Department of Pharmaceuticals , Ministry of Chemicals & Fertilizers

Call for Expression of Interest (EOI)

The Department of Pharmaceuticals (DoP), Ministry of Chemicals & Fertilizers, Government of India intends to facilitate setting up/upgrading following facilities in Public Private Partnership (PPP) mode:

a) **GLP Compliant Chemical Testing Laboratories**
b) **GLP Compliant Biological Testing Laboratories**
c) **GLP Compliant Large Animal House**

For this purpose it is proposed to engage a Consultant of repute to carry out:

1. Assessment of above mentioned existing facilities in the country vis-à-vis requirements of Pharma industry, gaps if any, and indicate the manner in which this gap could be filled in.

2. Based on the result of exercise at (1) above drawing up Schemes for establishing GLP compliant Chemical/ Biological Testing Laboratories *and GLP compliant Large Animal Houses or upgrading the existing facilities so as to make them GLP compliant laboratories or Large Animal Houses. A combination of both of the above options may also be considered. The Schemes have to be drawn in PPP mode.*

The EOI document containing the details regarding the scope of work, prescribed proforma and qualification criteria etc can be downloaded from the website of DoP at http:// pharmaceuticals.gov.in. The completed EOI documents in all respects have to be submitted by 4.00 PM on 25.4.2011 along with the prescribed fee at the following address.

The Director, Department of Pharmaceuticals,
Room No. 346, A- Wing, Shastri Bhawan, New Delhi-110001

DEPARTMENT OF PHARMACEUTICALS
MINISTRY OF CHEMICALS & FERTILIZERS
GOVERNMENT OF INDIA

EXPRESSION OF INTEREST (EOI)

FOR

1) **ASSESSMENT OF EXISTING GLP COMPLIANT TESTING FACILITIES VIS-À-VIS REQUIREMENT OF PHARMA INDUSTRY, GAP ANALYSIS AND RECOMMEND THE MANNER IN WHICH THIS GAP COULD BE FILLED IN.**

&

2) **BASED ON THE RESULT OF EXERCISE AT (1) ABOVE DRAWING UP SCHEMES FOR ESTABLISHING GLP COMPLIANT CHEMICAL/ BIOLOGICAL TESTING LABORATORIES *AND GLP COMPLIANT LARGE ANIMAL HOUSE OR UPGRADING THE EXISTING FACILITIES SO AS TO MAKE THEM GLP COMPLIANT LABORATORIES OR LARGE ANIMAL HOUSES. A COMBINATION OF BOTH OF THE ABVOE OPTIONS MAY ALSO BE CONSIDERED. THE SCHEMES HAVE TO BE DRAWN IN PPP MODE.***

MARCH 2011

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DISCLAIMER

- Department of Pharmaceuticals (DoP) has prepared this document to give interested parties background information on the Project. While Department of Pharmaceuticals and Ministry of Chemicals & Fertilizers have taken due care in the preparation of the information contained herein and believe it to be accurate, neither Ministry of Chemicals & Fertilizers, Government of India nor Department of Pharmaceuticals of the Government of India, any of its authorities or agencies or any of their respective officers, employees, agents or advisors gives any warranty or make any representations, express or implied as to the completeness or accuracy of the information contained in this document or any information which may be provided in association with it.

- The information is not intended to be exhaustive. Interested parties are required to make their own inquiries before taking decision to submit their Expression of Interest. The information is provided on the basis that it is non – binding on Ministry of Chemicals & Fertilizers, Government of India or the Department of Pharmaceuticals, any of its authorities or agencies or any of their respective officers, employees, agents or advisors.

- Ministry of Chemicals & Fertilizers, Government of India reserves the right not to proceed with the Project or to change the configuration of the Project, to extend the time table reflected in this document or to change the process or procedure to be applied. It also reserves the right to decline to discuss the matter further with any party expressing interest.

- No reimbursement of cost of any type will be paid to persons or entities expressing interest in response to this document.

SCHEDULE FOR THE SUBMISSION OF EOI

EVENT	DATE
Date of availability of EOI documents on DoP's website	10.3.2011
Date of publication of press advertisement in all editions of **The Times of India & Economic Times**	12.03.2011
Last date for receiving queries	05.04.2011
Time and Date of Pre- Application conference in room No. 346 - A wing	2.30 PM on 11.04.2011
Date of issue of Addendum, if any	15.4.2011
Application Due Date	25.4.2011

The completed EOI documents have to be submitted before 1600 hrs on the Application Due Date of submission of applications along with the prescribed fee and necessary attachments at the following address:

The Director,
Department of Pharmaceuticals,
Room No. 346, A- Wing,
Shastri Bhawan,
New Delhi-110001
Telephone No. 23389840
Tele-fax: 23389840

Incomplete EOI documents or as are received after the prescribed date viz. 25.04.11 would stand rejected without any reference to the applicants.

Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

EXPRESSION OF INTEREST

Department of Pharmaceuticals(DoP) in the Ministry of Chemicals & Fertilizers, Government of India, intends to facilitate establishing afresh or upgrading the following kinds of existing facilities in Public Private Partnership (PPP) mode:-

- GLP Compliant Chemical Testing Laboratories,
- GLP Compliant Biological Testing Laboratories and
- GLP Compliant Large Animal Houses

For this purpose it is proposed to engage a Consultant of repute to carry out:

i) Assessment of above mentioned kinds of existing facilities in the country vis-à-vis requirements of Pharma industry, gaps if any, and indicate the manner in which this gap could be filled in. It has to be clearly stated if the gap should be filled in by establishing new GLP Compliant facilities or upgrading the existing facilities so as to make them GLP Compliant or a combination of both.

ii) Drawing up detailed Schemes based on the result of exercise at (i) above, in PPP mode. The extent of investment required in establishing new facilities **and/or** upgrading the existing facilities should be indicated. The funding pattern i.e. the share to be borne by the private entity and the Government of India should be indicated. The manner in which the facilities would be operationalised and managed should be stated indicating clearly whether these would be financially viable and prove helpful in promoting the development of Pharmaceuticals Industry.

Interested registered consulting organizations or individual consultants, duly registered under law and having experience in conducting surveys/studies in the field of Pharma innovation and R & D and preparation of detailed Schemes for setting up GLP compliant Laboratories/ Large Animal Testing Facilities of magnitude envisaged above are hereby invited to submit their **"Expression of Interest" (EOI)** as per prescribed proforma to the Director, Department of Pharmaceuticals, Room No. 346, A Wing, Shastri Bhavan, New Delhi 110001 **on or before 1600 hrs on 25.04.2011,** in two separate sealed covers indicating (i) their Technical capabilities w.r.t. the criteria mentioned in para 1.4 of EOI. and (ii) Rates and time lines. The detailed EOI document containing the prescribed proforma, scope of work, qualification criteria etc. can be downloaded from the website of **http:// pharmaceuticals.gov.in.**

DEFINITIONS

Until otherwise stated so, the following terms & expressions used in this document would have following meanings:

"EOI" means Expression of Interest.

"RFP" means Request for Proposals.

"Applicant" means a reputed registered firm or other legal entity registered under any Indian law and having requisite experience and who has downloaded the EOI document from the website of Department of Pharmaceuticals in the Ministry of Chemicals & Fertilizers and applied for undertaking the job described in the said document.

"Application" means the EOI submitted by an Applicant interested in the Project in the prescribed format

"DoP" means Department of Pharmaceuticals in the Ministry of Chemicals & Fertilizers, Government of India, who have invited the Applications for EOI.

"Facilities" means the GLP Compliant Chemical/ Biological Laboratories or Large Animal Houses

"GLP" means Good Laboratory Practices as laid down by National GLP Authority of India or relevant international bodies such as OECD.

"GLP Compliant Laboratories" signifies such of the labs that have got relevant GLP Compliant approval by the prescribed Authority(s).

"LAH" means Large Animal Houses.

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EXPRESSION OF INTEREST

FOR

1. **Assessment of existing GLP Compliant infrastructure vis-à-vis requirements of Indian Pharma Industry and gap analysis**

&

2. **Drawing up Schemes for establishing GLP Compliant Chemical/ Biological Testing Laboratories and GLP Compliant Large Animal Houses or upgrading existing facilities so as to make them GLP Compliant laboratories or Large Animal House. A combination of both of the above options may also be considered. The Schemes have to be drawn in PPP Mode"**

Through the above initiative the Department expects facilitation by way of inspiring innovation and catalyze and compliment the R&D efforts of the Indian Pharma Industry.

SECTION –I

1 INSTRUCTIONS TO APPLICANTS

1.1 INTRODUCTION

1. The DoP intends to facilitate establishing GLP Compliant Chemical/ Biological Testing Laboratories and GLP Compliant Large Animal Houses or upgrading existing facilities in the country so as to make them GLP Compliant laboratories or Large Animal Houses. A combination of both of the above options may also be considered. The Schemes have to be drawn in PPP Mode"

Through the above initiative the Department expects facilitation by way of inspiring innovation and catalyze & compliment the R&D efforts of the Indian Pharma Industry.

The proposed laboratories to be established or upgraded under the Scheme have to comply with international (OECD) GLP norms as well as guidelines laid down by the National GLP Authority of India.

For this purpose it is proposed to engage a Consultant of repute to carry out:

i) Assessment of existing GLP Compliant facilities vis-à-vis requirements of Indian Pharma industry, gaps if any, and indicate the manner in which this gap could be filled in. It has to be clearly stated if the gap could be filled in by establishing new facilities or upgrading the existing facilities to make them GLP Compliant or by a combination of establishment of new facilities and up-gradation of existing facilities.

ii) Drawing up detailed Schemes in PPP mode for setting up these facilities based on the result of exercise at (i) above. The extent of investment required in establishing new facilities or upgrading the existing facilities should be indicated. The funding pattern i.e. the share to be borne by the private entity and the Government of India should be indicated. The manner in which the facilities would be operationalised and managed should be stated indicating clearly whether these would be financially viable and help promote and facilitate the development of Pharmaceuticals Industry.

1.2 ROLE OF THE CONSULTANT

Applicants are expected to carry out the job in following two main Stages:

Stage I

- Assessment of existing Good Laboratory Practices (GLP) Compliant facilities available in the country vis-à-vis requirements of the Indian Pharmaceutical industry.

- The gaps, if any and the manner in which this gap could be addressed.

- The assessment could be done through interactions for eliciting response from the Indian Pharma industry including the possibility of utilizing the GLP Compliant infrastructure that may be created/ upgraded.

- It has to be clearly stated if the gap could be filled in by upgrading the existing facilities to achieve GLP status or by establishing new facilities or by combination of both viz establishment of new labs & upgrading existing facilities.

- Exact number of different types of GLP compliant laboratories (namely Chemical / Biological Laboratories or Large Animal Houses) needed to be upgraded or established or upgraded have to be mentioned.

- The recommended geographic distribution of each type of such laboratories keeping in view the likely demand in different locations in the country as may be projected by the Industry and assessment of the Consultant.

Stage II: Based on the outcome of the exercise at Stage I above, the consultant will be required to draw up detailed Schemes covering following major components.

- The scope of the project, its detailed components, costing etc need to be determined and clearly indicated.

- The extent of investment required in establishing new facilities or upgrading the existing facilities should be clearly mentioned.

- The scope and mode of Public- Private Partnership (PPP) in terms of financial viability of project, responsibility & mode of operating the labs should be pointed out.

- The suggested funding pattern i.e. share of the private entity and the Government of India should be indicated.

- The manner in which the proposed facilities would be operationalised/ managed.

- The manner in which these labs would be self sustaining and significantly promote the development of Pharmaceuticals Industry.

- The major types and categories of studies/ jobs or services that are expected to be delivered by these labs alongwith the corresponding revenue generation at different levels of capacity utilization during the project life cycle.

- Analysis of break-even point and expected profit generation alongwith Intended Rate of Return as well as the Return on Investment.

- Approximate rates of charges for various testing or other services to be rendered by these laboratories separately for private companies, Government labs or academic institutions to be clearly indicated and the manner in which these are to be determined.

- The system of periodic revision of service charges to be spelt out.

- The likely benefits that the Government can expect in terms of growth of Indian Pharma Industry as a result of this initiative.

- Recommend the process and institutional mechanism of short listing the applicants/ private partner for setting up / upgradation of various types of facilities.

- Drawing up of the document for inviting proposals in PPP mode for implementation of these Schemes need to be drawn up in accordance with guidelines contained in the OM No. 24(1)/PF-II/2006 dated 18.05.2009 by the Plan Finance Division of Department of Expenditure in Ministry of Finance. Relevant guidelines of the Planning Commission would also be taken on to account.

- Provide format of applications to be invited from interested parties to set up/and or upgrade the GLP compliant laboratories or Large Animal Houses.

It needs to be clarified that the Applicants have to mandatorily apply for both of the stages of the Job as described in this document.

1.3 TIME SCHEDULE FOR PROVIDING THE CONSULTANCY SERVICE

a) The services to be provided in Stage I are expected to be completed within 08 weeks of issue of Letter of Authority (LOA) by the Department of Pharmaceuticals.

b) The services to be provided in Stage II are expected to be completed within 10 weeks of completion of stage I.

c) The appointed consultant shall have to prepare the EOI document and formats for the Request for Proposal (RFP) for the applicants to establish/and or upgrade existing facilities, the new GLP Compliant facilities. This work shall commence during the progress of Stage II activities and final RFP document will have to be submitted within 2 weeks of completion of Stage II.

1.4 ELIGIBILITY CRITERIA FOR APPLICANTS FOR THE EOI**:**

- Consulting registered Organizations or individual consultants registered under any Indian law and applying in response to this advertisement should have relevant experience of undertaking this kind of jobs and should be in this line for at least a period of last five years.

- The Entities submitting their EOI should be profit making during the last three financial years, ending 31st March 2010.

- The applicant should have qualified and experienced scientists, architects, engineers and management professionals capable of executing the responsibilities required for completing the job detailed through this document.

1.5 INSTRUCTION FOR FILLING UP THE APPLICATION FORMS:

1.5.1 All information called for in the forms provided in Section II should be furnished against the relevant columns in the forms. If for any reason,

information is furnished on a separate sheet, this fact should be mentioned against the relevant column. Even if no information is to be provided in a column, a 'nil' or 'no such case' entry should be made in that column. If any particulars/ query is not applicable in case of the applicant, it should be stated as 'not applicable'.

1.5.2 The applicants are cautioned that not giving complete information called for in the application forms or not giving it in clear terms or making any change in the prescribed forms or deliberately suppressing the information may result in the applicant being summarily disqualified.

1.5.3 The application should be type-written in English Language.

1.5.4 The applicant may furnish any additional information, which is deemed necessary to establish their capability to successfully complete the envisaged project. Superfluous information need not be furnished and no information shall be entertained after submission of EOI document unless specifically called for.

1.5.5 Any information furnished by the applicant found to be incorrect either immediately or at a later date, would render the firm liable to be debarred from taking up the project Consultancy.

1.5.6 Applications sent by telegram or fax or incomplete applications or received after last date of receipt of application shall not be entertained.

1.5.7 The applicant should submit a checklist as per the Form provided in page no 24 along with Application indicating necessary attachments.

1.6 Processing Fee

1.6.1 The applicant shall pay a non-refundable amount of **Rs. 5,000 (Rupees Five Thousand only)** as processing fee. This amount should be paid through a Demand Draft drawn in favour of "Account Officer, Department of Pharmaceuticals" and payable at New Delhi. The Demand Draft should be enclosed with the application at the time of submission, failing which the application shall be rejected.

1.6.2 The Applicant shall bear all costs associated with the preparation and submission of its application. The Department of Pharmaceuticals will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the pre-qualification process.

1.7 SIGNING OF THE APPLICATION AND NUMBER OF COPIES:

1.7.1 The Applicant shall prepare one original set of the EOI documents for both the tasks indicated as i) & ii) under para 1.2 and clearly mark them "ORIGINAL". The original of the Application shall be signed on all the pages by the person duly authorized to sign on behalf of the Applicant. The power of attorney duly notarized and on a stamp paper authorizing the person to sign and act on behalf of the applicant/firm should be submitted.

1.7.2 The Applicant shall submit two signed hard copies of Original Application and clearly mark them "COPY". In the event of any discrepancy between the original and the copies, the original shall prevail. A soft copy of the Application may also be provided on a CD-ROM alongwith the Application.

1.7.3 An authorized representative shall have the authority to conduct all business and incur liabilities related thereto for and on behalf of the Applicant, during the short-listing process and thereafter.

1.8 SEALING OF APPLICATION

The Original & the copies of Application enclosed in separate envelopes shall be sealed in a large envelope and submitted on or before the time on last date viz 25.04.2011 prescribed for submission of the Application as specified in Schedule of submission of EOI

1.9 DEADLINE AND ADDRESS FOR SUBMISSION OF APPLICATIONS

1.9.1 Applications shall be submitted to the address given in Schedule of submission of EOI by hand or through registered post or courier service latest by16.00 Hrs on 25^{h} April 2011. In respect of Applications received by post or courier, DoP shall not assume any responsibility for any

delayed delivery and such applications received after 1600 hrs on 25.04.2011 will not be entertained.

1.9.2 The Application should be addressed to:

The Director, Department of Pharmaceuticals,
Room No. 346, A- Wing, Shastri Bhawan,
New Delhi-110001
Telephone No. 23389840 : Telefax: 23389840

1.9.3 All envelopes shall be titled **"Submission of EOI to DoP for setting up /upgrading GLP compliant Chemical Testing Laboratories, GLP Compliant Biological Testing Labs and GLP compliant Large Animal House in PPP Mode"** and clearly marked in English with typed name and address of the Applicant.

1.9.4 DoP may, at its discretion, extend the deadline for the submission of Applications, in which case all rights and obligations of DoP and the Applicants subject to the previous deadline shall thereafter be subject to the deadline as extended.

1.10 LATE APPLICATIONS

Application received after the deadline of submission of Application will not be considered or opened under any circumstances.

1.11 CLARIFICATIONS

1.11.1 The Applicants shall be evaluated on the basis of the Contents of the Application and the supporting documents submitted by them. DoP shall not be under any obligation to seek any further information or clarifications.

1.11.2 Without prejudice to Clause 1.11.1 above, in order to assist in the evaluation of Applications, DoP may, at its sole discretion, ask any Applicant for any clarification on its Application which shall be

submitted within a stated reasonable period of time. Any request for clarification and all clarifications shall be in writing.

1.11.3 If an Applicant does not provide clarifications requested by the date and time set in DoP's request for clarification, its Application is liable to be rejected.

1.11.4 It is clarified that Applicants shall not be required to submit on their own, additional information or material subsequent to the date of submission and such material if submitted shall be disregarded. It is therefore essential to ensure that all questions are answered fully on the proforma or otherwise. The pages of the EOI document and Annexures and additional information if any submitted shall be numbered sequentially and signed. General responses such as "included in brochure" without specific item reference may be avoided.

1.12 RESPONSIVENESS OF APPLICANTS

1.12.1 An application, which does not meet all the requirements of the EOI document, shall be rejected forthwith

1.12.2 Applicants should note that this EOI Enquiry and Questionnaire is intended to provide preliminary information. The information contained herein shall not in any way be construed as binding on DoP, its agents, successors or assignees.

1.12.3 Applicants are advised that selection of consultants for this Project shall be entirely at the discretion of DoP. Applicants shall be deemed to have understood and agreed that no explanation or justification of any aspect of the EOI process shall be given by DoP and that the results of the EOI process shall be without any right of appeal to the Applicants whatsoever.

1.12.4 All documents and other information submitted by an Applicant to DoP shall become the property of Department of Pharmaceuticals. Applicants are to treat all information as strictly confidential. DoP will not return any EOI document submitted to it by the Applicants.

1.12.5 DoP shall notify successful Applicants after evaluation. It will not entertain any query or clarification from Applicant(s) who are not short listed in the EOI process.

1.13 WITHDRAWAL OF APPLICATIONS

1.13.1 No modification or substitution of the submitted application shall be allowed.

1.13.2 An Applicant may withdraw its Application after submission, provided that written notice of the withdrawal is received by DoP before the last date for submission of Applications. In case an applicant wants to resubmit his application, he shall submit a fresh application following all the applicable conditions.

1.13.3 The withdrawal notice shall be prepared in Original only and each page of the notice shall be signed and stamped by authorized signatories. The copy of the notice shall be duly marked "WITHDRAWAL".

1.14 RIGHT TO ACCEPT/REJECT ANY OR ALL APPLICATIONS

The DoP reserves the right to accept or reject any or all Applications and to annul the qualification process at any time without any liability or any obligation for such acceptance, rejection or annulment, without assigning any reasons.

1.15. ATTACHMENTS

1.15.1 Applicants should attach clearly marked and referenced continuation sheets in the event that the space provided in the EOI Document, Questionnaire or Annexure is in-sufficient.

1.15.2 While responding to the EOI advertisement the Applicants should demonstrate their capabilities, by providing material based on their experience, past performance, their personnel and financial resources

1.15.3 It is expressly clarified that before submitting the EOI, Applicant must have examined carefully the contents of all the attached documents and any failure to comply with any of the requirement of EOI document will be at the Applicant's risk.

1.16 VALIDITY OF APPLICATIONS

1.16.1 Application shall be valid for a period of 180 days from the last date of submission of Applications after which the Department may choose to destroy these application in a manner deemed fit by it.

1.16.2 The DoP retains the right that in exceptional circumstances at its own discretion, it may ask the applicants to extend the validity of their application for a specified period. The Applicant not submitting the letter of extension of the validity period at that time shall not be further considered.

1.17 JURISDICTION

All disputes arising shall be subject to the jurisdiction of the appropriate court at Delhi and will be governed by the laws of India.

SECTION –II

EXPRESSION OF INTEREST (EOI)

FOR

1) **ASSESSMENT OF EXISTING GLP COMPLIANT TESTING FACILITIES VIS-À-VIS REQUIREMENT OF PHARMA INDUSTRY, GAP ANALYSIS AND RECOMMEND THE MANNER IN WHICH THIS GAP COULD BE FILLED IN.**

&

2) **DRAWING UP DETAILED SCHEMES BASED ON THE RESULT OF EXERCISE AT (1) ABOVE FOR *SETTING UP / UPGRADING GLP COMPLIANT CHEMICAL TESTING LABORARORIES, GLP COMPLIANT BIOLOGICAL TESTING LABORATORIES AND GLP COMPLIANT LARGE ANIMAL HOUSE IN PPP MODE.***

PROFORMA APPLICATION FORMS

LETTER OF SUBMISSION OF EOI

FROM:

To:

The Director,
Department of Pharmaceuticals,
Room No. 346, A- Wing, Shastri Bhawan,
New Delhi-110001

SUBJECT: EOI for 1) Assessment of existing GLP compliant testing facilities vis-à-vis requirement of Pharma Industry, gap analysis and recommend the manner in which this gap could be filled in.

&

2) Drawing up detailed schemes in PPP mode based on result of exercise at (1) above for setting up and/or upgrading GLP compliant Chemical Testing Labs, GLP compliant Biological Testing Labs and GLP compliant Large Animal House.

Sir,

Having gone through the details given in EOI Notice and EOI document for the above project, I/we hereby submit the relevant information for considering my/our EOI.

1. I / We agree to abide by all the instructions, terms and conditions mentioned in the EOI document.
2. I / We hereby certify that all the statements made and information supplied in the enclosed forms 'I' & 'II' and accompanying statements are true and correct.
3. I/ We have furnished all information and details necessary for EOI and have no further pertinent information to supply.
4. I / We authorize Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India or their authorized representatives to approach individuals, employers and firms to verify our competence and general reputation.
5. I /We enclose in the prescribed formats certificates in support of our suitability , technical know-how and capability for having successfully completed the projects:
6. I/We shall be jointly and severally liable to the Client for all the project Consultant's obligation and liabilities as per the contract.

Signature(s) of Applicant(s)

Enclosures
Seal of applicant
Date of submission

FORM -I

GENERAL INFORMATION

1. Name of the Consulting Organization/Individual Applicant:……
(Attach an attested photocopy of Certificate of Registration.)

2. Legal Status of the Applicant

3. Registered Address, telephone, Tele-fax.
……
……..
……
4. Contact Person, Designation and Address including e-mail id
……
……
……
……

5. Number of years in Consultancy for conducting surveys and studies about Pharma R& D infrastructure and preparation of project report for new Schemes for consultancy to Government or private sector entities .

6. State whether the in-house expertise is available for executing the job expected under this advertisement. If not details of sub-consultants to be provided.

7. Has the applicant, or any constituent partner in case of partnership firm, ever been debarred / black listed by the Central/ State Government at any time for competing in any organization? If so, give details.

8. Has the applicant, or any constituent partner in case of partnership firm, ever been convicted by any court of law?

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Signature of the Applicant/Authorized representative

Annexure -I

DETALS OF GLP COMPLIANT LABS FOR WHICH CONSULTANCY WAS PROVIDED IN THE LAST FIVE YEARS

SL No.	Name and location of the Project	Name and address of the client	Details of the Project with Cost	Nature of consultancy work with specific areas addressed	Year of Start & Completion of the Project	Litigation/ Arbitration, if any with details

- Value of the work for which services were provided by the consultant only need to be provided.
- The applicants are required to provide Proof of award of work & completion certificate.

Signature of the Applicant/ Authorized representative

Annexure II

ONGOING PROJECTS

Name and location of the project	Name and address of the Agency for whom the project is being undertaken	Value of the project	Duration of the project	Expected Completion in year	Exact role	Whether by Self or by Associated Entities

Signature of the Applicant / Authorized representative

Annexure III

KEY PERSONNEL PROPOSED TO WORK FOR THE ASSIGNED JOB

SL. No.	Designation	Number of proposed personnel	Designation	Technical qualification	Total years of Relevant Experience	Details in Annexure
1.	Project Mananger (s) /Team Leader(s)					
2.	Members of the Team					
3.	IT/hardware Engineer					
4.	Landscape Architect					
5.	Fire Detection & protection systems officer					

Note:

1) A summary of the qualification, CV and work experience of each key staff, to be attached.

2) The minimum qualification for the key personnel is Degree in respective field, recognized by the respective countrywith 5 years experience in relevant field.

3) Incase of Sl No.1 an Engineer or Post Graduate Management professional with adequate experience should be deployed.

4) The team Should have experience in the preparation of DPR for at least one Chemical/ Biological Testing Lab or a Large Animal House

5) The team Should have experience in designing and establishing or upgrading of implementing at least one Chemical/ Biological Testing Lab or a Large Animal House.

CVs OF EACH OF THE KEY STAFF MEMBERS TO BE INVOLVED

Name of the Staff		
Designation		
Years with the Applicant firm		
Position in the Proposed project (describe degree of responsibility also)		
Qualifications (Technical and General)		
Membership in professional bodies		
Experience and Training (Relevant in the context of assignment)		
Employment Record		
Name of the Firm	Position Held	Years of Employment

Signature of the Applicant / Authorized representative

Annexure IV

FINANCIAL STATUS OF THE APPLICANT

SL NO.	YEAR	2007-08	2008-09	2009-10
1	Total assets			
2	Current assets			
3	Total liabilities			
4	Profit before liabilities			
5	Profit before taxes			
6	Profit after taxes			

Attach audited balance sheets in support of the data clearly marking the relevant portion. Also attach copies of Income Tax Returns filed**.**

All such documents should reflect the financial situation of the applicant

Historic financial statements submitted must be audited by a Chartered accountant

Historic financial statements must correspond to the accounting periods already completed and audited (no statements for partial periods will be accepted.)

Signature of the Applicant / Authorized representative

CHECK LIST OF DOCUMENT TO BE SUBMITTTED WITH THE EOI

DETAILS	REFERENCE TO CLAUSE NO.	PAGE NO.
Processing fee		
Letter of Submission of EOI		
Power of Attorney		
Details of projects for which consultancy was provided for last five years in the field GLP Compliant Labs …..Annexure ( )		
Details of ongoing projects in the field of EOI….. Annexure ( )		
Details of key personnel and their CV in Annexure ….( )		
Financial Status in ….Annexure ( )		
Performance report … Annexure ( )		

Signature of Applicant /Authorized representative

Additional Information about the EOI posted on 15th April 2011

In accordance with the Schedule for the EOI a **Pre-Application Conference** was held on 11th April 2011. A brief about the issues raised and clarifications provided is as follows:

Query: Whether the appointed consultant would be required to submit a business model for operationalizing the GLP compliant labs?

Response: Yes, as per the EOI document on the website the consultant will be required to suggest a suitable road map and the business model to provide specific information and procedure to be followed for sustenance of the proposed labs.

Query: The timelines provided in the document provide relatively less time for part 1 of the study as this stage would involve interaction with the Industry as well as the relevant institutions.

Response: The timelines provided in the document are in accordance with the guidelines of Planning Commission and are considered adequate.

Query: Whether DoP would help the consulting organization in collection of relevant details from the Pharma Industry.

Response: DoP would be willing to provide a general communication in favor of the selected consultancy organization indicating the objective of DoP and the expectations of support from the industrial or research organization contacted by the consultant in proper discharge of their responsibilities.

Query: How the confidentiality of the information gathered from the Industry or Research laboratory will be ensured.

Response: Confidentiality is an important component of all professional studies and the concerned consulting organization has to take due care to ensure that the information gathered in the course of studies assigned by DoP, is not misused during or after the completion of assignment. In case the selected consulting organization itself has its own Pharma related activities/ laboratories, it is all the more important for them to be extra careful in view of the possible conflict of interest.

Query: Whether there would be a minimum number of industrial units or Labs to be contacted for completing the part 1 of the survey?

Response: DoP has not prescribed any such limit and it is expected that the consulting organization would itself decide the sample size. However it is expected that entire country is covered for a suitable and reasonable outcome.

Query: Whether more than one consulting organizations can jointly submit the EOI based upon the specific experience and qualifications of a group of consulting organizations.

Response: As per the detail EOI such combination of applicants will not be admissible.

Query: What does DoP expect the applicants to provide information about performance report required as part of the checklist besides the financial status?

Response: In addition to the other details in the checklist the performance report is expected to provide a positive assessment of the projects undertaken in the past.

The above information is being placed on the website for the benefit of those interested in submitting their EOI in response to this call for submission of EOI by the Department of Pharmaceuticals.

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