No.B .1206/2015

Office of the Director,
Institute of Animal Health &
Veterinary Biologicals, Palode.
Date: 16.06.2015.

From

The Director

To

The Director
Public Relations Department
Thiruvananthapuram.

Sir,

Sub:- AHD - IAH & VB, Palode –Cell Culture Vaccine
Production Unit—Expression of Interest—reg.

Ref:-

I am herewith enclosing 3 copies of notification
for invitation of Expression of Interest for publication in major
English and Malayalam dailies. The targeted firms / agencies
are experts at National level Consultancy Service and hence, I
request that the notice of Expression of Interest may be
published at least in 3 major English dailies and Government
Website.

Yours faithfully,

DIRECTOR

Enclo:

✓ 1. Additional Director (Planning), Vikas Bhavan.
NOTICE FOR EXPRESSION OF INTEREST

Request for Expression of Interest (EOI) for fixing Consultancy Service for IAH & VB, Palode, Department of Animal Husbandry, Government of Kerala for establishment of a new Cell Culture Vaccine Production Facility as per Current Good Manufacturing Practices (cGMP) standards from Reputed Firms/Organizations/Agencies.

Period of Consultancy: From the day of award of consultancy till successful commissioning and handing over of the facility as per cGMP standards.

Consultancy Charge: Shall be mentioned as a lump sum amount based on terms of payment envisaged hereafter in this document and not as a percentage of the total project cost.

Last date and Time of receipt of intention paper: On or before 07:08:2015, 3:00 PM

I. Location and general description:

The Department of Animal Husbandry, Government of Kerala owns a Veterinary Biologicals Production Unit - the Institute of Animal Health and Veterinary Biologicals located at Palode which is approximately 40km from Thiruvananthapuram Central on the Thiruvananthapuram Shenkotta State highway. The institute extends over 4.66 hectares of land and at present produces various Viral & Bacterial Vaccines against livestock and poultry diseases. The institute envisages establishing a Cell Culture Vaccine production facility in compliance with cGMP standards to take up production of cell culture based Livestock & Poultry Vaccines.

II. Selection of the Firm:

The participating firms should present a concept plan of the production facility before an Expert Committee. The concept plan should be prepared based on a thorough study of the premises of the institute and with due importance for conservation of environment. The participating firms should identify an ideal location within the campus for establishing the production
facility and waste disposal facility as per the current pollution control board norms. The design of the laboratory should be in line with the schedule M Guidelines ultimately to get cGMP certification for the product manufactured in it. The cell culture facility should be designed to produce 20 lakh doses of PPR vaccine per year with scope for adding on production lines for three other cell culture vaccines like Rabies (10 lakh doses per annum), Classical Swine Fever (5 lakh doses per annum) and Duck plague (50 lakh doses per annum). The central facility for common utilities should be designed for simultaneous operation of two production lines. The technical competence of the consultancy firms shall be arrived based on the concept plan presented before the expert committee and the documentary proofs in support called for. The date, time and venue of presentation of concept plan before the expert committee will be intimated later through email only. The soft copy of the concept plan to be presented should be enclosed in cover A. The selected firm should submit a hard copy of the concept plan duly signed by the authorized signatory of the firm.

II. Prequalification of Firms:

a) Work Experience:

Three successful up-gradation/ original design works in India in Vaccine manufacture/ sterile injectable pharmaceuticals executed. Out of this at least one should have obtained GMP/GLP certification in the last ten years and should be fully operational at the time of quoting EOI. Documentary evidence of GMP certification obtained for the labs need to be enclosed. The participating firms must provide the names of institutions, their full address and contact numbers of the concerned persons at the facilities where they have carried out or are carrying out all such works.

b) Financial turnover of the firm:

Should enclose their turn over/ balance sheet for the past three years duly evaluated and certified by a competent charted accountant for the purpose of evaluation.

c) The firm should have a registered status under Indian company/ Society Act at the time of application.

d) Certificate of income tax returns for the last three years duly attested.

e) All true copies of the documentary evidence submitted shall be attested by a Notary.
III. Qualification of personnel required

a) The applicant firms should have a single contact person who shall be responsible for the function of the entire consortium. The name, address, contact number and other contact details of the designated contact person shall be furnished as an affidavit duly notarized.

b) The applicant firms should have in their panel/should have assured access to the following:

1) Graduate Civil Engineer with ten years experience in lab/manufacturing up-gradation process.

2) Graduate Bio-medical engineer with 5 years experience in instrumentation of laboratories/ manufacturing establishments.

3) Graduate Electrical/Electronics Engineer with 5 years experience in laboratory equipment design/maintenance.

4) An expert with 10 years experience in vaccine production/sterile injectable pharmaceutical preparations.

5) Necessary supporting staff.

6) Documentary evidences in support of credentials of the above personnel have to be enclosed.

IV. Scope of work of consultant:

Stage I

a) Prepare and submit a detailed project report for establishing a cGMP Standard Cell Culture production facility at IAH & VB, Pulode on a turnkey basis in full agreement with the approved concept plan within 30 days from the date of award of work order.

Stage II

a) Prepare and submit detailed plan and estimate with all necessary drawings as per cGMP norms and detailed bid documents with complete BOQs and specifications of material of construction to invite tenders for award of work within 60 days of receipt of order subsequent to approval of detailed project report.

b) Prepare and submit bid documents with detailed specifications of all equipments and installation required for establishment of the cGMP compliant Cell Culture production facility within 60 days of receipt of order subsequent to approval of detailed project report.
c) Subsequently, the firm shall make a presentation in front of the expert committee and during this presentation, they will give the details of their final design of this project, details of works involving the individual works of their consortium via a viz architectural design, layouts, work execution, validation procedures etc. The consultant is bound to incorporate any necessary changes as recommended by the expert committee and as directed by the undersigned.

d) Submission of final tender documents.

**Stage III**

a) Assist in tender processing till award of work order to the firm executing the work.

**Stage IV**

a) Verification of equipment/installation specification, monitoring and supervision of entire project execution, validation and submission of interim reports of various stages of implementation.

**Stage V**

a) Render required service for preparation of documents and related liaison works for obtaining license and cGMP certification for the newly established facility.

b) Ensure imparting of required training to the personnel of this institute in the use of all installed equipment and facility as per cGMP standards and guidelines.

**V. Terms of Payment:**

- After successful completion of Stage I: 10% of the sanctioned consultancy charges.
- After successful completion of Stage II: 20% of the sanctioned consultancy charges.
- After successful completion of Stage III: 20% of the sanctioned consultancy charges.
- After successful completion of Stage IV: 20% of the sanctioned consultancy charges.
- After successful completion of Stage V: The balance 30% of the sanctioned consultancy charges.

**VI. Period of consultancy:**
a) The period of consultancy will be effective from the date MOU is signed and would remain in force for a period of three years or till the successful completion of the project, whichever is earlier.

b) The time period of the contract may be extended on mutually agreed basis if any need arises due to reasons beyond the control of both the parties.

VII. Force Majeure:

a) The general terms and conditions of force majeure shall be applicable for this contract also and will be binding on the consultant till completion of the contract.

VIII. Other Conditions:

a) In the event of dispute arising out of operation of this indenture or violation thereof, the Director, Animal Husbandry Department, Kerala shall be the sole Arbtrator.

b) In the event of any legal disputes, the court of law at Thiruvananthapuram shall be the sole jurisdiction to sort out legal issues.

IX. The interested consultancy firms/organizations/agency should furnish full information about their relevant activities supported by documentary proof attested by notary public, work experience, financial turn over, registration status, qualification and strength of personnel etc.

X. The expression of interest should be delivered to the office of the Director, Institute of Animal Health and Veterinary Biologicals, Pacha.P.O, Palode, Thiruvananthapuram district, Pin-695562 on before 3 PM on 07:08:2015 under “two cover system” in sealed envelopes.

XI. Both the Cover A and the Cover B should be placed in one sealed cover and should be superscripted as “Quote for offering consultancy towards establishment of a cGMP compliant cell culture vaccine production facility at IAH & VB, Palode” and should be addressed to the address mentioned in clause X. The cover A should contain only the technical details and documentary evidence called for and the Cover B should contain the Financial Bid as a lump sum amount and not as a percentage of the project cost. It may be noted that terms of payment of the consultancy charges offered shall be as mentioned above based on the satisfactory completion of the different stages of scope of work envisaged.
XII. Intention papers received after the scheduled date and time are liable to be rejected.

XIII. The consultancy firm will not be eligible to take part in any tender/purchase procedures related to the establishment of the facility or supply of material or equipment for construction directly in the present project.

XIV. All the right to reject any or all the responses received, without assigning any reason, whatsoever, is reserved. The undersigned reserves the right to cancel the notification or make any modification in scope of work or in any matter pertaining to this project at any stage in finalizing the firm and his decision in this regard will be final and binding on all the participants.

[Signature]

Director IAH & VB,
Pacha.P.O, Palode,
Thiruvananthapuram District,
Kerala