

## NOTICE INVITING EXPRESSION OF INTEREST (EOI)

#### ON BEHALF OF ITS SUBSIDIARY, HLL BIOTECH LIMITED (HBL)

#### **FOR**

SHORTLISTING VACCINE/ PHARMACEUTICAL MANUFACTURERS
FOR USE OF HBL'S FACILITIES AT INTEGRATED VACCINES COMPLEX
(IVC), CHENGALPATTU, ON "AS IS WHERE IS BASIS" FOR
PRODUCTION OF COVID-19 /OTHER VACCINES.

# EOI NO.HLL/HBL-VACCINE MANUFACTURE/EOI/2020-21/02 DTD: 10/02/2021

BY

#### **HLL LIFECARE LIMITED**

[CIN U25193KL1966GOI002621]

#### **Director (Technical & Operations)**

Corporate & Registered Office, HLL Bhavan Poojappura P.O Thiruvananthapuram -695012 Email: hbleoi@lifecarehll.com

www.lifecarehll.com

Phone: 0471-2354573, 9995484947/8848788053

#### **HLL LIFECARE LIMITED**

[CIN U25193KL1966GOI002621]

#### **Director (Technical & Operations)**

## Corporate & Registered Office, HLL Bhavan, Poojappura P.O Thiruvananthapuram - 695012, Kerala

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EOI Submission Details		
EOI NO. HLL/HBL-VACCINE MANUFACTURE/EOI/2020-21/02 DTD: 10/02/2021		
EOI re-publishing Date	:	10/02/2021 11:00 Hrs
Last date for submission	:	16/02/2021 15:30 Hrs
Date & time of opening	:	17/02/2021 16:00 Hrs

#### NOTE:

- Those parties who have already submitted the EOI (Ref: EOI NO. HLL/HBL-VAC/EOI/21-22 dated 16-01-2021 and e-Tender Id: 2021\_HLL\_66105\_1) need not submit again, as it is re-invited considering more participation only.
- Original EOI (ref No: HLL/HBL-VAC/EOI/21-22 dated 16-01-2021 and e-Tender Id: 2021\_HLL\_66105\_1), its subsequent corrigenda & Minutes of pre-bid meeting are enclosed and form part of this EOI.
- All other terms & conditions of the EOI remains the same.

Director (Technical & Operations)

# ORIGINAL EOI DOCUMENT & CORRIGENDA



## NOTICE INVITING EXPRESSION OF INTEREST (EOI)

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#### **FOR**

SHORTLISTING VACCINE/ PHARMACEUTICAL MANUFACTURERS FOR USE OF HBL'S FACILITIES AT INTEGRATED VACCINES COMPLEX (IVC), CHENGALPATTU, ON "AS IS WHERE IS BASIS" FOR PRODUCTION OF COVID-19 /OTHER VACCINES.

# EOI NO.HLL/HBL-VACCINE MANUFACTURE/EOI/2020-21 DTD: 16/01/2021

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#### **HLL LIFECARE LIMITED**

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EOI Submission Details		
EOI NO.HLL/HBL-VACCINE MANUFACTURE/EOI/2020-21		
DTD: 16/01/2021		
e- EOI reference no		
EOI publishing Date	:	16/01/2021 11:00 Hrs
Pre EOI Meeting	:	22/01/2021 11:00 Hrs
Last date for submission of EOI	:	29/01/2021 15:30 Hrs
Date & time of opening of EOI	:	30/01/2021 16:00 Hrs

#### 1.0. INTRODUCTION

This Notice inviting Expression of Interest (EoI) seeks response from Vaccine/Pharmaceutical manufacturers for utilizing HBL's existing facilities at Integrated Vaccine Complex [IVC], Chengalpattu, Tamilnadu on "As is Where is Basis" for the production of COVID-19 vaccines or any other Vaccine. The facilities at IVC are offered on long-term lease/ contract manufacturing or any other mutually acceptable arrangement.

#### 2.0. ABOUT HLL BIOTECH LTD

HLL Biotech Limited ("HBL") has been established under the Ministry of Health and Family Welfare, Government of India, as a 100% owned subsidiary of HLL Lifecare Limited (HLL), (A Government of India Enterprise) and a company incorporated under Companies Act 1956 with its registered office at HLL Bhavan, Poojappura, Thiruvanathapuram-695012, Kerala and having its Corporate Office at Integrated 192&195, Vaccine Complex (IVC) Survey no.: Thirumani Thirukazhukundram Taluk, Chengalpattu District, Tamil Nadu, India. HBL was formed in March 2012 for establishing Integrated Vaccines Complex (IVC) for manufacturing various vaccines required for Universal Immunization Programme (UIP) of Government of India. HBL is located in a campus of around 100 acres of government land, made available by CLTRI (Central Leprosy Teaching and Research Institute), Chengalpattu near Chennai. The different facilities/ units for bulk production, formulation, filling and support functions were established as per the CGMP requirements and some of the facilities are validated.

During the current COVID-19 pandemic, the development of COVID-19 vaccines is progressing in India and all over the world. HBL has been receiving communications from different companies in India for a partnership with HBL for COVID-19/Other vaccine production, formulation and filling activities.

Some parties have also visited the facility to check the feasibility to commence operations in the facility. Based on these enquiries, HLL received the direction to invite this EOI to shortlist potential party/parties for contract manufacturing/long term lease or any other mutually acceptable arrangement, for production of COVID-19 or other vaccines.

#### Vaccine production facilities available with HBL

HBL has established facilities for the production of following vaccines:

- Bulk production facilities for bacterial and viral vaccines.
- Formulation and filling facilities for liquid vaccines and lyophilized vaccines.
- Supporting facilities: QA, QC, warehouse, packaging, utility, animal house etc.

Some of the vaccine production facilities at IVC are commissioned and validated and some other facilities require commissioning and validation to make them ready for operation. The list of facilities at IVC and its current status is available at HBL website:www.hllbiotech.com and www.lifecarehll.com

#### 3.0. INSTRUCTIONS TO PARTIES

- No Party shall submit more than 1 (one) EOI.
- Notwithstanding anything to the contrary contained in this document, the detailed terms specified in the Partnership agreement shall have overriding effect.
- HLL reserves the right not to proceed with the process at any time, without notice or liability, and to reject any EOI without assigning any reasons.
- The parties shall sign and seal all the pages of the EOI and attached documents while submitting the EOI.

#### 4.0. ELIGIBILITY CRITERIA

- 1 The party shall be certified as a Vaccine OR Pharmaceutical manufacturer with at least 10 years own manufacturing experience. Copy of certificate to be submitted.
- 2 A brief write up about the applying company/entity to be submitted.
- 3 The party shall have at least one production facility in India or abroad, which is either certified by WHO/ US-FDA. Proof shall be submitted.
- 4 The party should have average annual turnover of INR.500 Cr or above during the last three Financial Years (2017-18, 2018-19, 2019-20). Audited balance sheet / CA certified turnover sheet should be submitted.
- 5 The party shall have a minimum net worth of Rs. 300 Cr as on 31.03.2020.
- 6 The party shall submit the tentative project operational plan with indicative time line for commercial production of vaccines from IVC.
- 7 Party shall be ready to make capital investment for making required facilities ready (not to be considered as equity) and working capital infusion for operationalizing the existing infrastructure/ invest for additional infrastructure, as per the requirement.
- 8 The party shall submit the details of the vaccines, which they intend to manufacture at HBL utilizing the facilities available.
- 9 Along with the EoI, the parties shall submit proof of the back-to-back arrangements with vaccine suppliers/manufacturers, technology providers in case they do not have own technology or knowhow for manufacture of Vaccine(s).
- 10 Corporate management approval for submission of Eol in response to this notification.

11 The party shall submit the willingness to operate the facility with existing manpower available with HBL and recruit/engage additional manpower as per the requirement.

#### 5.0. CHECKLIST: DOCUMENTS TO BE SUBMITTED ALONG WITH SIGNED EOI

SI.	Name of document to be submitted	Document enclosed
No		(Yes/No)
1	Copy of company incorporation certificate	
2	Brief write about the company, products and	
	services.	
3	Production facility certification: WHO GMP certificate	
	or USFDA certificate.	
4	Audited balance sheet/CA certified turnover sheet	
	for last three financial years (2017-18,2018-19,2019-	
	2020)	
5	Company net worth statement certified by	
	Chartered Accountant	
6	Project operational plan document along with	
	tentative time line for commercial production of	
	vaccines from IVC.	
7	Letter from the party indicating the readiness for	
	capital investment in IVC for making certain required	
	facility ready for vaccine production and	
	commissioning & validation of such facilities as	
	required.	
8	Details of the vaccines proposed to be	
	manufacturered from IVC.	

9	Proof of arrangements made for supply of		
	bulk/technology transfer for vaccines Or copy of MOU		
	signed with different manufacturers for supply of bulk		
	& technology transfer OR Agreement signed with		
	different parties/manufacturers for supply of bulk &		
	technology transfer for vaccines planned to be		
	manufactured at IVC.		
10	Letter indicating willingness to operate the facilities		
	with available manpower and to add additional		
	manpower as per the requirement.		
11	Corporate management approval for submission of		
	EOI.		

#### 6.0. PRE EOI MEETING

A Pre EOI meeting to discuss and clarify the details & requirements of EOI is scheduled on 22/01/2021 at corporate office, HLL Lifecare Limited, Trivandrum; 11:00 am to 12:00 pm through online platform. The online meeting link and details will be uploaded in CPP Portal as corrigendum.

#### 7.0. EOI EVALUATION

- The shortlisting of parties shall be based on the evaluation of documents submitted as part of EOI.
- The shortlisted parties shall be provided the Request for Proposal (RFP)
  directly by HLL, which shall seek indicative financial terms for the
  partnership.
- Party/Parties for operationalizing IVC shall be finalized based on evaluation of RFP.

#### 8.0. GENERAL

- i. Pre EOI meeting is scheduled for 22/01/2021
- ii. The deadline for submission of the EOI is 29/01/2021.
- iii. EOI should be valid for a period of 90 days from the date of opening of EOI response.
- iv. Conditional offers are liable for rejection.
- v. The Bidders should give clause by clause compliance of EOI with references to supporting documents; otherwise the offers are liable for rejection.
- vi. The Expression of Interest has been prepared in good faith and the parties shall sign & seal all pages of EOI & supporting documents. Parties are requested to do their own due diligence before submitting the EOI.
- vii. The parties are requested to keep the information and details strictly confidential. We are looking for your support and co-operation in getting fully responsive Expression of Interest.
- viii. HLL shall not be responsible for any expense incurred by Parties in connection with the preparation and delivery/submission of their EOI and other expenses.
- ix. HLL reserves the right to reject any or all the Expressions of Interest without assigning any reason thereof.
- x. HLL reserves the right to deal with the proposal in any manner without assigning any reasons for the same. The decision of HLL in this regard shall be final.

#### 9.0. MODE OF SUBMISSION OF EXPRESSION OF INTEREST

Interested parties qualifying the eligibility criteria may submit the EOI and supporting documents in CPP portal, i.e., etenders.gov.in/eprocure/app.

The instructions regarding online EOI submission are given below:

 Party may download the EOI document from <u>www.etenders.gov.in/eprocure/app</u> or <u>www.lifecarehll.com</u>, or <u>www.hllbiotech.com</u>.

- 2. Party may have valid Digital Signature Certificate with encryption.
- 3. Parties are requested to read the help document on e-tender web site link before proceeding for EOI submission.
- 4. The prospective applicants have to register with the E-procurement system at https://etenders.gov.in/eprocure/app. On completion of the registration process, the applicants will be provided user ID and password. In order to submit the EOI electronically, applicants are required to have a valid Class 2/3 Digital Signature Certificate (signing and encryption/ decryption certificates).
- 5. Applicants are requested to register for issuance of User ID and Password well in advance in order to avoid last minute rush. The process normally takes 03 days' time.
- 6. Post receipt of User ID & Password, parties can log on for downloading & uploading EOI document.
- 7. Parties shall ensure that their EOI is complete in all respect (all supporting documents duly signed and sealed), are to be submitted online through e-procurement portal ONLY (as described above). No DEVIATION is acceptable.
- 8. A person signing (manually or digitally) the EOI or any documents forming part of the contract on behalf of another shall be deemed to warrantee that he has authority to bind such other persons and if, on enquiry, it appears that the persons so signing had no authority to do so, the purchaser may, without prejudice to other civil and criminal remedies.

The applicants may also contact toll free no. of the Central Public Procurement Portal for obtaining guidance to submit the EOI online.

#### 9.0 Applicable Law and Jurisdiction:

This EoI, its meaning and interpretation, etc shall be governed by the Applicable Laws of India and shall be subject to the jurisdiction of the Courts at Madras.

For and on behalf of HLL Lifecare Ltd,

Director (Technical & Operations)
Corporate & Registered Office , HLL Bhavan
Poojappura P.O
Thiruvananthapuram-695012

Email: <a href="mailto:hbleoi@lifecarehll.com">hbleoi@lifecarehll.com</a>
Website:<a href="mailto:www.lifecarehll.com">www.lifecarehll.com</a>

Phone: 0471-2354573/9995484947/8848788053



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#### CORRIGENDUM -1 (Schedule of Pre- EOI Meeting)

- 1. This is with reference to the Notice Inviting EOI (No: HLL/HBL-VACCINE MANUFACTURE/EOI/2020-21) for Shortlisting Vaccine/ Pharmaceutical Manufacturers For Use of HBL's Facilities At Integrated Vaccines Complex (IVC), Chengalpattu, On "As Is Where Is Basis" for production of COVID-19 /Other Vaccines, published on 16<sup>th</sup> January 2021 in CPP Portal, HLL/ HBL Websites and the advertisement published in Times Of India Newspaper.
- 2. The interested parties are hereby informed that the Pre-EOI meeting is scheduled on **22-01-2021 (Friday) at 11:00 AM** and it will be conducted via <u>online mode</u> through ZOOM application.
- 3. The link, ID and passcode for attending the Pre- EOI meeting is as follows:

Link: https://us02web.zoom.us/i/82390865796?pwd=UHk1Zm5IUmNndIFSdXFVUWttYkRLQT09

Meeting ID: 823 9086 5796

Passcode: 232080

4. Prospective parties requiring any clarification regarding the EOI may send the queries/request to Shri. Renjith M. C (Senior Manager - HCS, Phone: by email (<a href="https://hbleoi@lifecarehll.com">hbleoi@lifecarehll.com</a>) within 1 (one) day of pre-EOI meeting i.e., upto 23-01-2021 (Saturday) 6:00 PM.

Sd/Director (Technical & Operations)
HLL Lifecare Limited



#### Feedback on queries raised at the Pre-EOI Meeting held on 22.01.2021

Time: 11:00 AM - 12:30 PM

#### Participants:

- 1. Bharat Biotech International Limited, Hyderabad
- 2. Dr. Reddy's Laboratories
- 3. Reliance Lifesciences
- 4. Invex Health Pvt. Ltd.
- 5. Morepen Laboratories
- 6. SBI CAPS (Transaction Advisor to HLL)
- 7. HLL and HBL

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SI.No	Queries from the parties	Clarification from HLL
1	What is the timeline proposed by HLL for completing the process of EOI and selection of partners	HLL proposes to complete the process of shortlisting, selection of partner /partners by 31/03/2021. And hope to enter in to a workable agreement to start operation in April 2021
2	Requested for visit to HBL facility during the process of EOI	The visit to HBL facilities is allowed during the EOI process; parties can contact CEO, HBL in advance.
3	HBL is currently under MoHFW and have the benefits of PSU to get the supply orders; will the benefits of PSU under Ministry may continue or not when private party enter in to contract manufacturing/ leasing arrangements.	* * *
4	Is HBL looking to operationalize IVC with a single party or multiple parties?	HBL is looking forward for operationalizing the facilities already established, including formulation and filling facilities and bulk production facilities. The parties based on their requirement for bulk production and formulation and filling may submit their expression of interest and business/ operational plan.



## Feedback on queries raised at the Pre-EOI Meeting held on 22.01.2021

		1
		Accordingly, HBL may select single or multiple parties as per the requirement and feasibility.
5	What is the financial model HBL is looking forward as part of the investment proposed by the partners - Is there any equity participation.	We are looking forward to select parties to complete the commissioning and validation of facilities as required and make them operational for production of one or more vaccines at this stage. The capital infusion requested now is not to be treated as an equity.
6	How long will it take to make ready the BVF and VVF facilities	The re-validation of BVF facility may require 2-4 months; Commissioning and validation of VVF facilities may require 4-6 months.
7	Approximate fund infusion required for operationalizing each facility	<ul> <li>Liquid vaccine formulation facility (BVF): Rs. 5 Cr.</li> <li>Lyophilized vaccine Formulation facility (VVF) with 2 filling suites and lyophilizers: Rs. 15 Cr.</li> <li>Tissue culture bulk production facility: 5 Cr</li> <li>Bulk &amp; Formulation Block: 10.00-12.00 Cr</li> <li>Multiple Bulk Block: 10.00-12.00 Cr</li> </ul>
8	Does HBL have the requisite manpower in place to manage the operation	HBL is having manpower in different disciplines for managing the operation; however, for the technical side, specific for vaccines, the manpower need to be strengthened by recruiting additional technical/ production based manpower. The partner can recruit/depute manpower for disciplines to augment the existing team.
9	Can the VVF facility handle two viral vaccines simultaneously	The viral vaccine facility is having two independent formulation and filling suites. As per requirement, parties can handle production of 2 different vaccines from this facility. The BVF Facility can handle only one vaccine at a time.
10	In incase a foreign company is interested to participate in the EOI, what is the procedure?	The foreign company shall participate through the Indian Joint venture partner.



## Feedback on queries raised at the Pre-EOI Meeting held on 22.01.2021

	Does the company require an Indian counterpart/partner to proceed	
11	Can the financial credentials of the foreign company produced as part of the EOI.	Yes. If any foreign collaborator is already, collaborating along with Indian partner for manufacture of Pharma/Vaccines then the partnership is acceptable and the partnership /Joint venture agreement need to be submitted along with the EOI.
12	Why the facility is not having R&D and pilot plant, which is a requirement for vaccine production process development.	R&D and Pilot plant facility is currently not available and this may be established as per the requirement in future.
13	The viral bulk production facility is completed with all infrastructure and equipment; however, the facility is not installed with bioreactors - any reason for the same.	The viral vaccine bulk production facility is planned for production of Rabies/ JE vaccines where the production process is based on tissue culture by using roller bottle/ cell factories. Bioreactors may be installed based on the production process requirement for new vaccines planned in the facility.
14	Before signing the MoU is there any due- diligence to be completed	All due diligence as per the requirement shall be done.
15	Is there any financial proposal to be submitted along with the EOI.	No Need to submit financial proposal along with EOI. However, parties shall submit the proposed business plan based on assumptions as deemed fit.
16	Vaccine manufacturing is a time driven process, so in that case short-term arrangements may not be beneficial. Hope the partnership model is for long term arrangements.	HLL is open for long-term partnership models as indicated in the Notification inviting Eol.
17	How the EOI to be submitted; is it through only online platform.	EOI and supporting documents shall be uploaded in CPP portal as per the details provided and no hardcopies to be submitted.

Please Note: Relevant documents as required shall be shared to shortlisted parties.





**Sub:** Revised schedule for submission of EOI for Shortlisting Vaccine/ Pharmaceutical Manufacturers for Use of HBL's facilities at Integrated Vaccines Complex (IVC), Chengalpattu, On "As Is Where Is Basis" for production Of COVID-19 /Other Vaccines.

**Ref**: Notice Inviting EOI (No: HLL/HBL-VACCINE MANUFACTURE/EOI/2020-21) dtd. 16-01-2021 (Tender ID: 2021\_HLL\_66105\_1)

The proposed schedule for submission as per the Notice inviting EOI dated 16-01-2021:

EOI Submission Details		
EOI NO.HLL/HBL-VACCINE MANUFACTURE/EOI/2020-21		
DTD: 16/01/2021		
Last date for submission of EOI	:	29/01/2021 15:30 Hrs
Date & time of opening of EOI	:	30/01/2021 16:00 Hrs

The schedule for submission of EOI is revised as below:

EOI Submission Details			
EOI NO.HLL/HBL-VACCINE MANUFACTURE/EOI/2020-21			
DTD: 16/01/2021			
Last date for submission of EOI : 05/02/2021 15:30 Hrs			
Date & time of opening of EOI	:	06/02/2021 16:00 Hrs	