REQUEST FOR PROPOSAL (RFP)
To obtain CDSCO Manufacturing license for an AI Software as a Medical Device (SaMD) as per Medical Device Rules 2017

Opening date of RFP: 14/11/2025

Closing Date of RFP: 25/11/2025 – 23:59 hours

I. INTRODUCTION

Lords Education and Health Society (LEHS), registered under Societies Registration Act XXI of 1860 is a charitable organisation with its head office in New Delhi, India working in the health, Agriculture and education Domain for the poor. LEHS in furtherance of charitable objectives through its flagship unit i.e. Wadhwani AI aims to build equitable and sustainable systems to the underserved population and to bring the benefits of modern AI technology to underserved populations by building and deploying AI solutions for social impact across domains such as healthcare, agriculture, governance and education in India.

LEHS aims to promote the integration of technologies, particularly in emerging domains like artificial intelligence and innovations into the Indian mainstream primary healthcare, education, and agriculture systems through a partnership with the State and National Government, apex institutions, international agencies, and private sector partners e.g. innovators, social enterprises and other ecosystem contributors in line with its stated objectives for the betterment of society particularly focusing on projects of national and social significance. In line with its mission to support projects of national and social significance, LEHS also undertakes rigorous monitoring, evaluation, and learning (MEL) activities to assess the impact, usability, and scalability of different programmatic interventions.

II. BACKGROUND

Wadhwani AI (LEHS), in collaboration with AIIMS Delhi, has developed an Artificial Intelligence-based Software as a Medical Device (SaMD). As part of the domestic regulatory process, AIIMS Delhi has secured a Test License for this solution. As a next step, Wadhwani AI (LEHS) would like to engage professional services to support the documentation and licensing processes necessary for obtaining a manufacturing license for this SaMD.

III. SCOPE OF WORK

Grant of CDSCO Manufacturing license (Class C Central) for AI solution by adhering to all required protocols including the ones outlined below:

1. Implementation of Quality Management System (First Deliverable)
   - To prepare quality manual in accordance with Schedule V of Medical Device Rules 2017, ISO 13485:2016.
   - Prepare Standard Operating Procedures.
   - Providing formats and guidance on filling formats.
   - Coordination with NABCB Body for submission, audit visits, and compliances, if any for ISO 13485.
   - Grant of ISO 13485 Certificate, three-year license, audited from NABCB Body.

2. Grant of Manufacturing License Class C Device, Central (Second Deliverable)
   a. Registration on Online Portal
      - To Register the firm on online Central Drugs Standard Control Organization for medical devices.
   b. Device Master Files (DMF)
      - To prepare device master files in accordance with Appendix II, Part III, Schedule IV of Medical Device Rules, 2017
   c. Essential Principles Checklist (EPC)
      - Essential principles checklist prepared in accordance with notification Vide F No. X.11035/656/2017-DRS dated 19/04/2018
   d. Risk Management file (RMF)
      - To prepare Risk management files in accordance with ISO 14971:2019 "Medical Devices- Application of risk management to medical devices" and ISO 24971:2022 "Medical Devices- Guidance on the application of ISO 14971"
   e. Design History File (DHF)
      - Preparation of Design history file in accordance with Clause 7.3 "Design and Development" of ISO 13485:2016 "Medical Devices- Quality Management System- Requirements for regulatory purposes"
   f. Plant Master Files (PMF)
      - Plant master file prepared in accordance with Appendix I, Part III, Schedule Four, Medical Device Rules, 2017
   g. Manufacturing License (Class C & D on MD-9) (Central)
      - To prepare documents for applying Manufacturing License on form MD-7
      - To apply Manufacturing License on form MD-7
      - To reply to any queries received from CDSCO
      - To get successful audit conducted by CDSCO
      - To get license granted in Form MD-9

IV. Proposal Requirements

Your proposal must include:

1. **Technical Proposal**
   - Understanding of the scope of work
   - Key Team members composition and qualifications with their CV's or Profile
   - Quality assurance mechanisms
   - Ethical safeguards
2. **Financial Proposal – Password Protected**
   - Deliverable wise Cost breakdown
   - Applicable taxes
   - Timeline-based payment schedule

V. Eligibility Criteria

Proposals will be considered from Agencies / vendors that meet the following:

- Demonstrable track record of supporting achievements of CDSCO Manufacturing license and implementation of Quality Management System.
- Prior similar experiences in software as medical device (SAMD)

VI. Evaluation Criteria

Proposals will be evaluated based on:

- Technical approach and methodology – 10%
- Team qualifications and experience – 20%
- Past performance and references – 20%
- Financial proposal – 50%

VII. Submission Instructions

- Both Technical and Financial Proposals must be submitted electronically to rfp.lehs@wadhwaniai.org **separately**.
- Financial Proposal must be password protected.
- All documents should be in PDF format.
- Subject line of the email:
  - **"Technical Proposal - CDSCO Manufacturing license for an AI Software as a Medical Device (SaMD) – [Agency / Vendor Name]"**
  - **"Financial Proposal - CDSCO Manufacturing license for an AI Software as a Medical Device (SaMD) – [Agency / Vendor Name]" along with password**
- Submission Deadline: [25/11/2025 & 23:59 Hours]

Bidders who submit complete technical with password protected financial proposals and all mandatory enclosures (Section IX) will be considered only.

Individual consultants are also eligible to apply.

Prospective bidders should submit their queries to take this forward. **Please direct all queries to rfp.lehs@wadhwaniai.org by 19/11/2025 which will be responded through email/ phone calls by the respective team on 21/11/2025** helping bidders to submit their proposals well within time line.

- Any proposals received by LEHS after the deadline for submission of proposals prescribed in the RFP are liable to be rejected.

VIII. Data Security and DPDP Compliance (Where applicable)

1. Credentials of data creators will be compiled in a Word document and uploaded securely to an S3 Bucket/secure folder link shared by Wadhwani AI.
2. These credentials will be stored in case the identity or qualifications of the data creators are requested in the future, during open-sourcing, or to verify the authenticity of our work.

3. All PII will be stored securely in compliance with the DPDP Act, 2023.
4. All PII used for model training will be anonymised or masked before further processing.
5. The agency must use the Excel sheet format provided by Wadhwani AI to create and upload the conversational QA pairs as part of Activity 1. The document must be uploaded to a secure server link that will be provided by Wadhwani AI
6. The image collection protocol and tool, and the annotation tool will be shared by Wadhwani AI with the agency selected for the task. Regardless of the tool used, the agency must strictly adhere to the provisions of the Digital Personal Data Protection (DPDP) Act, 2023, as Wadhwani AI is also fully compliant with this law.
7. The agency shall be fully responsible for ensuring the privacy, security, and protection of all personal data involved in this project. Any data leakage, unauthorised access, or misuse—whether by the agency or any third-party platform it engages—will be considered a breach of the DPDP Act. In such cases, the agency will be held accountable and subject to any legal or contractual consequences arising from such violations.

IX. Mandatory Enclosure

Please submit the following as enclosures or attachments with your quotation. The agency must provide all the information requested above in section VII. Quotations that do not provide the required information and certificates, or do not follow the submission requirements, may not be reviewed.

- Company Profile, testimonials for the previous three years, work completion reports, purchase orders, reference (NGOs)
- GST registration certificate.
- PAN & TAN registration.
- MSME Certificate, if any
- Audited Financials or Income Tax Return with computation of Income for the last three years
- Cancelled cheque.
- Copy of registration documents/certificate and most recent renewal as a legal entity

This section is mandatory for consideration of the proposal.

Note: Only Technically shortlisted Bidders will be eligible for the opening of the financial proposal. Bidders selected by the LEHS could be asked for presentations and negotiations.

If bidders do not hear from LEHS within two weeks of closer of the RFP, consider your proposal not selected. LEHS reserves the right to reject any or all proposals at any given time without giving any justification or response to the bidders.