REQUEST FOR Expressions of Interest (EoI)

Consulting Services

For

(a)Pre-Shipment Inspection and (b) Laboratory Testing

Government of Nepal
Ministry of Health
Department of Health Services
Logistics Management Division
Teku, Kathmandu

Government of Nepal
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NHSP-II/DOHS/S/NCB-215/(a) Pre-Shipment Inspections – (b) Laboratory Testing/2015-16

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REQUEST FOR EXPRESSIONS OF INTEREST (EoI)

The Government of Nepal (GoN), Ministry of Health, Department of Health Services, Logistics Management Division invites the Expression of Interest for the Quality Assurance and Inspection services of Pharmaceutical and non-Pharmaceutical Products from the interested firms/ Service providers.

At present different more than 100 types of drugs and medical consumables are in the pipeline of procurement and supply.

LMD now invites EoI from established national and international firms having experience to carry out the pre-shipment inspections and laboratory testing services of Pharmaceutical and Non-Pharmaceutical commodities before the commencement of the dispatch from the manufacturers' premises as per the detailed Terms of Reference for the services to be performed. In order to qualify, interested firms for the laboratory testing must be certified by ISO/IEC 17025:2005.

The service required will be for one year and possible of extension depending on the completion of delivery schedule of contract of the FY 2072-73 and previous contract.

Firms may express an interest for (a) Pre-shipment Inspection or (b) Laboratory Testing or both.

The complete set of EoI documents is available at DOHS/LMD. They may be downloaded from LMD's website (www.dohslmd.gov.np). Nepali firms are required to submit their duly renewed firm and VAT/PAN registration certificates along with the request for EoI documents. This does not apply to firms submitting proposals from outside Nepal. All the short-listed firms will be selected using the criteria attached and will be invited to submit a Proposal.

The proposer can either be a firm involved in the pre-shipment inspection having an accredited laboratory of its own or supported by an independent accredited test laboratory. Alternatively, an accredited testing laboratory may also bid for the services provided such laboratory is involved in the inspection and sampling of drugs or is supported by such other inspection firm or agent. It is permitted for an inspection agent and an accredited laboratory to form a consortium, provided this is clearly declared and the lead firm identified.

The laboratory offering the quality assurance services through laboratory tests must have ISO 17025:2005 certification, preferably participating in inter-laboratory proficiency trials and/or

accredited under a scheme that is accepted by the International Laboratory Accreditation Cooperation (ILAC). A copy of the certificate is to be included with your EoI.

Selection criteria include, but are not limited to, the following:

Interested eligible organizations must provide information indicating that they are qualified to perform the services (brochures, description of similar assignments, experience in similar conditions, availability of appropriate skills among staff, etc.).

From the EoI, a short list will be populated using the criteria of the EOI document. LMD will send the technical and financial proposal only to the short listed firm/company .

A consulting firm will be selected in accordance with the procedures laid down in the Nepal Public Procurement Act and Regulations.

Organizations may obtain further information from the Logistics Management Division at the address above, during office hours.

All sealed Expressions of Interest (EoI) must be delivered to the address below via direct mail in a sealed envelope marked "**Expression of Interest**", **Notice No. NHSP-II/DOHS/S/NCB-215/(a) Pre-Shipment Inspections – (b) Laboratory Testing/2015-16** under cover of a letter addressed to the **Director, Logistics Management Division, Department of Health Services, Ministry of Health** on or before **12:00 noon (Nepal time) on 22 May 2016** along with relevant documentation to demonstrate intent and qualification to undertake the services requested. The EoI will be opened at **13:00 hour of 22 May 2016** at LMD.

Government of Nepal
Ministry of Health
Department of Health Services, Logistics Management Division
Pachali, Teku, Kathmandu, Nepal

INSTRUCTIONS FOR PREPARING THE EXPRESSION OF INTEREST (EoI)

1) Expression of Interest: *(Following information must be included)*

1.1) Brief introduction of organization

Name of the organization:
_____
Head of Organization (name and position, personal phone number):

Address of organization: _____

Phone #, Email address: _____

Fax #: _____

Post Box.# _____

Place/address of registration of organization _____

Major on-going current programme/s: [Use as much space as needed]

S. No.	Title of the project/program	Project Duration and sites	Contractual Amount	Purchasing Agency

1.2) Past Work experience on similar services **(1 page max). NOTE: A minimum of two (2) years' experience is required.**
1.3) Past work experience on specific services (1 page) Max. **Note: A minimum of two (2) years' experience is required**

2) The following documents/information must be submitted along with EoI

A) Legal Documentation providing organization's eligibility to undertake the work:

A.1) Include relevant certification (Registration Certificate; PAN and VAT Registration Letter, Tax Clearance certificate of FY 2071-72)

A.2) Include a copy of Organization's constitution and Diagram of Organizational Structure)

B) Governance and Management of Your Organization:

B1) Include a copy of authenticated audit reports of last two (2) fiscal years.

B2) Governing Board profile

Full name	Position	Gender

B3) Total Number of Staff Implementing Programs on **(a) Pre-shipment Inspection and (b) Laboratory Testing services**

Full name	Gender	Position	Qualification	Experience

C) Experience:

C.1) Provide Institutional references (Reference letters) from whom the proposer has carried out a similar services.

D) Key Human Resources:

D.1) Include a signed copy of Bio-Data of key human resources (Programme/Admin Finance/M&E) to be involved in the proposed assignment

4) Joint Venture (If one or more organisations plan to collaborate to provide services as a group/joint venture, please mention the role and responsibilities of lead agency and supporting agency and name, address, profile of such organizations) – **One page max**

Terms of Reference for Consulting/Non-Consulting Services (a) Pre-Shipment Inspections and (b) Laboratory Testing)

1. Background

The most commonly used Quality Assurance and Inspection services required from Inspection Agencies will be Pre-Shipment inspections (PSI). Other less frequently requested services may include, but not be limited to, works inspections of manufacturing units, loading supervision, laboratory testing and Post-Shipment Inspections. The service requirements are detailed in the Statement of Work.

2. Purpose of the Terms of Reference for Services (ToR)

These ToR are issued with the aim of establishing the services for the provision of Quality Assurance and Inspection Services for the Logistics Management Division (LMD) of the Department of Health Services (DoHS) of the Ministry of Health (MoH) of the Government of Nepal (GoN).

The inspection and laboratory services will apply to both Pharmaceutical and Non-Pharmaceutical products and services as detailed in the Scope of Work.

The services required from inspection agencies and laboratories will generally be requested based on the demonstrated technical ability of the agency and/or laboratory to provide a value-added service to the procurement process.

The value of pre-shipment inspection and laboratory testing services will be approximately 5,000,000.00 NPR based on estimated budget allocated. The estimates are provided in good faith and shall not in any way be deemed to be a commitment on the part of LMD regarding any quantity for future purchases.

Proposals must clearly demonstrate how your company is qualified to undertake inspections in the Asian region of the following products:

- Drugs and Medical consumable
- Vaccines
- Nutritional commodities

For further product details kindly refer to the Technical Specifications detailed on the LMD website: www.dohslmd.gov.np

3. Required Documentation (Mandatory)

Proposers must submit the following documentation in sufficient detail to allow full evaluation for technical compliance.

a. Company Profile- including:

- Summary of corporate structure and business area
- Corporate directions and experience
- Locations of regional and local offices and agents worldwide
- Number and type of inspectors and Laboratory professional by profession
- Information of pending lawsuits, if any
- The most recent audited financial statements
- Examples of Pre-Shipment inspection reports (PSI) and Laboratory Testing reports
- Indication of what services other than those listed under Scope of Work can be provided and
- Any other documents deemed relevant

b. Expertise and Experience

Documentary evidence of the following must be provided:

- Your expertise in the provision of services required under the Scope of Work,
- A minimum of one (1) reference of client for whom the proposer has carried out a similar scope of projects - especially with reference to other International Organizations for whom such services have been successfully provided in the Asia Region
- LMD may contact referees for feedback on performance. Details of the references must include:
    - Name, details and description of the client company/organization
    - scope/duration of the contract
    - type of inspections conducted/services provided
    - geographical location of service provided

Documentary evidence must be provided.

4. Scope of Work – (a) Inspection Services

The following Inspection Services may be required (this list is not inclusive and may be increased by mutual consent).

5.1 Pre-Shipment Inspection (PSI)

PSI shall be conducted by a third party agency, at the Supplier's premises, or any other location specified by LMD. LMD will issue a work order detailing the PSI requirements. Generally, PSI will consist of checking that the goods or services are being provided in accordance with the Supplier's contractual requirements. For this, a copy of each relevant portion of the Contract will be provided to the successful Proposer.

The PSI will include such tests and measurements necessary to verify the requirements described in the Contract. LMD may also request that the loading and sealing of containers is subject to inspection at the time of the PSI.

The PSI will include, but may not be limited to, the following activities:

a. Check quality of the consignment, with samples drawn based on the batch size and sample plan as described in ISO 2859-1 – latest issue, as further defined by ISO 3534-2 or as specified and agreed in advance between the parties
b. Check items listed in the Contract requirements against the contract technical specifications, technical drawings (where appropriate) and other relevant documents or standards.
c. Check the quality and finish of the items listed in the Purchase against the contractual requirements
d. Conduct dimensional checks
e. Verify manufacturer's test reports for raw materials, if required, witness the testing of the raw materials.
f. Check the packing, pallet size, shipping marks against instructions specified in the Contract and stamp the supplies as "Inspected" using the Inspector's stamp.
g. Collect and forward samples as requested by LMD for further **laboratory testing to designated laboratory..**
h. Report any damage or non-conforming aspects observed and
i. Any other agreed ad hoc inspection requirement.

These activities listed above shall either be performed by the representative nominated by the Inspection Agency or performed by others and witnessed by a nominated representative.
The Inspection Agency shall issue a Certificate of Inspection along with an Inspection Report and laboratory test report and provide LMD with relevant photographs for each consignment. The Certificate of Inspection shall be signed by an authorized representative of the Supplier. Exceptionally, a draft report detailing any major issues may be accepted, by agreement, where the reporting will take longer due to any complicated or technically challenging inspections that have been conducted.

In the event of an abortive inspection the inspection agency will submit details of non-conformities in relation to Contract requirements, with noted deficiencies duly acknowledged (signed and stamped) by the authorized representative of the Supplier.

A normal sampling plan will be followed as described by ISO 2859-1: Latest Issue.

AQL[1] will be 1.0 for Major Defects and 2.5 for Minor Defects, unless otherwise specified. Consignments with Major Defects exceeding the AQL will not be accepted. In order to make

[1] *Acceptance Quality Limit*

inspections more cost-effective, Inspections against different Contracts must be combined, if the Supplier, place and date of Inspection are the same.

Should consistently good quality be achieved, LMD may switch to reduced inspection (as per sampling plan ISO 2859-1). Alternatively, should a deterioration in quality be detected, LMD may require increased inspection.

LMD shall take the final decision to release any consignment for shipment after receipt of Inspection Report and Laboratory Test Report.

5.2 Factory Inspection

The purpose of a factory inspection is primarily to assess the manufacturing capacity, capability and available infrastructure of potential Suppliers to meet LMD's stringent quality requirements. Normally these inspections, if required, will be conducted by LMD staff. However, LMD may engage the services of a third party inspection agency to conduct this/these inspections on its behalf.

As a factory or Supplier inspection can be varied, the scope for this type of inspection will be agreed on an individual basis as required.

A typical factory inspection may include, but not be limited to, the following:

a) The general information about the manufacturing plant and its capacity to consistently meet the requirement of the specified product in quantity, quality and time.
b) The details of skilled, semi-skilled or unskilled workers, including qualification of key staff.
c) Verification of industrial licenses, factory lay-out, working environment, safety, ventilation and pollution control system.
d) Manufacturing processes, plant and equipment machinery and the production infrastructure.
e) Verification of Quality Control System, adherence to ISO or domestic standards verified by LMD
f) Laboratory, Inspection tools and testing equipment.
g) Previous successful orders and a short list of customers/buyers.
h) Handling and Storage facilities/warehousing of raw materials and semi-finished products.
i) Packing and Shipping departments.
j) Confidential appraisal of a company's financial standing.
k) Non-employment of Child labour in any area of operation and no connection with production of anti-personnel land mines or components for land mines.

On completion of the investigation, a comprehensive Works Inspection Report of the Inspector's findings and recommendation, with relevant photographs will be issued and submitted.

5.3 Supervision of Loading

Typical functions are as follows:

a) Report any damage or non-conforming aspects observed.
b) Ensure full compliance to Packaging Instructions as described in the Contract.
c) Check of the general appearance of the packing or palletized supplies.
d) Verify storage conditions.
e) Ensure that the number of packages and shipping marks comply with the contract requirements.
f) Witness handling of all loading and unloading operations.
g) Check the standard of transport, condition of containers.
h) Ensure the stowing, fastening and wedging on all transport is adequate to withstand the conditions likely to be encountered during shipment.
i) Check all relevant documents.
j) Stamp and Seal both consignment and container as required.

A detailed supervision report, supported with photographic evidence of loading and supervision shall be submitted.
The inspection agent should collect the report from the lab and dispatch the inspection report along with the laboratory testing report to LMD.

Scope of Work – (b) Laboratory Testing

Typical functions of the lab may include, but are not limited to, the following:

a) Confirm that the items received by the Inspection Agent are in accordance with the Contract.

b) Perform the laboratory testing to ensure the quality of the received samples as per the required standard (Pharmacopeial Standard) at earliest.

c) Issue the test report in the prescribed format clearly stating that the product Complies/Not Complies according to pharmacopeia after completion of the test at earliest to the inspection agent.

Evaluation Criteria

EOI will be evaluated in accordance with the criteria below. (a) For Preshipment Inspection

Criterion/Parameter		Maximum Points	Mark Obtained	Remarks
		Total	Total	
1. General experience		**10**		
1.1 Year of Experience				
1.1. More than 5 years		10		
1.2 More than 2 to 5 years		8		
1.3: 1 to 2 years		5		
2. Specific Experience Excellent = 100%, Very good = 80%, Good = 60%, Acceptable = 40%, and not acceptable = 0		**30**		
2.1 Experience on the Pre-shipment Inspection of Pharmaceuticals products under IP or BP or USP or other equivalent Pharmacopoeias recognized by DDA Nepal		**10**		
2.2 Experience of the Pre-shipment inspection of Medical Consumables		10		
2.3 Experience on the Pre-shipment inspection of Family Planning commodities (Male Condom, IUD etc) and nutrition commodities		**10**		
3. Organizational structure:		**10**		
Availability of adequate number of professionals				
3.1 Excellent (2Pharmacist, 3 Diploma Pharmacy and 1 BBA or equivalent)		10		
3.2 Good (1 Pharmacist, 2 Diploma Pharmacy and 1 BBA or equivalent)		6		
3.3 Acceptable (1 Pharmacist, 1 Diploma Pharmacy and 1 BBA or equivalent)		5		

Evaluation Criteria

EOI will be evaluated in accordance with the criteria below. (b) For Laboratory Testing

Criterion/Parameter		Maximum Points	Mark Obtained	Remarks
		Total	**Total**	
1. General experience		**10**		
1.1 Year of Experience				
1.1. More than 5 years		10		
1.2 More than 2 to 5 years		8		
1.3: 1 to 2 years		5		
2. Specific Experience Excellent = 100%, Very good = 80%, Good = 60%, Acceptable = 40%, and not acceptable = 0		**30**		
2.1 Experience on lab testing of Pharmaceuticals products under IP or BP or USP or other equivalent Pharmacopoeias recognized by DDA Nepal		10		
2.2 Experience of lab testing of Medical Consumables		10		
2.3 Experience lab testing of Family Planning commodities (Male Condom, IUD etc) and Nutrition commodities		10		
3. Organizational Standard		**10**		
Having the standard of ISO 17025		10		