



Call for Offers of Service in Concept Design and Review of Facilities for Vaccines Manufacturing Compliant with Global GMP

1. Adjudication power

1.1 Non-official Adjudicator and Organizer of call for expression of interest : DCVMN International

Chemin du Canal 5, 1260 – Nyon – Switzerland, Tel. +41 22 595 1393, fax. +41 22 595 6700

Email : executivesecretary@dcmn.org URL www.dcmn.org

1.2 Offers to be submitted to the following address :

Chemin du Canal 5, 1260 – Nyon – Switzerland, Tel. +41 22 595 1393, fax. +41 22 595 6700

Email : executivesecretary@dcmn.org

1.3 Deadline for open questions before submission

All questions should be submitted in English latest by 15.10. 2014

Answers will be provided before 30.10.2014. Questions posted after 15.10.2014 cannot be considered.

1.4 Limit for submission of formal expression of interest for consideration

Date: 15.11.2014. For companies already engaged in the informal consultation in the preparation of projects are subject to the requirements and condition outlined here below.

Requirements:

Any offer should be submitted in electronic format and one paper copy by mailing.

Acknowledgement of receipt will be sent electronically only with the date of receipt, and the date of the electronic submission is recognized as formal. Paper copy could be mailed any time, while clearly indicating on the envelope “Confidential – do not open”.

The submitting party should keep all records to prove that submission was timely effected. After the deadline no additional dossiers may be considered.

1.6 Procedure : Open access

1.7 Type of offer : consulting services

2. Subject of the call for offers

2.1 Type of services:

Engineering consulting services for vaccine manufacturing buildings/facilities

2.2 Title of the project

Mock-inspection or self-inspection for design and/or review of facilities for vaccines manufacturing compliant with global GMP requirements

2.3 Reference / number of project

DCVMN/OPP1113279/ initiative01- service provider

2.4 Vocabulary common to public markets

Engineering design and consulting services on GMP compliance

2.5 Description

The present call for proposals refers to independent expert technical assistance providing consulting services for concept design or review of vaccine manufacturing facilities and operating systems compliant with global GMP requirements (WHO-GMP) based on initial assessment of manufacturers through mock-audit or self-inspection tools. The location of services can be any of the following countries: Argentina, Bangladesh, Brazil, Egypt, India, Indonesia, Mexico, South Africa, South Korea, Thailand, Vietnam, China and Taiwan. Additional countries may be added.

The main services may include, but not be limited to assessment of :

- Concept design, material flow,
- Clean rooms, aseptic rooms layout
- Water systems: purified water and water for injection
- HVAC (heating, ventilation, and air conditioning systems)
- Environmental wastage monitoring
- Other

2.8 The proposal should outline the corporate history, organization and capabilities, tools for assessment of facilities, and approximate timeline. Any modifications should be notified by written to the steering committee.

2.9 Execution:

Probable start: 01.01.2015

Probable end: 31.06.2015

3. Conditions

3.1 Conditions of participation

Payment upon receipt of invoice of services effected.

3.2 Cautions/guarantees

None. DCVMN reserves all the rights to withdraw the call for expression of interest, and to modify or cancel the project at any point in time before agreement signature, if funds are not available timely.

3.3 Conditions of payment for consulting services

Within 30 days after receipt of invoice at DCVMN International.

3.4 Costs of the services offered

The payments and costs should be all covered by the offer documents, and include the complete execution of the contracted services, and only those services.

3.5 Consortium

Consortium of two or more companies is allowed provided the commercial partners are clearly indicated in the offer and that the technical and administrative responsibility is entirely assumed by one contractor.

3.6 Subcontracting is not allowed, to foster transparency.

3.7 Capability criteria :

All consulting service providers economically and technically capable to assume entire responsibility for the project, and providing evidence of their capabilities are invited to submit a proposal (in USD)

Capabilities should include:

- a) Technical capabilities of the enterprise and global presence
- b) Economic and financial capabilities of enterprise
- c) Experience of the project leader (key person responsible for the execution of the project)
- d) Declaration of availability of experts for the time period required
- e) Evidence of relevant geographical presence

3.8 Required justifications:

The following required certificates/justifications are to be included in the dossier for the offer to be considered:

For a) Technical capabilities of the enterprise

- Certificate of ISO 9001 (for the company directing and responsible for the project)

- At least one reference of a comparable project previously executed with success for a vaccine manufacturing facility in a developing country. The cost of the previous project, if possible.

- The reference provided should refer to the company or consortium of companies, and not refer to each individual company of a consortium separately. List of global registered offices.

For b) Economic and financial capabilities of enterprise

- Recent annual report from the service provider regarding revenues/ expenses of the consulting and engineering activities (for company or group of companies participating in the project)

For c) Experience of the project leader (key person responsible for the execution of the project)

- Project leader CV and other references regarding provision of similar services

- Deputy project leader – same as project leader (cf. above)

For d) Declaration of availability for the time period required

The project leader and the deputy project leader should declare and guarantee a joint availability of 25 to 50%, during the project period of 06 months.

3.9 Approval criteria:

The Steering committee should consider the following criteria and weight:

I : Costs (weight 30%)

II : Project leader capability (weight 30%)

- Project leader 20%

- Deputy project leader 10%

III : Analysis and description of proposed procedures for design and validation plan, including risk analysis (weight 40%)

- Analysis of proposed procedures : 10%

- Analysis of concept : 10%

- Risk analysis : 10%

- Quality management plan : 10%

Evaluation will be made attributing notes from 0 to 5 :

Cost evaluation

The maximal note (5) is to be attributed to the lowest project cost. A cost estimate that represents double the lowest cost receives the note "0". Other cost estimates receive notes proportionally linear between the lowest and the double of the lowest costs.

Quality evaluation:

0 = impossible; no information provided

1 = insufficient, incomplete and not relevant information

2 = sufficient information and not relevant to the project

3 = insufficient information and relevant to the project

4 = sufficient and relevant information to the project

5 = excellent large body of information relevant and important for the project

Points are multiplied by weight to give 500 maximum.

3.10 Conditions for payment : upon proper invoicing of effected services.

3.11 Languages

English

3.12 Validity

6 months after deadline of submission

3.13 Call for proposals will be available at www.dcvmn.org from 15.09.2014 to 30.11.2014

4. Additional information

4.1 Negotiations

The steering committee will consider only offers that guarantee the respect of local and foreign laws (when applicable), legal working conditions and protect workers and working environment, as well as respect gender equity regarding compensation policy.

4.2 Other requirements

- i. Site visits : at least one
- ii. The project will be granted provided the customer is mature and receives required credit.
- iii. The work related to developing the offer application should NOT be covered by the project. The not-granted dossiers will not be returned and after completion of the project will be destroyed.
- iv. The opening of the offers is not public.

4.3 Publication : the retained offers may be published at www.dcvmn.org if agreed by parties.

4.4 Settlement : any dispute or settlement are subject to Swiss law terms and conditions.

Disclaimer : This call for expression of interest includes forward looking statements which are based upon the current beliefs and expectations of DCVMN management and are subject to significant risks and uncertainties. There can be no guarantees with respect to projects that they will advance or prove to be successful.