F. No. 15011/3/2012-O&M
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
***

Shastri Bhawan, New Delhi
Dated the 21st March, 2013

INVITATION FOR EXPRESSION OF INTEREST

TO

IMPLEMENT A PROJECT FOR ISO 9001:2008 CERTIFICATION

Department of Pharmaceuticals, Government of India, invites Expression of Interest from interested ISO 9001consultants and Service Providers for providing consultancy. Services to Department of Pharmaceuticals, for obtaining ISO 9001:2008 certification for the first phase of implementation of department-wise ISO9001 implementation. This document provides the scope, pre-qualification criteria, bidding terms and conditions and suggested response formats.

PART I: GENERAL TERMS

1 GOALS OFTHIS EXPRESSION OF INTEREST (EOI)

The objective of this EoI is to solicit proposals from the interested bidders for participation in a bid process for selection of consultants to help the Department obtain ISO 9001 certification for the first phase of ISO 9001implementation.

2 EoI ISSUING AUTHORITY

This Expression of Interest (EoI) is issued by the Department of Pharmaceuticals, intended to short-list potential bidders. Ministry's decision with regard to the short-listing of bidders through this EoI shall be final and the Ministry reserves the right to reject any or all the bids without assigning any reason.

1.	Project Title	Selection of Service Provider for obtaining ISO 9001:2008 certificate
2.	Project Initiator Details	
3.	Department	Department of Pharmaceuticals

4.	Contact Person	Ms. Monika Verma Director , Department of Pharmaceuticals, Phone 011-23313431 Fax No. 23359301 Email id:- verma.m@nic.in
5.	Contact Person (Alternate)	Sh. Pradeep Yadav, Joint Secretary Department of Pharmaceuticals, Phone No:- 23385131 Email id:-pradeep.y@nic.in
6.	Contact details	Department of Pharmaceuticals, M/o Chemicals & Fertilizers, 'B' Wing, 3rd Floor, Janpath Bhawan, New Delhi- 110001
7.	Website	www. pharmaceuticals.gov.in.

3 TENTATIVE CALENDAR OF EVENTS

The following table enlists important milestones and timelines for completion of bidding activities;

S. No.	Milestone	Date and Time
1.	Release of Expression of Interest	21.3.2013 17:00 Hrs.
2.	Bidders Conference	01.04.2013 15:00 Hrs
3.	Last date for submission of written questions by bidders	05.04.2013 17:00 Hrs.
4.	Response to the Queries	10.4.2013 16:00 Hrs
5.	Last date for Submission of EoI Response	15.4.2013 16:00 Hrs.
6.	Opening of EoI Responses	18.4.2013 16:00 Hrs
7.	Declaration of Shortlisted Firms	To be informed later

4 AVAILABILITY OF THE EoI DOCUMENTS

EoI can also be downloaded from the Ministry's website **www.pharmaceuticals.gov.in.** The bidders are expected to examine all instructions, forms, terms, project requirements and other details in the EoI document. Failure to furnish complete information as mentioned in the EoI documents or submission of a proposal not substantially responsive to the EoI documents in every respect will be at the bidder's risk and may result in rejection of the proposal.

5. BIDDERS' CONFERENCE

Department of Pharmaceuticals will host a bidder's Conference in Delhi at the address given under Contact Details Section 2 above. The Conference is tentatively scheduled as per the schedule given in Section 3 above. The representatives of the interested organizations (restricted to two persons) may attend the bidders' conference at their own cost. The purpose of the conference is to provide bidders with any clarifications regarding the Eol. It will also provide each bidder with an opportunity to seek clarifications regarding any aspect of the EoI and the project. The venue for the bid conference will be at the address given in Section 2.

6 EOI PROCESSING FEES

A non refundable (except successful bidder) processing fee for Rs.5,000 (Five Thousand Rupees only)in the form of a Demand draft or a Pay Order drawn in favour of Pay & Accounts Officer, Department of Pharmaceuticals, payable at New Delhi has to be submitted along with the EoI Response. Bids received without or with inadequate EoI Processing fees shall be liable to get rejected.

7 VENUE & DEADLINE FOR SUBMISSION OF PROPOSALS.

Proposals, in its complete form in all respects as specified in the EoI, must be submitted to the Department of Pharmaceuticals at the address specified above in Section 2. Department of Pharmaceuticals in exceptional circumstances and at its discretion, extend the deadline for submission of proposals by issuing an addendum to be made available on the Department of Pharmaceuticals website, in which case all rights and obligations of Department of Pharmaceuticals and the bidders previously subject to the original deadline will thereafter be subject to the deadline as extended.

PART II: SCOPE OF SERVICES

8 GENERAL BACKGROUND

Under the Performance Monitoring and Evaluation System (PMES) for Government Departments, each Government Department is required to prepare a **Results Framework Document (RFD).** An RFD provides a summary of the most important results that a department/ministry expects to achieve during a financial year. Under RFD, there is a set of mandatory indicators that are common to all departments preparing

RFDs. One such important mandatory indicator is obtaining ISO 9001: 2008 certifications. Accordingly, government departments have to start the work of implementing ISO 9001: 2008 requirements. It is envisaged that government departments will need the services of competent consultants to implement the requirements of ISO 9001:2008. This expression of interest (EOI) has been developed to assist government departments select a competent consultant who may be engaged for providing ISO 9001:2008consultancy services.

9 TERMS OF REFERENCE:

The terms of reference for the Consultant will include the following:

a. To fine tune the scope of ISO 9001:2008 implementation under the first phase, and finalize the same through discussion with the Steering Committee so that the ISO 9001:2008 requirements may be implemented within a time period of four months.
b. To perform gap-analysis of the existing documentation of the department .against requirements of ISO 9001:2008 and produce a gap analysis report.
c. To plan together with the ISO project team of the department on the ways to address the gaps in order to develop the necessary documentation for ISO 9001:2008 certification
d. To develop all mandatory procedures as required in ISO 9001:2008 and guide t h e ISO project team on implementing the same.
e. To develop customized training course material in soft copy (as well as hard copy) for conduct of all necessary trainings.
f. To conduct required trainings that will include (i) top/senior management briefing; (ii) planning, documentation and implementation workshop for ISO project team and, (iii) awareness programme for all employees.
g. To advise the ISO steering committee on change management and the success factors to support effective implementation of ISO 9001:2008.
h. To conduct Internal Auditors training and guide the Internal Auditor team conducting required numbers of internal audits.
i. To assist in evaluation of implemented ISO 9001:2008 quality management system through internal audits including closure actions.
j. To offer close guidance in the preparation and review of final documents prior to certification.
k. To assist in coordination of required management reviews prior to certification.

l. To guide the ISO project team to take the necessary corrective actions on identified non-conformities and final review of documents.
m. To guide the ISO Project team in making an application for certification
n. To co-ordinate during final certification of the Department and ensure the Ministry is certified by as select certification body.
o. Any other task to ensure the certification of the Department.
p. Submit weekly MIS report to Top Management of the Department with a copy to QCI appointed experts and Performance Management Division (PMD), Cabinet Secretariat.

10 TIME FRAME:

The ISO 9000: 2008 will be implemented in phases. The time period for the first phase will be 4 months from the date of award of the contract. In the first phase, the scope of application will cover such sections/activities consisting of a maximum of 100 staff members

PART III: BIDDING TERMS AND PRE-QUALIFICATION CRITERIA

11 CONDITIONS UNDER WHICH THIS EoI IS ISSUED

i. This EoI is not an offer and is issued with no commitment. Department of Pharmaceuticals reserves the right to withdraw the EoI and change or vary any part thereof at any stage. Department of Pharmaceuticals also reserves the right to disqualify any bidder, should it be so necessary at any stage.

ii. Department of Pharmaceuticals reserves the right to withdraw this EoI if it determines that such action is in the best interest of the Government of India.

iii. Timing and sequence of events resulting from this EoI shall ultimately be determined by the Department of Pharmaceuticals.

iv. No oral conversations or agreements with any official, agent, or employee of the Department of Pharmaceuticals shall affect or modify any terms of this EoI and any alleged oral agreement or arrangement made by a bidder with any department, agency, official or employee of the Department of Pharmaceuticals shall be superseded by the definitive agreement that results from this EoI process. Oral communications by the Department of Pharmaceuticals to bidders shall not be considered binding on the Department of Pharmaceuticals, nor shall any written materials provided by any person other than the

Department of Pharmaceuticals.

v. Neither the bidder nor any of the bidder's representatives shall have any claims. Whatsoever against the Department of Pharmaceuticals or any of their respective officials, agents, or employees arising out of, or relating to this EoI or these procedures (other than those arising under a definitive service agreement with the bidder in accordance with the terms thereof).

vi. Applicants who are found to canvass, influence or attempt to influence in any manner the qualification or selection process, including without limitation, by offering bribes or other illegal gratification, shall be disqualified from the process at any stage.

vii. Each applicant shall submit only one Pre-qualification requirements proposal.

12 RIGHTS TO THE CONTENT OF THE PROPOSAL

For all the bids received before the last date and time of bid submission, the proposals and accompanying documentation of the Pre-Qualification proposal will become the property of the Department of Pharmaceuticals and will not be returned after opening of the pre-qualification proposals. Department of Pharmaceuticals is not restricted in its rights to use or disclose any or all of the information contained in the proposal and can do so without compensation to the bidders. Department of Pharmaceuticals shall not be bound by any language in the proposal indicating the confidentiality of the proposal or any other restriction on its use or disclosure.

13 ACKNOWLEDGEMENT OF UNDERSTANDING OF TERMS

By submitting a proposal, each bidder shall be deemed to acknowledge that it has carefully read all sections of this EoI, including all forms, schedules and annexure hereto, and has fully informed itself as to all existing conditions and limitations.

14 EVALUATION OF PROPOSALS

The bidders' Proposals in the bid document will be evaluated as per the requirements specified in the EoI and adopting the qualification criteria spelt out in this Eol. The Bidders are required to submit all required documentation in support of the qualification criteria specified (e.g., detailed project citations and completion certificates, client contact

information for verification, profiles of project resources and all others) as required for evaluation.

15 LANGUAGE OF PROPOSALS

The proposal and all correspondence and documents shall be written in English.

16 ELIGIBILITY CRITERIA

The consultant who will be engaged should have extensive and proven mix of skill and expertise in the field of ISO 9001:2008 certification. Previous experience of similar work is essential. The consultant must meet the following minimum criteria

a) It is desirable that Consultant should have executed minimum five (5) ISO 9001 projects in the government/PSU sector/large public limited organisations.
b) Consultant should have a minimum of 10 years of professional experience in ISO 9000 consulting
c) The team members of the Consultant will be qualified lead assessors.

The consulting organizations can also be allowed to bid as a consortium for this project. However, in such a situation consultants in individual partner organizations need to have an active role. In such case evidence towards existence and rationale for consortium needs to be furnished.

17 DOCUMENTARY EVIDENCE TO BE SUBMITTED TO SUPPORT ELIGIBILITY

a) Contract/work orders indicating the details of assignment, client, value of assignment, date and year of award.
b) Detailed resume of the team leader and team members indicating the details of qualifications and professional experience.
c) Certificate of lead assessor course undergone by the team leader and team member(s).
d) Completion certificates of previous projects undertaken (Desirable). In case the organization is notable to submit completion certificates, submission of complete contact details (Telephone no, address, organization name) of the contact person where the work has been done is mandatory.

18 PROPOSAL SUBMISSION

Interested Consultant should submit both technical and financial proposals in two parts namely.

A. Technical

B Financial

The technical and financial proposals must be submitted in two separate sealed envelopes indicating clearly on envelopes as "**TECHNICAL PROPOSAL**" and "**FINANCIAL PROPOSAL".** Financial proposal to indicate a warning "**DO NOT OPEN WITH THE TECHNICAL PROPOSAL".** The envelopes containing the Technical and Financial Proposals shall be placed into an outer envelope and sealed. This outer envelope shall bear the title of the assignment *"Engagement of Consultant for providing consultancy services for obtaining ISO 9001:2008 certification of Government Departments".*

i TECHNICAL PROPOSAL CONTENT

Technical Proposal should be prepared considering the Terms of Reference, Detailed Approach & Methodology, Activity Schedule & Deliverables, Time period and any other information to highlight the capability of the consultant.

Technical Proposal must include:

a. Brief description about the Consultant

b. **Consultants experience:** In addition to overall experience of the consultant, details of specific consultancy projects/studies undertaken may be provided including Assignment/project name, description of services provided, appx. value of assignment, country & location, duration of assignment, name of client, starting & completion dates, names of associates (other than employees), if any. Consultancy experience of helping government departments/PSUs/large public limited organizations obtain ISO 9001:2008 may be specifically mentioned.

c Approach

d Methodology

e Work Plan and schedule

f. Team size

g Detailed Resume of the Team leader and team members of the

consultant (with copies of certificates to support qualifications)

ii. FINANCIAL PROPOSAL CONTENT

- Financial proposal (In Indian Rupees) should be in the form of a lump sum amount inclusive of all taxes for the entire *Scope of Services.*
- The lump sum quote should be inclusive of all expenses which the consultant may incur while executing the assignment including Travel, Boarding &Lodging as required.
- Under phase I, two slabs of consultancy fees have been proposed: The upper limit of financial proposal under the two slabs will be asunder:
- For manpower upto 100 employees Consultancy fees:Rs.1,80,000 +service tax
- For Manpower upto 200 employees Consultancy feesRs.2,50,000 + service tax

19. THE EVALUATION OF THE PROPOSAL

The technical proposal will be evaluated as per the following criteria:

S. No.	**Description**	**Break up of marks**
1.	Past Experience in work of similar nature (Govt.PSU/ Large public limited organisations)	50 marks
1.1.	Past experience of similar nature in terms of no of assignments (facilitation in ISO Implementation projects) • Number of assignments: Less than 5 (20 marks) • Number of assignments: *10 (30 marks)* • Numberofassignments:between10 and 20 (40 marks) • Number of assignments: 20 & above (50 marks) Marks will be awarded based on work order of assignments of similar nature, enclosed along with the Technical proposal.	
2.	**Skills & competencies**	40 marks
2.1	Professional experience • Between 10 and 15 years (10 marks) • Above 15 years (20 marks)	
2.2	Team leader qualification • Graduation and qualified lead assessor (10	

	marks) • Post-graduation/Engineering qualification and qualified lead assessor (20 marks)	
3.	Team Size	10 marks
3.1	Team size including team leader • Up to 4 (5 marks) • More than 4 (10 marks)	
	Total	100 marks

- Evaluations will be based on documentary evidence submitted by the applicant with respect to evaluation /selection criteria.
- The technically qualified consultants will be ranked based upon their marks.
- The financial proposals of consultants getting above 70 %marks ONLY will be opened and the final selection will be made based upon the lowest cost quoted.
- In case of a tie in the financial bid opening, the Consultant having scored higher marks in technical qualification will be given preference.
- The consultant can bid for any number of projects with Departments but accept award of projects for a maximum five Government organisations under this scheme. Once five projects have been accepted by the consulting organization, it cannot bid for more.

20. DATE FOR SUBMISSION OF PROPOSAL

The last date for submission of proposal is 15.4.2013 by 17:00 Hrs.

21 SUBMISSION OF PROPOSAL

Proposals should be addressed to:

Shri Mrutyunjay Tripathy,
Section Officer,
Department of Pharmaceuticals
Room No. 307, 'B' Wing, Janpath Bhawan,
New Delhi- 110001

(Monika Verma)
Director
Phone No.23313431