

HLL BIOTECH LIMITED

(Subsidiary of HLL Lifecare Limited)

Government of India Enterprise

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GLOBAL NOTICE INVITING EXPRESSION OF INTEREST

FOR

STRATEGIC ALLIANCE / TIE-UP IN THE AREA OF TECHNOLOGY TRANSFER

AND PRODUCT DEVELOPMENT SUPPORT FOR MANUFACTURING OF

VACCINES

EOI No. HBL/IVC/TECH TRANSFER/2012-13 dated 7th January, 2013

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 technologies supporting the product development and production of vaccines for immunization program like:

- Hepatitis B vaccine
- Haemophilus influenza type b vaccine
- Japanese encephalitis vaccine
- DwPT+HepB+ Hib – formulation
- Measles vaccine

Introduction

HLL Biotech Ltd is in the process of setting up a centralised vaccines manufacturing facility in public sector, a project of national importance for strengthening the immunization program of Government of India.

The Cabinet Committee on Economic Affairs, Government of India has approved the proposal of the Ministry of Health & Family Welfare for establishment of an Integrated Vaccine Complex (IVC) at Chengalpattu, Kanchipuram district (Tamil Nadu).

The complex will be established by M/s HLL Life Care Limited, a public sector undertaking of the Ministry at an estimated cost of Rs. 594 crore. The project is likely to be completed by 2014.

M/s HLL Lifecare Limited has formed a 100% subsidiary company, HLL Biotech Limited (HBL) for implementing the project and operation of the facility thereafter.

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. The vaccines to be manufactured in the IVC are pentavalent combination (DPT plus Hep B plus Hib), BCG, measles, Hepatitis B, Human Rabies, Hib and Japanese Encephalitis vaccine. The annual capacity of IVC is expected to be around 585 million doses. The vaccines manufactured in the IVC complex are proposed to meet about 75% of the total requirement of vaccines covered under the UIP and shall be able to meet the requirements of the major disease preventable vaccines in the country to a large extent.

The project is of national importance and will provide vaccine security and consequently the health security of 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. The state-of-the-art WHO pre-qualified facility, the first of its kind in public sector, will also have the capacity to manufacture vaccines for Meningococcal meningitis, Rota viral diarrhoea, Dengue fever and Pneumococcal pneumonia.

HBL is in discussion with Global technology suppliers/manufacturers for the technology transfer for production and formulation of bacterial and viral vaccines. To enlist more partners in the field, it is decided to publish a global Expression of Interest.

Section I

Invitation of Expression of Interest:

HBL invites expression of interest from potential partners having expertise in technology transfer/ product development of human vaccines for technology/research tie-ups for development of vaccines for the Integrated Vaccines Complex.

The following are the vaccines which will be manufactured by HBL and the support which HBL seeks from the bidder for technology transfer/ product development:

1. Bacterial Vaccines

a. Hepatitis B vaccine (yeast cell based recombinant vaccine)

b. Haemophilus influenza type B (Polysaccharide –protein conjugation)- (Hib)

- Technology transfer (know-how) and training for development and production of Hepatitis B and Hib vaccines
- Documents – proving the yield/batch
- Formulation methodology- documents
- Supply of pre-master and GMP – master Hepatitis B clone and Hib seed strain copies
- Technical support for process standardization
- Process scale up and optimization support
- Support for establishment of analytical method
- Support during pre-clinical and clinical trial studies
- Detailed report on conjugation methodology
- Process scale up and optimization support
- Support for establishment of analytical method
- Support during pre-clinical and clinical trial studies

2. Formulation technology – Liquid Pentavalent combination vaccine (DPT+HepB+Hib)

- Technology transfer (know-how) and training for formulation process standardization of liquid Pentavalent vaccine by using the bulk antigens of DPT from Indian sources (CRI, Kasauli / Pasteur Institute of India , Coonoor) and Hep B and Hib bulk from the technology provider
- Detailed report on formulation process
- Documentary evidence of expression of antigenicity of all antigens after formulation
- Supply pre-clinical and clinical trial study reports
- Technical support during the formulation process standardization
- Formulation scale up and optimization support
- Support for establishment of analytical methods of formulated vaccine
- Support during pre-clinical and clinical trial studies

3. Viral Vaccines

a. Japanese encephalitis vaccine (cell culture based using the virus strain more suitable for Indian epidemiologic conditions)

b. Measles vaccine

- Technology transfer (know-how) and training for development and production of JE vaccine and Measles vaccine (cell culture based)
- Details on the seed virus and characterization study
- Detailed list of manufacturers – using the same technology
- Supply for Pre master and Master (GMP) seed strains and cell lines
- Trial batch production and training at technology providers facility
- Supply 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

Section II

General Information

1. The deadline for submission of the EOI bid is 15:30Hrs. (IST) on 28/01/2013. 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 FOR TECHNOLOGY TRANSFER AND PRODUCT DEVELOPMENT OF HUMAN VACCINES FOR INTEGRATED VACCINES COMPLEX."
2. Organizations are advised to carefully review and submit all relevant information with their EOI.
3. The bidder must be :

A. Existing vaccine manufacturer, who is manufacturing and supplying any of the vaccines mentioned in Section I.

Or

B. Research and development organization that has developed the technology for any of the vaccines mentioned in Section I and have transferred the technology to other vaccine manufacturing organizations for commercial production.

The bidders will be evaluated separately based on the categories (A or B) under which they fall.

4. 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:
 - a. Background about the bidder (Organization brochure) along with an overview on the products which they handle.
 - b. The Core Competencies/ Core Area of working of the Organizations.
 - c. The vaccines from Section I for which the technology can be provided.

- d. The bidder should have experience in India, and/or other key markets in the technology transfer/ product development of vaccines.
- e. The bidder must furnish the list of Organizations to which the technology has been transferred (in case the bidder falls under 'B' category)
- f. Audited annual report of the bidder for the last three financial years (2009-10, 2010-11, 2011-12)
5. 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.
6. 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.
7. 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.
8. HBL reserves the right to reject any or all the Expressions of Interest without assigning any reason thereof.
9. 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.
10. Organizations shall also prepare 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.
11. EOIs submitted in electronic formats like fax, emails etc will not be accepted.
12. The Expression of Interest reaching HBL after the prescribed date and time shall be considered as late and will be rejected.
13. The commercial proposal will be invited from the parties once HBL short lists the parties based on the party's expertise and experience in the 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.

14. The organizations who have already contacted and signed the NDA/CDA /MOU in this regard need not apply again.

Interested bidders qualifying the above conditions may send their expression of interest with the necessary documents to the below mentioned address on or before

**The Chief Executive Officer
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