MINUTES OF THE MEETING

EXPRESSION OF INTEREST (EOI) FOR ENGINEERING & DESIGN SERVICES – RESEARCH & DEVELOPMENT (R&D) / PILOT PLANT DEDICATED TO THE DEVELOPMENT OF VACCINES (BOTH BACTERIAL AND VIRAL) AND BIOPHARMACEUTICALS AT HBL, INTEGRATED VACCINE COMPLEX AT CHENGALPATTU

Document No.	:	**HBL/IVC/EOI/ENGG_DESIGN SERVICES/25-26 DATED 02nd AUG, 2025**
Venue	:	**Video Conference @ HLL Biotech Limited**
Date	:	**07-08-2025 @ 12.00 Hrs**
Project	:	**Integrated Vaccine Complex, Chengalpattu**
Attendees	:	**See attached list of attendees**
Issued on	:	**08-08-2025**
Issued by	:	**Procurement**

Agenda	
1.	Pre-bid Meeting for Expression of Interest (EoI) for Engineering & Design Services – Research & Development (R&D) / Pilot Plant dedicated to the development of vaccines (both bacterial and viral) and biopharmaceuticals at HBL, Integrated Vaccine Complex (IVC) at Chengalpattu

S. No	EOI No: HBL/IVC/EOI/ENGG_DESIGN SERVICES/25-26 DATED 02nd AUG, 2025 Clarification to vendor queries
1.	**Project Nature:** The current project is a brownfield project, as the necessary civil infrastructure and power facilities are already available.
2	**Quality Control area:** The Quality Control (QC) facility does not need to be included in the scope of this project, as a common QC facility is already available. However, if necessary, an in-process quality control (IPQC) testing room may be considered.
3	**Basic Design Consideration:** The basic requirement of the facility design is that the vendor must develop a single, integrated development block that incorporates well-segregated functional areas, each with clearly defined workflows and dedicated personnel entry and exit points to prevent cross-contamination. The facility should include, but not be limited to, the following areas: i. **Virus Bulk Manufacturing Area:** This section must accommodate operations such as cell culture, virus culture, purification, and inactivation. Proper containment and segregation measures are critical to maintain biosafety and product integrity. ii. **Bacterial Bulk Manufacturing Area:** This area should support bacterial culture, purification processes, and conjugation activities. The design must ensure process flow separation to avoid cross-contamination between viral and bacterial streams. iii. **Common Formulation Area:** A shared space for final product formulation activities such as blending and fill-finish. This area should be strategically located to serve both viral and bacterial bulk streams without compromising GMP requirements. iv. **Common Support Areas:** These include dedicated zones for material washing, material preparation and sterilization, as well as media and buffer preparation. These areas should support both manufacturing streams while maintaining appropriate segregation. Additionally, personnel entry and exit routes must be independently designated for each of the four functional areas (viral, bacterial, formulation, and common support) to ensure biosafety, workflow efficiency, and regulatory compliance.

4	**Facility Usage:** The facility will be utilized for vaccine product development, including Phase I and Phase II clinical trial manufacturing. It is essential that the facility complies with current Good Manufacturing Practices (cGMP) as per the guidelines and standards set by the national regulatory authorities. This compliance ensures that the facility meets the necessary requirements for the safe, consistent, and high-quality production of human clinical trial materials.
5	**Biosafety Level of the Facility:** The facility should be designed to comply with Biosafety Level 2 (BSL-2) standards, while incorporating selected BSL-3 practices where necessary. This means the facility must support the handling of moderate-risk biological agents typically managed under BSL-2, while also including enhanced safety features to accommodate larger volumes of biological agents.
6	**Facility Capacity:** The facility design should accommodate a production capacity ranging from 4,000 to 10,000 vials per batch, ensuring scalability and flexibility to support various stages of product development and clinical manufacturing.
7	Closing date & time for receipt of Tender has been extended till 19-08-2025,15:00 Hrs
8	Date and Time of opening of Technical Bids has been extended till 19-08-2025 @ 15:30 Hrs.

For HLL Biotech Limited

08/08/2025.

Authorized Signatory

HLL Biotech Limited (A Government of India Enterprise) Integrated Vaccine Complex Survey No : 192 & 195 Thirumani Village Thirukalukundram (TK) Chengalpattu (D) Chengalpattu-603001. Ministry of Health & Family Welfare