

**Minutes of Pre-Bid Meeting for Request for Proposal
Manufacturing, Management, Maintenance & Operation of Dialyser Hollow Fiber
Membrane Extrusion Facility
(Tender Ref No: AMTZ/Proc./ATE/2021/003, Dated:07/10/2021)**

1. The Meeting was held on 12/10/2021 at 12:30 Hrs. through online video conferencing:

Name of the Attendees	Designation	Organization
Mr. A V J L Gupta	HOD – Procurement	AMTZ
Mr. Rakesh Bhatia	Sales Head	AMTZ
Mr. Shivam Anand	Scientist D	AMTZ
Mr. Shahrukh Khan	Scientist C	BVIC
Ms. U S Mithra	Intern	KIHT
Mr. Pratik Shah	Representative	Sentiss Pharma
Ms. Replica Sharma	Representative	Sentiss Pharma
Mr. Gagan Kapoor	Representative	Deckmount Electronic
Mr. Brajesh Singh	Representative	Consona Healthcare
Mr. Subramanian	Representative	Atrium Medical Technologies

2. Revised Due date & Time for submission of bid is 03:00PM, 15/11/2021 & Date & Time of Technical Bid opening will be 04:30PM, 15/11/2021. Tender Fee & Bid Security Fee/EMD is not applicable for this RFP.
3. Following amendment (Revised Schedule I, II, III & Format of Price Bid (Annexure II)) is being issued to the referred RFP Document. It may be noted that below mentioned amendment shall be applicable to all the relevant section of RFP.
4. Minimum Eligibility Criteria shall be amended as under:

RFP Document Clause No. & Page No.	Existing clause	Amended as
Clause No: 2.2.2 (i) Minimum Eligibility Criteria (Page No: 12)	The Bidder shall have experience of operating and managing a Dialyser hollow Fiber Membrane Extrusion Facility for a minimum period of 2 (two) years and at least 2 (two) clients from medical device/health care industry and/or academia who are associated as hollow fiber experts	The Bidder shall have experience of operating and managing any pharmaceutical (sterile/ non-sterile) or medical devices manufacturing facility for a minimum period of 2 (two) years and at least 2 (two) clients from medical device/ pharmaceuticals / healthcare industry

For, Andhra Pradesh Medtech Zone Ltd

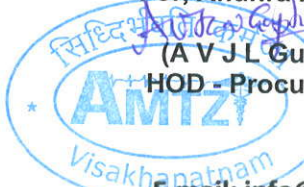
(A V J L Gupta)

HOD - Procurement

ANDHRA PRADESH MEDTECH ZONE LIMITED

(An Enterprise of Government of Andhra Pradesh)

E-mail: info@amtz.in, Contact: +91 88830 92122/33 CIN – U85190AP2016SGC103153



Schedule I: Scope of Work (Terms of Reference)

- 1 Andhra Pradesh MedTech Zone Ltd. (AMTZ) is proposed as a park with 200-300 manufacturing units of size 2 Acre / 1 Acre / 0.5 Acre / 0.50Acre each and a set of common scientific facilities for manufacturing of electronic, electrical, electro-medical, radiological and biomaterial medical devices. The required infrastructure for industry facilitation will be developed by the AMTZ. While the manufacturing units shall be leased out, Common scientific facilities shall be created on Build and Operate Model. Government visualizes establishing state of the art civil and electrical infrastructure for industry to walk in and establish the interiors of their units/assemblies in least amount of time possible.
- 2 The Selected Bidder- Developer and Operator (Concessionaire) shall be leased out land or building space for a period of 33 years for operations, management and maintenance of the project facility.
- 3 AMTZ shall invest in the equipment & machinery while the selected bidder shall invest on building the facility & making it operational, routine maintenance, operation & management of the facility.
- 4 The payment for the services availed will be done directly by the users availing the services at the project facility, as per standard norms applicable for all occupying the zone.
- 5 The selected bidder would have to ensure that at least 75% of all the production of the hollow fiber extrusion facility would be towards medical products and only upto a maximum of 25% of the facility shall be for other sectors such as water filtration and other technologies.
- 6 The Selected Bidder- Developer and Operator (Concessionaire) will share the following with AMTZ after the facility has been operationalized:
 - a. A share in revenue on monthly basis shall be payable to AMTZ from the day of start of operation upto 10 years. AMTZ revenue share shall be minimum to 5% of sales revenue. The bidder may consider 5% as minimum & can quote higher values. Incase of selected bidder, the sales revenue share shall be the percentage quoted or Rs. 7.5Lac per month whichever is higher.
- 7 The broad scope of work will comprise of the following,
 - The extrusion of hemodialysis and allied healthcare application-based grade fibers.
 - The fabrication of these fibers poses a great challenge due to delicate balance between the polymer flow rate, water flow rate, the rheology of the polymer solution along with the flow pattern of the fluids in the thin flow conduit. The bidder should propose a validated and economically viable system of extrusion of the fibers for commercial applications.
 - The bidder should have access to spinneret for extrusion as well as technically viable mass extrusion protocol for a capacity of three hundred thousand per year.

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- An affordable and innovative indigenous technology to produce hemocompatible dialysis and allied healthcare application-based grade fibers using simple needle- in needle assembly spinnerets which has grown over the years to produce more compact and advanced design.
- The dialysis and allied healthcare based application grade hollow fibers would be made by polysulfone (PSF) as the base polymer, N,N-Dimethyl formamide (DMF) as solvent with polyvinylpyrrolidone (PVP) as additive or similar innovative resources. The process of manufacturing the Dialyser hollow fibers is explained in the following schematic,

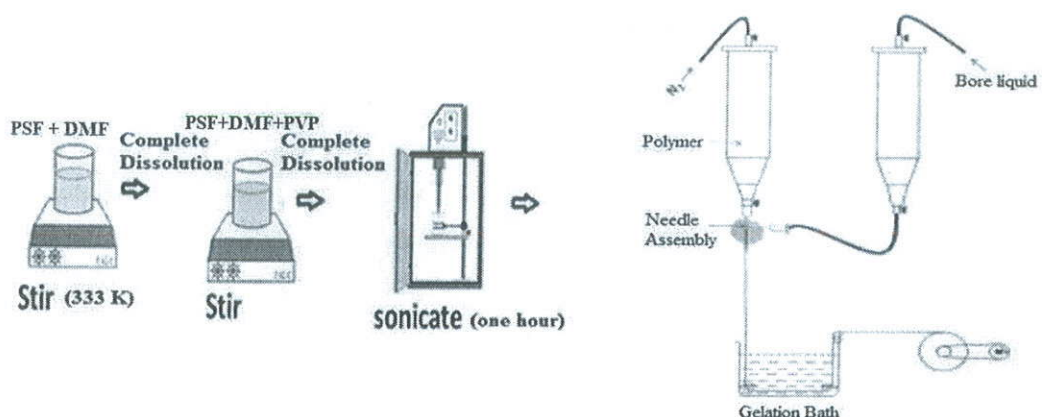


Fig. 1. Schematic of the hollow fiber spinning process.

Depending on the diameter of the needles, hollow fibers should be spinned for applications like, fruit juice processing, water treatment, extraction and purification of bioactive compounds, etc and other healthcare based applications. Dialysis grade fibers have an inner bore diameter of 200-220 μm and thickness of 35-40 μm . These constraints in the dimension for dialysis grade fibers are very stringent as they ensure the safe and quick operation of dialysis. The identification of the appropriate solution composition, needle diameter and spinning conditions to produce hemodialysis grade hollow fibers at a very low cost would be required as a pre-requisite by the applicant.

- The indigenously prepared dialysis grade fibers were packed into small modules of 0.3 and 0.6 m^2 and were tested successfully on dogs. The bigger cartridge of 1 m^2 area awaits trial on real life patient affected by acute renal failure.

In addition, it is recommended if the bidder has internal capability of potting and assembly of fibers into appropriate housing units, for hemodialyzer, oxygenator, water purification fiber bundle cartridges and similar healthcare applications.

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8 The facilities should also have a safety kit which includes: - □

Laboratory Coat

- Gloves
- Safety Glasses
- Eye Wash station
- Fire Extinguisher
- First Aid Kit

9 General Operations and Management

The developer and operator (concessionaire) will hire and depute adequately qualified staff, depending upon the requirements of tests listed in Schedule V-A. In addition to the technical staff, other administrative staff will also need to be deployed at the facility, as listed below,

- One (1) Plant Head.
- One (1) Quality Assurance Manager, responsible for quality assurance, health and safety management and environmental management
- Adequate number of technicians within each department/ unit to support manufacturing and operation activities as per the defined SOP and other request activities

10 The developer and operator (concessionaire) will develop SOPs, as per the quality management system guidelines for the following set of parameters,

- Acceptance criteria for products
- Sample preparation.
- Description of methods, including validation of results.
- Quality control.
- Maintenance and calibration records of equipment.
- Job descriptions, including responsibilities and continuing competence of individual technical staff.
- Training records of technical staff, covering which methods they can perform, level of training, whether they can perform a method independently or under supervision, and their ability to train others, etc.
- Traceability and storage of raw data.
- Cleaning procedures for the laboratory.

Employee Safety and Health and Security

11 The developer and operator (concessionaire) will be responsible for other operational requirements for the facility which will include,

- Making necessary security and access protocols/ restrictions
- Entire facility should have CCTV cameras, such that the primary lab area is under surveillance
- Safety gear including gowns, safety wear, masks, gloves and other essential inventory should be available for the staff at all times.
- Data and Records Management

12 The developer and operator (concessionaire) will be primarily responsible for



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maintaining records and documents, as may be required for scientific and regulatory purposes. This information should be shared with AMTZ officials from time to time, as mutually agreed.

Standards and Accreditation

- 13 The applicant will be responsible for acquiring all the necessary registrations and approvals from the applicable authorities, as may be required for operations of such a lab.
- 14 Compliance to ISO 13485 standards is essential as per international practices. The applicant will also be responsible to apply for accreditation from national or international accreditation agencies.

Arjun Gupta
28/10/21



Arjun Gupta

Schedule II: Obligations of the Private Partner and AMTZ

2.1. Obligations of Private Partner

- 1 The Selected Bidder (Concessionaire) will operate the facility in accordance with international benchmarks and design approval of the facility by AMTZ.
- 2 The Selected Bidder (Concessionaire) will get the layouts, drawings and plans approved by AMTZ and its appointed Project Monitoring/ Management Agency, prior to initiating development of the facility.
- 3 The selected bidder (concessionaire) is mandated to commence the operations within 3 months of the installation of machinery.
- 4 The Selected Bidder (Concessionaire) will keep AMTZ and its Project Monitoring/ Management Agency about the status of the development and procurement of equipment on regular basis.
- 5 The Selected Bidder (Concessionaire) will follow the environment, health & safety, regulations as may be applicable from time to time.

2.2. Obligations of AMTZ

- 1 AMTZ will provide all support for clearances and licenses as required.
- 2 AMTZ will release funds for equipment procurement from time to time based on bills/ invoices raised by the Developer and Operator (Concessionaire). However the amount will not exceed the investment support committed by Authority.
- 3 Delays caused due to lack of clearances and approvals will be given due consideration, however the Selected Bidder (Concessionaire), will need to bring this to the timely notice of the Project Monitoring/ Management Agency.

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Schedule III: Penalty and Termination Performance Security

The Selected Bidder shall have to provide a Performance Security of 3% of the total value of funds required from AMTZ. It should be in the form of Bank Guarantee for a duration of ten years and six months and also extendable till the completion of performance obligation of contract.

Penalty for Delays

- 1 Failure to initiate Operations of the facility within 3 months of installation of machinery, shall attract a penalty 5% of performance bank guarantee for every 30 calendar days of delay in initiation on operations.
- 2 The selected service provider shall however be responsible for testing, calibration, performance qualification, quality inspection & approval as and when required, and commissioning of the equipment.

Contract Termination Parameters

- 1 The Selected Bidder (concessionaire) is expected to comply with the agreement and charge service fees as stipulated in the financial bid. Any deviation in these charges will result in the termination of the contract.
- 2 The Selected Bidder (concessionaire) is required to seek third party accreditation/ certification or approval, as the case may be. AMTZ will notify the concessionaire of the accreditations/ certifications that are required at the time of signing the contract. The developer and operator (concessionaire) will have to apply for these certifications / accreditations within one year of commercial operations, failing of which, the performance security will be forfeited. A fresh performance security (of equal value) will need to be submitted by the developer and operator (concessionaire) to continue the contract.
- 3 Failure to achieve accreditation/ certification within three years from the date of start of commercial operations (unless otherwise specified by AMTZ), result in termination of the contract.
- 4 The concessionaire will share data regarding turnaround time and some select quality parameters, on a regular basis with AMTZ. AMTZ (and its appointed team) will constantly monitor performance and determine acceptable benchmark standards (mutually with the concessionaire), which may be revised every 12 months. Repeated failure on the part of the Concessionaire to meet any of these benchmarks for three consecutive years, may result in termination of the contract and forfeiture of the deposits.

Atul Singh
28/10/21



- i) Lease developed land in the AMTZ premises at rate of INR 400 per square feet and construct building as per required specification at own cost.
5. I/We agree that AMTZ commitment for the above project cost shall be limited to a maximum of INR 14,000,0000 (Fourteen Crores) towards the machinery.
6. I/We undertake to ensure that at least 75% of all the production of the hollow fiber extrusion facility would be towards medical products and only up to a maximum of 25% of the facility shall be for other sectors such as water filtration and other technologies.
7. I/We agree to share in revenue on monthly basis shall be payable to AMTZ as committed above.
8. I/We agree and undertake to abide by all the terms and conditions of the Bidding Documents. In witness thereof, I/we submit this Bid under and in accordance with the terms of the RFP document.

Yours faithfully,

Date:

(Signature of the Authorised signatory)

Place:

(Name and designation of the of the Authorised

signatory) Name and seal of Bidder

Notes:

- i) The selection of bidder who has qualified on technical grounds would be based on the lowest quote indicated for the project, exclusive of land and building cost.
- ii) Price bid will be opened for technically qualified and responsive bidders.
- iii) Land/RCC space shall be allotted by the Authority in the premises of AMTZ, on leasebasis as per options indicated by the bidder.
- iv) Contribution by AMTZ for the machinery procurement is subject to a maximum of INR 14 crore.

Signature
28/10/21

