CSIR-INSTITUTE OF GENOMICS & INTEGRATIVE BIOLOGY
(Council of Scientific & Industrial Research)
MALL ROAD & MATHURA ROAD
PHONE: - 011-27667602/27667439/27666156/157 FAX NO. : 011- 27667471

EXPRESSION OF INTEREST (EOI)

(Ref. NO. - CSIR-IGIB/GMP/2023-24/01)

Subject:- Setting-up of prefab GMP container at CSIR-IGIB, Mathura Road, South Campus, New Delhi-110025

EOI is invited on behalf of the Director, CSIR-IGIB for submission of Technical proposal, Presentation, Design/Drawing etc. for the establishment of Good Manufacturing Practice (GMP) lab Facility / requirement as per FDA standard and confirming to international guidelines of sickle cell experimentations at CSIR-IGIB Mathura Road, South Campus, New Delhi-110025. The facility is intended for performing biomedical experimentations on sickle cell programme with manufacturing cell therapy products on prefab GMP lab at container. For further details please visit our website. www.igib.res.in.

The scope shall include design, supply, installation, testing, commissioning and validation on turn- key basis for cell therapy product manufacturing procedure room, ancillary rooms, to be accommodated within an area of approximately 2000 square ft. on clear ground near right side of existing building DG-1.

About GMP Lab

Designing a GMP lab can be a rigorous task since the regulatory agencies have several regulations regarding airflow, lab location, testing procedures, and more to ensure product quality and consistency and to protect public health. GMP regulations are used to govern day-to-day activities and operations and can be used as a resource for best practices and must be widely implemented and posted in writing throughout the facility.

Before presentation the parties should visit the site for an on-spot check on available area/facilities, prepare and submit technical proposals along with concepts, drawing(s), time schedule, project planning and expertise and its company profile and make presentations accordingly by the due date. For site visit, contact to **Dr. Debojyoti Chakraborty, Principal Scientist** / Sh. Ram Ranjan, Executive Engineer (E), CSIR-IGIB, South Campus, Mathura road, Sukhdev Vihar, New Delhi-110025.

Prequalification criteria

- The Firm should have average turnover of at least **Rs. 3.00 crores** during the last three years and should submit supporting documents on the same.
- The firm should have past experience of designing, building and commissioning

prefab GMP lab facility (for cell therapy products) for biomedical research abiding by necessary national / international regulatory norms, with necessary documentations.

- There should have been successful cell therapy trials in India/abroad where the manufacturing process has been completed in the GMP lab
- As a turn key project, all associated as per Annexure –"A" with drawing.

- •The Firm should have PF and ESI registration and should submit challans for last month along with registration certificates. ITR for last three years should also be submitted.

The Institute has the discretion to call either all the parties or selective few for presentation/demonstration.

Important Dates:

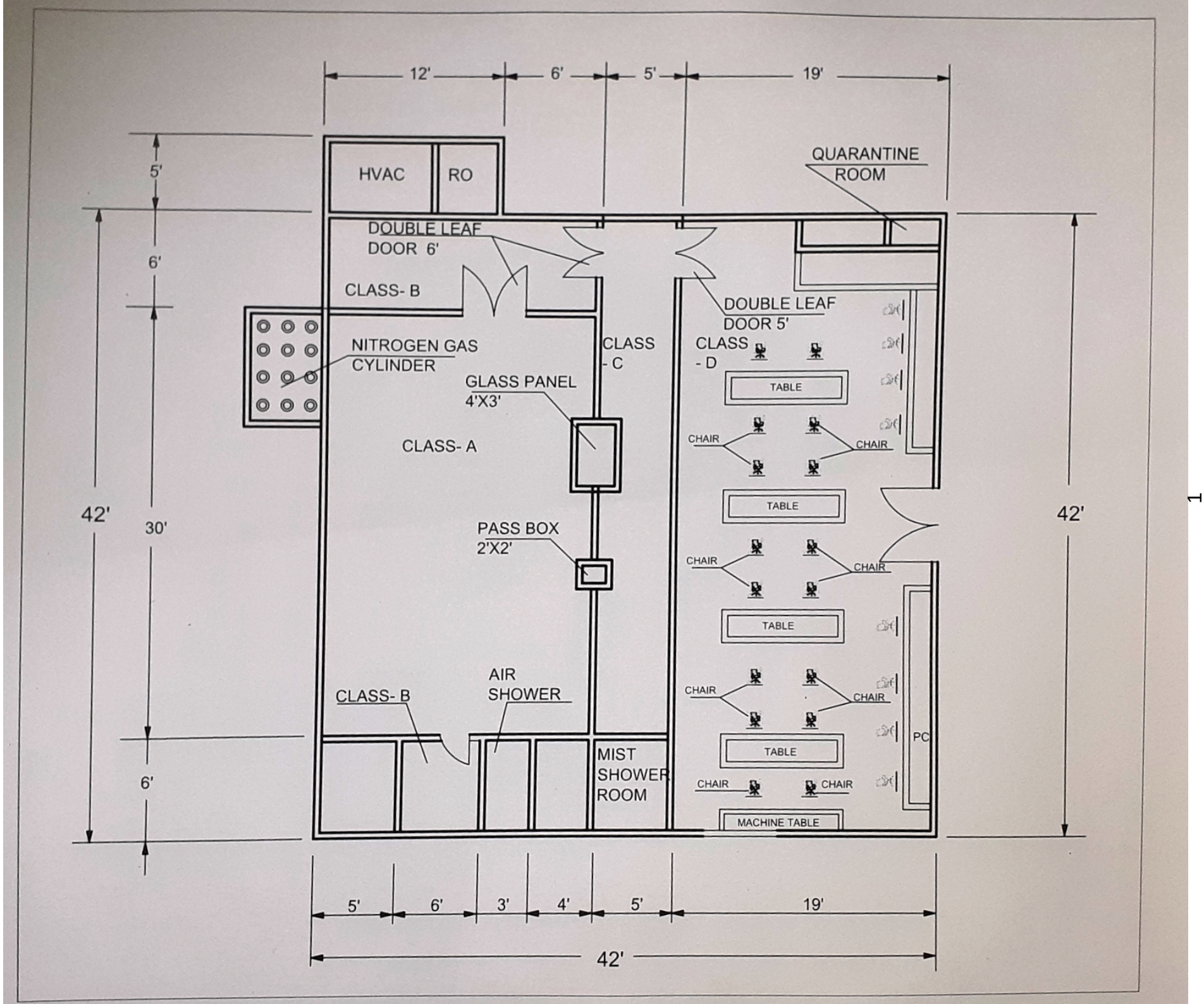
Date of publication of EOI	21.08.2023
Last date of submission of EOI	04.09.2023
Opening of technical proposals	05.09.2023
Date of presentation	To be informed later on through email

Annexure- "A"

Details of turnkey Project (Tentative/Indicative Scope of Work)

1. **The Facility to be developed on 42 feet X 42 feet area as per the attached Plan. The existing level of the Ground to be raised by 2 feet over which the facility is to be developed. The 2 feet wide passage all around the perimeter of the facility to be made Pucca by placing paver blocks.**
2. **A structure of size 42 feet X 42 feet to be built on the site. The walls of the outer structure as well as the inner walls of the internal rooms should made of at least 50 mm thick PUF Panel/SS panels/Other Material of Heat and weather resistant property and must be fire resistant.**
3. Inside this metal structure a steel clean room of 18 feet x 30 feet with 304 grade stainless steel puffed panels to be made as per the plan having different partitions and doors and pass box.
4. The doors should have door closers with security system for authorized entry.
5. A mist shower and air shower need to be installed.
6. A pass box 2 feet x2 feet to be installed having 2 doors and UV.
7. One wall should have a double glass panel for viewing 4 feet X 3 feet.
8. The floor of the clean room should have epoxy flooring.
9. The clean room to have different classes of room's i.e. class 100, 1000, 10000, 100000 (A, B, C and D).
10. There should be a HVAC system (8+8=16 TR)
    (a.) One HVAC system for the class 100/A room
    (b.) One for class 1000 and 10,000 with a Backup HVAC for both class of clean room connected in case of eventuality.
11. A RO plan with 100LPH to be installed with **Milli-Q system**.
12. Conning of the edges to be done in the clean room.
13. The HEPA filter in the clean room to be roof mounted covering the whole roof.
14. The air ducts should have air dampers to control the pressure.
15. There should be differential pressures in each room as per final specification of GMP lab.
16. The clean room should have the online differential pressure, RH, Temperature, and Particle count monitoring system installed connected to central computer for monitoring with BMS.
17. Two-way video communication.
18. Electrical supply with RAW power and UPS depending on the power requirements.
19. All doors should be biometric controlled/card reader connected to central computer for monitoring.
20. CCTV to be installed in all areas and connected to central computer.

21. The clean room Should have steel tables 304 grade 3 feet x 3 feet=6 nos, 3 feet x 7 feet= 3 nos
22. Cart 4 nos.(stainless steel 304)
23. Adjustable stools – 20 nos.
24. Steel dustbins foot operated - 50 Liters, 10 nos.
25. There should be a gas bank for Nitrogen & CO2 with connections (Gas pipeline) should be made as per the requirement at class A area.
26. The class D Area should have wooden paneling inside and should have A Depending on the area.
27. The class D Area should have a quarantine area for the stores & Microbiology area.
28. There should be lab working tables with Granite top in the class D area. Size of 2400x1500x900mm Modular lab Table (4 Nos.), Body, 2 nos. Drawer & 1 no. cupboard made out of 20 -24gauges thick CRCA Sheet duly powder coated 40-50 micron. Top should be made of 16-17mm black granite with polished edges. Provision for electrical raceway.
29. Electrical wiring for class A, class B, Class D area with Power DB, Light DB and UPS DB as per CPWD norms. All DB should be placed at class D area.
30. LED lighting for class A, class B, Class D area.
31. Fixing of MCP, smoke & heat detector with fire panel & extinguisher and as per fire safety norms.
32. Stainless steel cabinet (4 feet x 6 feet) – 2 nos.
33. **The underground water supply line is to be provided from the existing available source up to GMP facility (approx. 50 metre).**
34. **The roof of the facility is to be provided with proper drainage facility for rain water.(Preferably sloping). This drainage is to be connected with nearest drain line.**
35. **The discharge of waste water of RO plant and mist shower room or any other is also to be connected to nearest available drain line. However, any other discharge of chemical or biological nature to be taken care of as per relevant norms and procedures.**


12'
6'
5'
19'
5'
6'
42'
30'
6'
HVAC
RO
QUARANTINE ROOM
DOUBLE LEAF DOOR 6'
CLASS- B
NITROGEN GAS CYLINDER
GLASS PANEL 4'X3'
CLASS- A
CLASS - C
PASS BOX 2'X2'
AIR SHOWER
CLASS- B
MIST SHOWER ROOM
DOUBLE LEAF DOOR 5'
CLASS - D
TABLE
CHAIR
CHAIR
TABLE
CHAIR
CHAIR
TABLE
CHAIR
CHAIR
TABLE
PC
CHAIR
CHAIR
MACHINE TABLE
42'
5'
6'
3'
4'
5'
19'
42'