

HLL BIOTECH LIMITED

(Subsidiary of HLL Lifecare Limited)
Government of India Enterprise

Modules no. 013-015, TICEL Biopark Campus,
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GLOBAL NOTICE INVITING EXPRESSION OF INTEREST FOR STRATEGIC ALLIANCE / TIE-UP IN THE AREA OF SUPPLY OF BULK VACCINE AND TECHNOLOGY TRANSFER OF VACCINES FOR HUMAN USE

Introduction

HLL Biotech Limited (HBL), a 100% subsidiary of HLL Lifecare Limited, a Government of India enterprise is interested in potential partnering opportunities in the field of supply and technology transfer for production of vaccines for national immunization program:

HLL Biotech Ltd (HBL) is in the process of setting up a state of the art vaccines manufacturing facility "Integrated Vaccines Complex" (IVC) for human use at Chengalpattu, near Chennai. 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 the Government of India and also for exports.

This is a **Project of National Importance** for strengthening the immunization program of Government of India leading to vaccine security and consequently the health security of the nation. Various vaccines that would be manufactured in IVC are Pentavalent combination vaccine (DPT+ Hib +HepB), Hepatitis B vaccine, Hib-conjugate vaccine, BCG vaccine, Measles vaccine, Human Rabies vaccine and Japanese Encephalitis vaccine. The annual installed capacity of IVC is estimated to be 585 million doses. Vaccines produced in the IVC shall be utilized for immunization of pregnant women, men, infants and small children against various diseases throughout the country and if

required for export to other nations. The scope of the IVC would be expanded in future to manufacture vaccines for Meningococcal meningitis, Rota viral diarrhoea, Dengue fever and Pneumococcal pneumonia.

Invitation of Expression of Interest:

In view of the above, HBL invites **Expression Of Interest (EOI)** from potential partners having expertise in fields of supply, manufacturing and technology transfer of human vaccines for technology/research tie-ups for development and manufacturing of vaccines for the Integrated Vaccines Complex.

SECTION I

1. SUPPLY OF BULK VACCINES

- a. Bulk antigen for Diphtheria Toxoid
- b. Bulk antigen for whole cell Pertussis
- c. Bulk antigen for Tetanus Toxoid (for conjugation & formulation)
- d. Ready to fill bulk – JE vaccine

For the supply of bulk vaccine; the bidder must be:

- Existing vaccine manufacturer, who is manufacturing and supplying D, P and T group of vaccines and Japanese encephalitis vaccine for human use. If manufacturer, the bidder must be undisputed owner / authorized licensee of the technology used for manufacturer.
- Existing vaccine supplier, who is supplying D, P and T group of vaccines and JE vaccine for human use.
- The vaccine should have been commercialised for more than three years by 30th May, 2014.
- The vaccine should be WHO prequalified.
- The vaccine should meet IP, BP, EP and USP pharmacopeial requirements for combination vaccines.
- The bidder must list the minimum and maximum quantities that may be offered.

2. Technology Transfer at commercial scale for:

2.1 Haemophilus influenza type B conjugate vaccine.

2.2 Tissue Culture based Inactivated Japanese encephalitis vaccine

2.1 Haemophilus influenza type B conjugate vaccine.

The technology supplier must be able to offer the following:

- Supply of characterized Master Seed Culture for polysaccharide and carrier protein manufacturing
- Polysaccharide manufacturing technology
- Carrier protein manufacturing technology
- Protein Polysaccharide conjugation technology
- Formulation technology know-how
- Validated Analytical methods pertaining to above
- Timelines for the technology transfer
- Provide training to HBL personnel at mutually agreed terms and conditions

2.2 Tissue Culture based Inactivated Japanese Encephalitis vaccine

- Technology transfer (know-how) and training for development and production of JE vaccine (cell culture based and inactivated)
- Details on the seed virus and characterization documents
- Detailed list of manufacturers / licensees – using the same technology and volume of vaccines manufactured by them.
- Supply for Pre master and Master (GMP) seed strains and cell lines
- Trial batch production and training at technology providers facility
- Supply of pre-clinical and clinical trial study reports
- Technical support during the development and production
- Support for establishment of analytical methods of formulated vaccine
- Support during pre-clinical and clinical trial studies
- Provide training to HBL personnel at mutually agreed terms and conditions

For Offering the Technology Transfer; the bidder must be :

- Existing vaccine manufacturer, who is manufacturing and supplying HIB conjugate vaccine and Tissue Culture based Inactivated Japanese Encephalitis vaccine for human use.
- Research and development organization that has developed the technology for Hib conjugate vaccine and Tissue Culture based Inactivated Japanese Encephalitis vaccine for human use and have transferred the technology to vaccine manufacturing organizations for commercial production.
- The vaccine should have been commercial license for more than three years by 30th May, 2014.
- Undisputed owner of the technology offered for transfer /license
- The bidder must furnish the details of Organization(s) to which the technology has been transferred and volume of vaccines manufactured by them
- The vaccine should be WHO prequalified.
- The vaccine should meet IP, BP, EP and USP pharmacopeial requirements for combination vaccines.

Section II

General Information

1. A pre bid meeting is scheduled on 11th June 2014 at 11:00 Hrs at HLL Biotech Limited, Module no. 13-15, TICEL Biopark Campus, CSIR Road, Taramani, Chennai 600113. The EOI document can be submitted directly to HBL in case any party is not in a position to attend the pre bid meeting.
2. **The deadline for submission of the EOI bid is 15:30Hrs (IST) on 25th June 2014.** Expression of Interest shall be submitted in a sealed envelope clearly super scribing on top of envelope “EXPRESSION OF INTEREST (EOI) FOR STRATEGIC ALLIANCE/ TIE UP WITH HLL BIOTECH LIMITED IN THE AREA OF BULK SUPPLY / TECHNOLOGY TRANSFER FOR MANUFACTURING THE VACCINES”. Organizations are advised to carefully review and submit all relevant information with their EOI.

3. In response to this Expression of Interest, the bidder is requested to submit the following documents, which will prove their expertise and experience in the vaccine development field:

3.1. Background about the bidder (Organization brochure) along with an overview on the products which they handle.

3.2. The Core Competencies/Core Area of working of the Organizations.

3.3. Brief write-up of technology offered for transfer / licensing and the type of engagement sought with HBL

3.4. Description of Patent /Patent Application and other Intellectual Property Rights concerning the technology offered by the bidder

3.5. The bidder should have experience in India, and/or other key markets in the technology transfer/ product development of vaccines.

3.6. Audited annual report of the bidder for the last three financial years (2010-11, 2011-12, 2012-13)

3.7. A list of WHO pre-qualified Vaccine products, which the bidder has supplied

4. Bidders should note the following:

4.1 While the Expression of Interest has been prepared in good faith, HBL does not make any representation or warranty, express or implied, or accept any responsibility or liability, whatsoever, in respect of any statement or omission herein, or the accuracy, completeness or reliability of information contained herein, and shall incur no liability under any law, statute, rules or regulations as to the accuracy, reliability or completeness of this request, even if any loss or damage is caused by any act or omission on its part.

4.2 Organizations are requested to keep the information and details strictly confidential. We are looking for your support and co-operation in getting a fully responsive Expression of Interest.

4.3 HLL Biotech Limited shall not be responsible for any expense incurred by Bidder in connection with the preparation and delivery of their EOI and other expenses.

4.4 HBL reserves the right to reject any or all the Expressions of Interest without assigning any reason thereof.

4.5 HBL reserves the right to deal with the proposal in any manner without assigning any reasons for the same. The decision of HBL in this regard shall be final.

- 4.6 Organizations shall also submit Power Point presentations in respect of EOIs, submitted by them. HBL may invite Organizations, if required, to make Power Point presentations of their capability in the area.
- 4.7 EOIs submitted in electronic formats like fax, emails etc. will not be accepted.
- 4.8 The Expression of Interest reaching HBL after the prescribed date and time shall be considered as late and will be rejected.
- 4.9 The commercial proposal will be invited from the parties once HBL short lists the parties based on the party's expertise and experience in bulk vaccine supply/technology transfer and product development of human vaccines. After evaluation / examination 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.
- 4.10 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.
- 4.11 Interested bidders qualifying the above conditions may send their EOI with the necessary documents to the below mentioned address on or before 25th June 2014.

The Chief Executive Officer

HLL Biotech Limited

(A subsidiary of HLL Lifecare Limited)

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