

HLL Biotech Limited

(A Subsidiary of HLL Lifecare Limited)

Government of India Enterprise

Module no. 013-015, TICEL Biopark Campus,

CSIR Road, Taramani, Chennai – 600113.

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GLOBAL NOTICE INVITING EXPRESSION OF INTEREST

FOR

PRODUCTION ,CHARACTERISATION AND STORAGE OF cGMP VERO CELL

BANKS FOR THE MANUFACTURE OF VACCINES

EOI No. HBL/IVC/cGMP/CELLBANKING/001 dated 05.05.2015

HLL Biotech Limited (HBL), a 100% subsidiary of HLL Lifecare Limited, a Government of India enterprise invites Expression of Interest from the interested service providers for “The production, characterization and storage of cGMP Vero cell banks (Master Cell Bank, Working Cell Bank and Extended Cell Bank)” to be used in the manufacture of vaccines.

The scope, pre-qualification criteria, terms and conditions and other details are included in this document. Subsequent amendments/addendums if any, will be published in www.hllbiotech.com/www.lifecarehll.com.

About HBL

HLL Biotech Ltd is in the process of setting up a centralized vaccines manufacturing facility, Integrated Vaccine Complex (IVC), a project of National importance for strengthening the immunization programme of Government of India at Chengalpattu, Kanchipuram district, Tamil Nadu.

The vaccine complex shall be the nodal centre for research, manufacture and supply of vaccines at affordable prices for the Universal Immunization Programme (UIP) of Government of India. The vaccines to be manufactured at IVC are Pentavalent Combination (DPT + Hep B + Hib), BCG, Measles, Hepatitis B, Rabies, Hib and Japanese Encephalitis vaccines. The annual installed capacity of IVC for vaccines is 585

million doses. The vaccines manufactured at IVC is proposed to meet approximately 75% of the total requirement of vaccines covered under UIP and shall be able to meet the requirements of the major disease preventable vaccines in the country.

The project is of national importance and will provide vaccine security and consequently the health security to the nation. Vaccines produced in the complex shall be utilized for immunization of pregnant women, infants and small children against various diseases throughout the country.

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Section- 1

1.1 Goal of EOI

The objective of this EOI is to solicit proposals from the interested service providers for the production, characterization and storage of cGMP Vero cell banks (Master Cell bank, Working Cell bank and Extended Cell Bank). The characterization of Master and working cell banks used as substrates plays a vital role in the manufacture of vaccines for human use. As per the guidelines of Indian Pharmacopoeia 2014 and WHO TRS 978-Annex 3, 2013, Control tests are to be performed on cGMP cell banks. Interested service providers having requisite experience as stated in EOI are hereby invited to submit their Expression of Interest.

1.2 General Instructions

- 1.2.1 All information in the proforma provided in section 2.3 should be furnished against the relevant column. 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” 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”.
- 1.2.2 The interested service providers shall furnish detailed write up packed with adequate data explaining and establishing their available capacity/capability (both technical and Financial) to complete the envisaged project (if awarded) within the stipulated time period, after meeting all its current/present commitments. Superfluous information need not be furnished and no information shall be entertained after submission of EOI document unless specifically asked for.
- 1.2.3 The proposal and all relevant documents submitted by the service provider shall be written in English language. However, if the language of any document is in language other than English, English translation should be provided.
- 1.2.4 It is expressly clarified that before submitting the EOI, service providers 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 their own risk.

- 1.2.5 Any information furnished by the service provider found to be incorrect either immediately or at a later date, would render the firm liable to be debarred from taking up the project.
- 1.2.6 EOI sent by electronic media like emails, fax, incomplete proposals and/or received after last date of receipt of application shall not be entertained.
- 1.2.7 The commercial proposal will be invited from the parties once HBL shortlists the parties based on the party's expertise and experience in production, characterization and storage of cGMP cell banks. After evaluation and scrutiny of the offers, HBL may at its sole discretion decide further course of action. In responding to this EOI, all bidders shall comply with all applicable laws and regulations in India and laws of the country of their residence.
- 1.2.8 Bidder shall not undertake (or permit to undertake) at any time, any publicity activity with any section of the media in relation to this EOI/selection process without obtaining prior written consent of HBL.

1.3 Processing Fee

- 1.3.1 The service provider shall pay a non-refundable amount as processing fee of USD 100/- (USD One Hundred only) or equivalent amount as on tender publishing date. This amount should be paid through a Demand Draft/Banker's Cheque drawn in favour of HLL Biotech Limited and payable at Chennai. In case of cancellation of EOI by HBL, the processing fee shall be refunded.
- 1.3.2 The service provider shall bear all costs associated with the preparation and submission of EOI. HLL biotech Limited will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the pre-qualification process.

1.4 Tentative calendar of events

S.No.	Milestone	Date & Time (IST)
1	Release of Expression of Interest (EOI)	05.05.2015
2	Meeting with Service Providers	13.05.2015 @ 11:00 hrs
3	Last date for the submission of EOI Response	25.05.2015 @ 15:30 hrs

S.No.	Milestone	Date & Time (IST)
4	Opening of EOI Response	25.05.2015 @ 16:00 hrs
5	Declaration of Short listed Firms	will be informed later

Pre-bid meeting Venue:

**HLL Biotech Limited,
Module no. 013-015, TICEL Biopark Campus,
CSIR Road, Taramani, Chennai – 600113.**

1.5 Meeting Service Providers

HBL would host Service providers meeting at the venue mentioned in Section 1.6. Service providers meeting is tentatively scheduled as per the schedule in Section 1.4. The representatives of the interested organizations may attend the meeting at their own cost. The purpose of the meeting is to provide clarifications, if any to the service providers regarding EOI.

1.6 Venue and Last date for the submission of proposals

1.6.1 Proposals in complete form in all respects with the necessary documents mentioned under clause 2.2 as given in the EOI, may be submitted by hand or through registered post or courier service in the closed sealed envelope on or before 15:30 Hrs (IST). on 25.05.2015.

1.6.2 The EOI received after the prescribed time, will not be entertained and it will be considered as late EOI.

1.6.3 EOI should be addressed to:

**The Chief executive Officer,
HLL Biotech Limited,
(A Subsidiary of HLL Lifecare Limited),
Module no. 013-015, TICEL Biopark Campus,
CSIR Road, Taramani, Chennai – 600113.**

- 1.6.4 All envelopes shall be titled as **“Submission of EOI to HBL for Production, Characterization and Storage of cGMP Vero Cell Banks for the manufacture of vaccines”**
- 1.6.5 HBL, may at its discretion, extend the last date for the submission of EOI, in which case all rights and obligations of HBL and the service providers subject to the previous deadline shall thereafter be subject to the deadline as extended.
- 1.6.6 EOI received after the last date for the submission of EOI will not be considered or opened under any circumstances.

1.7 Clarifications

- 1.7.1 The service providers shall be evaluated on the basis of the contents of the proposal and the supporting documents submitted by them. HBL shall not be under any obligation to seek any further information or clarifications.
- 1.7.2 Without prejudice to Clause 1.7.1 above, in order to assist in the evaluation of proposals, HBL may, at its sole discretion, ask any applicant for any clarification on its proposal which shall be submitted within a stated reasonable period of time. Any request for clarification and all clarifications shall be in written document.
- 1.7.3 If an applicant does not provide clarifications with the set date and time in HBL’s request for clarification, its proposal is liable to be rejected.
- 1.7.4 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 EOI submitted to be complete in all respects. **The pages of EOI document, subsequent amendments/addendums if any, annexures and additional information if any submitted shall be numbered sequentially, stamped and 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.

1.7.5 General responses such as “included in brochure” without specific item reference may be avoided.

1.7.6 No modification or substitution of the submitted proposal shall be allowed.

1.8 Responsiveness of Applicants

1.8.1 A proposal, which does not meet all the requirements of the EOI document shall be rejected forthwith.

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

1.8.3 Applicants are advised to note that selection of firm for this project, shall be entirely at the discretion of HBL. 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 HBL and the results of the EOI process shall be without any right of appeal to the applicants whatsoever.

1.8.4 All documents and other informations submitted by an applicant to HBL shall become the property of HBL. Applicants are to treat all informations as strictly confidential. HBL will not return any of the EOI document submitted by the applicants.

1.8.5 HBL shall notify successful applicants after evaluation. It will not entertain any query or clarification from Applicant(s) who are not shortlisted in the EOI process.

1.9 Validity of proposals

1.9.1 Proposal shall be **valid for a period of 180 days** from the last date of submission of proposals after which HBL may choose to destroy these proposals in a manner deemed fit by it.

1.9.2 HBL retains the right that in exceptional circumstances at its own discretion, it may ask the applicants to extend the validity of their proposal for a specified period. The applicant not responding to the letter of extension of the validity period at that time shall not be further considered.

Section-2

2.1 Scope of work

- 2.1.1 Campaign production of cGMP Master and Working Vero Cell Banks.
- 2.1.2 Testing and Characterization of Master Cell bank, Working Cell bank and Extended Cell Bank shall be done as per Annexure-I.
- 2.1.3 15th passage of Vero cells from MCB shall be prepared by the service provider and tested as per requirements for Extended Cell Bank (ECB) mentioned in Annexure-I.
- 2.1.4 Storage of the prepared and tested MCB and WCB at service provider's facility.

2.2 Pre-qualification criteria

- 2.2.1 The firm must have proven experience in production, testing, characterization and storage of cell banks including mammalian cell lines under cGMP conditions for the last five financial years
- 2.2.2 The GMP facility used for production of the cell banks should have approval of their national regulatory agency
- 2.2.3 The clients list must include minimum three facilities approved by national regulatory bodies (Schedule M) / International regulatory bodies (Like WHO,USFDA,MHRA,TGA etc)
- 2.2.4 Average annual turnover of the firm during the last three financial years (2011-12, 2012-13,2013-14) must be minimum INR 7.5million (119030 USD)
- 2.2.5 Net worth of the company should be positive during the last three financial years (2011-12, 2012-13, 2013-14).

In support of Section 2.2, the service provider shall furnish the details as given in the table below.

S.No.	Pre-qualification criteria	Documents to be submitted
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S.No.	Pre-qualification criteria	Documents to be submitted
1	2.2.1	Service order/work order/Purchase order issued by the client /Documentary proof available in the public domain.
2	2.2.2	GMP certificate issued by National Regulatory Agency/International Regulatory agency
3	2.2.3	Client list along with Service order/work order/Purchase order issued by the client /Documentary proof available in the public domain
4	2.2.4	Annual Report (Balance Sheet and Profit & Loss Account) for last three years prior to the date of opening of EOI certified by a Chartered Accountant
5	2.2.5	Annual Report (Balance Sheet and Profit & Loss Account) for last three years prior to the date of opening of EOI certified by a Chartered Accountant

2.3 Proforma

As attached as Annexure-II

2.4 Selection Process

- 2.4.1 EOI received from service providers shall be scrutinized to determine whether they are complete and meet the essential requirements, conditions as prescribed in section 2.1 and 2.2.
- 2.4.2 EOI which do not meet the basic requirements as mentioned in section 2.2, are liable to be treated as non-responsive and will be summarily ignored.
- 2.4.3 Before expiry of the validity period, HBL will notify the firms which have been shortlisted in writing, by registered/speed post/courier or by fax/telex/cable(to be confirmed by registered/speed post/courier).

2.5 Rights of HBL

HBL reserves the right,

- 2.5.1 To accept or reject any or all proposals 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.
- 2.5.2 To limit or delete any part of scope of work and extend the last date of submission of EOI.
- 2.5.3 To unbundle the project into multiple blocks and award the project to more than a single party.

2.6 Jurisdiction

All disputes arising shall be subject to the jurisdiction of the appropriate court at Chennai and EOI will be governed and interpreted in accordance with the laws of India.