CEPI | New vaccines for a safer world

Request for Proposal

Fixed Term Consultancy Appointment: Chemistry, Manufacture and Control Consultants

About CEPI

CEPI is an international coalition of governments, academic, philanthropic, private, public, and intergovernmental institutions whose mission is to prevent outbreaks of emerging infectious diseases from becoming humanitarian crises. CEPI does this by financing and coordinating vaccine development to combat future epidemics.

CEPI's initial goal is to coordinate financing for and oversight of the development of vaccines to fight the following: MERS, Lassa fever and the Nipah virus. Moreover, CEPI works to develop platform technologies that enable rapid vaccine development against known and unknown pathogens.

CEPI is organized under the laws of Norway as a non-profit international association, and currently has three office locations:

- **Oslo (HQ):** Location of the Deputy CEO, Resource Mobilization, Vaccine Science, HR, Portfolio Management, and Finance and Operations teams.
- **London:** Location of the CEO, Communications, Legal and Business Development, and Vaccine Development teams.
- **Washington, DC:** CEPI representation office mandated to coordinate the efforts of partners located in the US, maintain relationships with the US government and educate the American public about the importance of developing vaccines to combat future global epidemics.

Current Need and Scope of Tender

CEPI is looking for limited term Chemistry, Manufacture and Control (CMC) consultants who can provide the services noted below for an initial period of **6 months** from July 2018 with the possibility of extending.

Senior Virology Consultant Requirement:

- Expected level of requirement around **1-2 days per week.**
- Provide ad hoc technical advice on CMC issues in the area of virology and more generally where appropriate
- Review data and advise collaboration partners on CMC strategy
- Assess technical data in cell banking, cell culture process development, analytical, virus manufacturing, downstream processing, formulation, fill finish
- Assisting in the preparation for audit visits, technical visits, CMO choice, etc.
- Provision of landscape analysis in manufacturing technology and release, assessment of new technologies if needed
- Provide expert opinion on cell physiology and cell and virus cycle in manufacturing environment (shear, oxygen, etc.), isolation, passaging, storage and maintenance of all biological materials involved in vaccine virus manufacturing
- Provide strict review based on scientific rationale for processing choices such as cell culture, purification and formulation conditions, in process holding time, adventitious agents testing, etc.
- Provide expertise for assay development for bioprocess monitoring and control
- Provide CMC expert opinion on new project proposals for CEPI

Qualification requirement for Virology Consultant:

- Publicly recognized scientific leadership in the field of virology and bioprocessing though Track of record of publications in the field
- Track of record of expert advice in regulatory settings (ICH writing guidelines, WHO, FDA)

- Track of record of editor level peer review for specific virology topics or publications in peer review journals as a single author
- Extensive and significant experience in CMC Virology
- Proven track of record to engage and active discussions with regulators from mature regulatory authority (FDA, EMA, MHLW, etc.)

Chemistry, Manufacture and Controls (CMC) Consultant Requirement

- Expected level of requirement around **2-3 days per week.**
- Provide ad hoc technical advice on CMC issues
- Review data and advise collaboration partners on CMC strategy
- Support of CMO selection, assess technical data in cell banking, cell culture process development, analytical, virus manufacturing, downstream processing, formulation, fill finish
- Advise on technology transfer to Contract Manufacturing Organisations (CMOs)
- Assisting in the preparation for audit visits, technical visits, CMO choice, etc.
- Provision of landscape analysis in manufacturing technology and release, assessment of new technologies if needed
- Provide expert opinion on cell physiology and cell and virus cycle in manufacturing environment (shear, oxygen, etc), isolation, passaging, storage and maintenance of all biological materials involved in vaccine virus manufacturing
- Provide strict review based on scientific rationale for processing choices such as in process holding time, adventitious agents testing, etc.
- Provide expertise for assay development for bioprocess monitoring and control
- Provide CMC expert opinion on new project proposals for CEPI

Qualification requirement for CMC Consultant:

- Publicly recognized scientific leadership in the field of virology and bioprocessing though Track of record of publications in the field
- Track of record of operating in regulatory settings (ICH writing guidelines, WHO, FDA)
- Extensive and significant experience in industrial vaccine CMC and operations, such as Vice President of Operations level
- Proven track of record to hosting inspections, engage and active discussions with regulators from mature regulatory authority (FDA, EMA, MHLW, etc.)

General requirements

Consults will be expected to:

- Participate in regular teleconferences
- Have the flexibility to attend site visits where appropriate
- Attend meetings in CEPI Offices in Oslo and London when required

All consultants put forward for these assignments must be able to demonstrate the following:

- Fluent in both written and spoken English
- Have the right or ability to travel freely and complete this work in various location throughout the world.

Tentative time plan

Activity	End Date
Request for Proposals advertised	31 May 2018
Deadline for submission of written proposal	10 June 2018
Selection process completed	15 June 2018
Consultants Ready to Start	1 July 2018

CEPI reserves the right to change the time schedule at any time.

Tender Instructions

To be considered for a contract award under this request, please submit the written proposal (not exceeding 5 pages + applicable resumes) in English, no later than **midnight (00:00hrs GMT) on Sunday 10 June 2018**. Proposals received after the deadline will be rejected. Costs for the preparation of proposals will not be refunded.

Your proposal must include the following:

- How you feel you (as an individual) or your organisation is best positioned to fulfil the requirements
- Competitive fee quote fee quote
- General overview of the schedule and timing of billings
- Fee rates for additional services
- Estimate and general description of the expenses you expect to incur and bill to CEPI. If CEPI will be billed for other than direct out-of-pocket expenses incurred in performance of services, please describe the costs.

Electronic copies of your proposals should be sent to: glenn.foster@cepi.net

Evaluation criteria

Our evaluation criteria include the areas of information solicited under scope of tender and bidder's qualification. The contract will be awarded to the bidder who has supplied the economically most advantageous offer based on the following criteria:

- Total Cost (30%)
- Assessment of bidders' qualifications and probability of achieving expected outcome (70%)

Confidentiality

By accepting to take part in this RFP process, your firm agrees to keep in confidence all information imparted to you by CEPI during the period of consultancy, not to disclose it to third parties, and not to use it for any other purpose than for participation in the RFP process.

Cancellation

CEPI reserves the right to change the time plan or cancel the competition without any obligation to cover any cost for the tenderers work on the tender.

Duration

The expected duration for this contract is five (6) months (1 July 2018 – 31 December 2018) with the option to renew based on an evaluation process.

Additional Information

If you have any questions, please contact glenn.foster@cepi.net