation and registration of API and DP as required by cGMP, ICH (International Conference of Harmonization) and FDA regulations
• Writing and reviewing documents for INDs / regulatory section submissions; represent the company as the CMC expert before U.S. and European regulatory authorities
• Prepare, review or edit cGMP batch records, CMC regulatory and Quality documents
• Prepare technical reports, publications and oral presentations

Skills and Background

• Experience in managing US and International CRO/CMOs for the manufacture of live virus products
• Experience with projects in clinical development e.g. Phase 1 through Phase 3 especially intranasally delivered drug product
• Experienced with cGMP manufacturing and IND, and knowledge of relevant FDA and EMEA regulations

• Experience in supply chain management.
• PhD or MS with 10+ years of experience
• Able to identify and resolve critical issues
• Experience implementing technical, strategic and operational plans
• Excellent written and verbal communication skills, exceptional interpersonal and management skills to collaborate with and direct the work of others on assigned projects (including both internal teams and external collaborators)

Please send 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- and long-term disability, vacation, sick, and holiday pay.

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.