

CEPI is looking for a Chemistry, Manufacturing and Control (CMC) Lead as part of its growing Vaccine Development team based in London. Full details of the role are included below. If you are interested in joining the CEPI team and think you have the appropriate qualifications for this role, please read the detailed job description below and follow the instructions for applying.

Chemistry, Manufacturing and Control Lead, London

OBJECTIVES

The primary role of the CEPI Vaccine Development team is to provide the technical leadership to advance our vaccines portfolio working closely with the Vaccine Science Team, partners and cross-cutting teams across CEPI.

The CMC Lead reports to the Head of CMC and will be the subject-matter expert in areas pertaining to CMC and supply chain in the development of vaccines. They will support the development of CEPI's portfolio of vaccine projects and the attainment of CEPI's broader and longer-term goals of vaccine delivery and access, preparedness and rapid response. The CMC Lead will be responsible for facilitating CEPI-funded projects in a manner that guarantees clear communication and project continuity which adheres to CEPI guidelines and governance, and ensures compliance with national and international regulations and current Good Laboratory Practice (GLP), Good Manufacturing Process (GMP) and current ICH guidelines.

We are looking for someone who can lead the technical CMC aspects of the projects, provide advice and support in the process development, manufacturing and supply chain oversight of these vaccines. An important area of responsibility for this role will be contributing to cross-cutting activities required to deploy investigational vaccines in emergency settings in LMICs, as well as the long-term sustainability manufacturing and supply strategy. They will need to interact with research groups and manufacturing partners at a global and local level. Project Management and Team Leadership experience, combined with working across multinational organisations, will be critical.

ACCOUNTABILITIES

- Support the development and management of the overall Chemistry, Manufacture and Controls (CMC) project strategy, development and manufacturing plan.
- Oversee the outsourced contract manufacturing and development organizations and associated timelines and budget of the awardees.
- Ensure the highest quality of CMC development and operations support is provided to all vaccine development projects in compliance with GLP, GMP, regulations and current ICH guidelines.
- Monitor timely and accurate accomplishment of key CMC project milestones and review CMC data for milestone decision processes.
- Advise on the process development, quality and supply chain of new vaccines, where requested, and guide awardees to manufacture, distribute and stockpile investigational vaccines for clinical use.
- Coordinate cross-cutting activities in CMC with CEPI stakeholders, regulatory authorities and CEPI portfolio partners, such as development of release testing specifications, development of thermostable formulations, etc.
- Support the technical evaluation and due diligence of new projects and CMC technologies in multi-functional teams as needed.

EDUCATION, EXPERIENCE, KNOWLEDGE AND SKILLS

To be successful in the role you will need to demonstrate:

- A minimum of 7-10 years of vaccine CMC in industry, consulting, NGO or public health sector (PhD degree preferred)

- An in-depth expertise of at least two areas of vaccine CMC (Process Development, USP, DSP, analytical, formulation, devices, GMP, QC, manufacturing, supply chain) with working knowledge of the others
- Team Leadership experience and Project Management
- Regulatory experience a plus
- International experience (ideally including LMICs) and ability to work on multinational teams
- Strong communication skills
- Entrepreneurial skills

TRAVEL AND LOCATION REQUIREMENTS

- Will be required to travel internationally on a frequent basis
- The position is based in London and the successful candidate will need to have and maintain the right to work in the UK

WHAT WE CAN OFFER YOU

- Experience from the international effort on developing vaccines against EIDs and accelerating vaccine development response to outbreaks
- An exciting job opportunity at a newly established international organisation focusing on funding and facilitating vaccine development
- Attractive benefit package including holidays, health benefits and private pension arrangements
- Competitive salary

HOW TO APPLY

If you are interested in being considered for this position, please send your Curriculum Vitae along with a covering email / letter to jobs@cepi.net.

If you have any questions about the position, please email glenn.foster@cepi.net.