	INDIAN INSTITUTE OF TECHNOLOGY BOMBAY **MATERIALS MANAGEMENT DIVISION** **Powai, Mumbai 400076.**

PR no. 1000053976 **RFx No :** 6100002790

Item Description : Advanced Perfusion system (Qty:1)

Sr. No.	Technical specifications	Technical Compliance (Yes / No)	Additional Information (if any)
1.	**Purpose** Benchtop cell culture bioreactor system for viral vector and mammalian cell culture applications. The system should be an automated, modular, and scalable benchtop bioreactor suitable for suspension cell culture, viral vector production and process development studies. The system should support precise control of critical process parameters and should be compatible with GMP lab. The system should be a fully automated sterile tube welding device designed to create aseptic, leak-proof connections between thermoplastic tubing used in biopharmaceutical processing, cell culture, and viral vector manufacturing. The system should enable sterile welding without compromising product sterility and should be suitable for GMP conditions.		
2.	**Vessel and working volume specifications:** I. Total vessel volume: Approximately 5 L or above II. Working volume range: 1 L to 5 L or wider III. Vessel material: Autoclavable borosilicate glass or equivalent IV. Vessel design: Double wall or jacketed vessel suitable for temperature control		

	V. Ports: Multiple aseptic ports for sampling, inoculation, sensors, gas inlet, and feed addition VI. Headplate: Multiport headplate with sterile connectors VII. Compatibility: Should support reusable glass vessels. VIII. Single control unit that can be connected to two culture vessels.		
3.	**Agitation system:** I. Agitation type: Magnetically coupled or top-driven mechanical agitation II. Agitator design: Marine impeller or equivalent suitable for mammalian cell culture III. Speed range: 30 to 300 rpm or better IV. Speed accuracy: ±1 rpm or better V. Agitation control: Programmable and automated		
4.	**Gas control and sparging system:** I. Gas mixing capability for oxygen, carbon dioxide, nitrogen, and air II. Mass flow controllers or equivalent for individual gas control III. Sparging options: Micro sparger and macro sparger or equivalent IV. Overlay gas control facility V. Capability for dissolved oxygen cascade control		
5.	**Temperature control:** I. Temperature control range: 4°C above ambient to 60°C or wider II. Temperature accuracy: ±0.1°C or better III. Temperature monitoring using high precision probes IV. Automated heating and cooling control		

6.	**pH and dissolved oxygen control:** I. pH measurement and control using autoclavable probes II. Dissolved oxygen measurement using optical or electrochemical probes III. Automatic control through gas flow, agitation, or feed addition IV. Control accuracy: ±0.05 pH units and ±2% DO or better		
7.	**Feeding and addition system:** I. Integrated peristaltic or equivalent pumps for acid, base, feed media, and antifoam addition II. Minimum 4 independent pump channels or more III. Programmable feed strategies including batch, fed-batch, and perfusion capability		
8.	**Foam and level monitoring:** I. Foam detection probe with automatic antifoam addition II. Liquid level monitoring or equivalent control mechanism		
9.	**Control system and software:** I. Touch screen or PC-based control system II. Real-time monitoring and graphical display of process parameters III. Recipe management and programmable control IV. Data logging and storage facility V. Compliance with electronic data integrity standards VI. Provision for data export and network connectivity		
10.	**Sterility and sampling:** I. Sterile sampling ports with aseptic connectors		

	II. Compatibility with sterile welding or sterile connection technologies III. Fully autoclavable vessel assembly		
11.	**Safety features:** I. Overpressure and overtemperature protection II. Alarm system for parameter deviations III. Emergency stop provision IV. Leak and sensor fault detection		
12.	**Utility requirements:** I. Power supply: 220–240 V, 50/60 Hz II. Compatible with laboratory compressed air and gas supply lines		
13.	**Accessories:** I. Standard glass vessel assembly (x2) II. Agitator and impeller set III. Sensor probes for pH, dissolved oxygen, and temperature IV. Tubing and connectors for fluid transfer V. Sampling assembly VI. Feed and addition bottles VII. Calibration kits for sensors		
14.	**Compliance and quality requirements:** I. Equipment should be suitable for GMP and GLP environments II. All product contact materials should be biocompatible and sterilizable III. Documentation including IQ, OQ, and operation manuals should be provided		
15.	**Tubing compatibility:** I. Compatible with thermoplastic tubing commonly used in bioprocessing applications II. Tubing outer diameter compatibility: Approximately 1/8 inch to 1 inch or wider		

	III. Capability to weld tubing of identical or different wall thickness within compatible range IV. Should support commonly used bioprocess tubing materials such as PVC, TPE, or equivalent sterilizable materials		
16.	**Welding performance:** I. Fully automated sterile welding process II. Welding cycle time: Typically less than 2 minutes or better III. Should provide strong, leak-proof weld joints suitable for liquid transfer IV. Weld integrity should maintain sterility and mechanical strength during process operations V. System should include automatic blade alignment and pressure control		
17.	**Sterility and contamination control:** I. Welding process should maintain aseptic conditions II. Disposable sterile blade or cutting element to prevent cross-contamination III. Closed system welding capability IV. Should minimize operator intervention during welding		
18.	**User interface and control:** I. Digital or touch screen control panel II. Display of welding parameters and status indicators III. Programmable welding parameters based on tubing size and material IV. Visual and audible alerts for process completion and error conditions V. Password or access control for user safety		
19.	**Safety features**: I. Protective enclosure to prevent user exposure to heated or moving components		

	II. Interlock system to prevent operation when device is open III. Automatic shutdown in case of malfunction or abnormal operation IV. Overheating and blade failure protection		
20.	**Data management and connectivity:** I. Capability to store welding operation records II. Data logging with date, time, and process parameters III. USB or network interface for data export IV. Compliance with electronic data integrity requirements where applicable		
21.	**Ergonomics and design:** I. Compact benchtop design II. Easy loading and unloading of tubing III. Low maintenance design with user-replaceable consumables IV. Easy cleaning and decontamination of external surfaces		
22.	**Utility requirements:** I. Power supply: 220–240 V, 50/60 Hz II. Should operate under standard laboratory environmental conditions		
23.	**Accessories and consumables:** I. Starter kit including sterile blades or cutting elements II. Tubing alignment guides or holders III. Cleaning and maintenance tools IV. User and operation manuals		
24.	**Compliance and quality requirements:** I. Equipment should be suitable for GMP and GLP environments II. All materials in contact with tubing should be biocompatible		

	III. Documentation including installation qualification and operational qualification should be provided.		
25.	**Documents for regulatory compliance** I. Test and calibration certificates traceable to national/international standards II. Installation qualification and operational qualification certificates III. Safety and compliance: certified to ISO and CE standards; floor bolting not mandatory, allowing flexibility in relocation.		
26.	**After sales support/ service / application support:** System should be supported by manufacturer or their authorized distributor with factory trained service engineer.		
27.	**Training** Training on operation and basic maintenance should be given at the time of installation for one week.		
28.	**Others** I. Service: a certified service engineer should be easily accessible and available on demand within 48 hours of any problem in the instrument. Two compulsory visit per year for maintenance must be included apart from the installation. II. Spares: the supplier of the instrument must confirm in writing that the spares for the entire instrument will be available for a period of at least ten years after the installation of the instrument. III. Manual: one set of operating manual and service manual (in English) should be provided with the instrument		
29.	**Warranty:** 3 years		