



**ONDERSTEPOORT BIOLOGICAL PRODUCTS LTD
PRIVATE BAG X7, ONDERSTEPOORT 0110**

From: Supply Chain Department
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REQUEST FOR INFORMATION - BENCHTOP, HIGH-CONTAINMENT 1L REUSABLE FERMENTER SYSTEM FOR ONDERSTEPOORT BIOLOGICAL PRODUCT

Kindly provide Information for the following: **RFI/OBP005/2026/27**

COMPULSORY/MANDATORY	
Company/ Individual Profile	That highlights years' relevant experience and capabilities In supplying Benchtops/ Fermenter System.
Proposal	Detailed proposal to include pricing and specification etc.
Additional Notes	All Bidders must be registered on CSD (Central Supplier Database)
Non - Compulsory Site briefing	None

<p>TERMS OF REFERENCE: REQUEST FOR INFORMATION - BENCHTOP, HIGH CONTAINMENT 1L REUSABLE FERMENTER SYSTEM FOR ONDERSTEPSOORT BIOLOGICAL PRODUCT</p>

1. INTRODUCTION

Onderstepoort Biological Products SOC Ltd (OBP) is a South African state-owned animal vaccine manufacturing company whose mandate is to manufacture animal vaccines with the aim of preventing and controlling animal diseases that impact food security, human health and livelihoods. The mandate is delivered through continued development of innovative products and efficient manufacturing, which ensures vaccine affordability and accessibility through varied distribution channels.

2. PROJECT BACKGROUND & OBJECTIVE

This Request for Information (RFI) is designed to evaluate market readiness for the supply, commissioning, and long-term support of a benchtop, high containment 1L Reusable Fermenter System. Submissions should address scalability across standalone single-unit configurations, multiple independent units, or multi-vessel cascade/parallel configurations controlled via a unified software interface.

Respondents are requested to complete the following specification matrix by indicating Yes or No regarding their capability to fulfil the requirement, alongside brief technical notes or reference documentation cross-references:

1. Core Technical Specifications				
Item / Parameter	Specification Required	Comply (Yes)	Comply (No)	Respondent Comments / Reference
1.1 Vessel Volume	1.0–1.2L total volume; working volume spanning 0.25L to 0.75L (25% to 75%).			

1.2 Vessel Type	Autoclavable, double-jacketed borosilicate glass vessel (or miniature 316L stainless steel jacketed vessel) with a baffled assembly and an integrated, water-cooled exhaust gas condenser.			
1.3 Exhaust & Gas Management	Integrated exhaust cooler paired with an automated solenoid valve assembly for precise off-gas control and pressure management.			
1.4 Agitation Mechanism	Top-driven, magnetic drive coupling or a mechanical shaft with a high-integrity double mechanical seal to prevent aerosol leakage. Equipped with 2–3 Rushton impellers.			
1.5 Agitation Speed Range	Speed range of 50–2000 rpm to optimize oxygen transfer rates (OTR) at low volumes.			

**Monitoring & Instrumentation
(Real-time)**

Item / Parameter	Specification Required	Comply (Yes)	Comply (No)	Respondent Comments / Reference
1.6 Primary Process Controls	Continuous, real-time closed-loop monitoring and control for pH, Dissolved Oxygen (DO), temperature, and foam/level.			
1.7 Sensor Technologies	Digital (e.g., Mettler Toledo Intelligent Sensor Management) or high-stability analog probes capable of withstanding repeated autoclave or sterilization cycles without calibration drift.			

<p>1.8 Advanced Off-Gas Analytics</p>	<p>Integrated exhaust gas analyzers to monitor bioreactor emissions in real time, tracking O₂ consumption and CO₂ production to dynamically calculate Respiratory Quotient (RQ) and Carbon Dioxide Evolution Rate (CER).</p>			
<p>1.9 Sampling & Inoculation</p>	<p>Autoclavable, zero-dead-leg sampling valve engineered for rapid, contamination-free sample collection. Includes an integrated septa port or autoclavable needle-free valve block for secure aseptic inoculation.</p>			
<p>1.10 Pressure Management & Safety</p>	<p>Dedicated pressure build-up sensors and safety interlocks engineered to detect over-pressurization immediately, mitigating risk and protecting vessel integrity.</p>			
<p>1.11 Bioreactor Steam Filters (Utility Quality Mitigation)</p>	<p>To accommodate environments with poor-quality utility steam, the system must include/accommodate the installation of sterilizing-grade filters. This ensures that clean steam entering the bioreactor is free of particulate matter, rust, scale, condensate droplets, and other contaminants that could compromise sterility or damage equipment.</p>			

Control Panel & Power Infrastructure

Item / Parameter	Specification Required	Comply (Yes)	Comply (No)	Respondent Comments / Reference
1.12 Central Interface	Central control panel with digital touchscreens for monitoring and controlling critical fermentation parameters in real time (connected to sensors, controllers, pumps, and valves).			
1.13 Uninterruptible Power Supply (UPS) & Power Conditioning	The system must include an integrated or dedicated industrial-grade UPS solution to protect system components against blackouts, brownouts, voltage sags, and frequency fluctuations.			
1.14 UPS Component Coverage	The UPS must back up the entire control panel, PLC, localized PC/SCADA system, and instrumentation sensors.			
1.15 Data Preservation	In the event of a power failure, the UPS must provide a minimum of 30 minutes of continuous power to maintain data logging, complete active audit trail entries, and prevent data corruption.			
1.16 Fail-Safe State	The system must utilize the UPS battery window to execute a controlled, automated safe-shutdown protocol or transition the bioreactor into a secure, non-hazardous holding state if utility power is not restored.			

**2.
Containment
Rating &
Architecture**

Item / Parameter	Specification Required	Comply (Yes)	Comply (No)	Respondent Comments / Reference
2.1 Biosafety Compliance	System architecture must safely secure biological risks up to Biosafety Level 2 and 3 (BSL-2/BSL-3).			
2.2 Filtration	Exhaust lines must feature dual 0.22µm hydrophobic sterile filters, with at least one actively heated to prevent condensation buildup and subsequent filter blinding.			
2.3 Footprint	The entire benchtop footprint must be highly compact and fully compatible with placement inside a Class III Biosafety Cabinet or a negative-pressure containment isolator.			

Control Software & System Architecture

Item / Parameter	Specification Required	Comply (Yes)	Comply (No)	Respondent Comments / Reference
2.4 Regulatory Compliance	Utilizes a SCADA/BioPAT MFCS or a localized PLC architecture fully compliant with 21 CFR Part 11 (including electronic signatures, unalterable electronic records, and comprehensive audit trails).			

2.5 Safety & Interlocks	The software must include hardware-level safety interlocks for overpressure, temperature runaway, and sensor failure, alongside automated predictive maintenance trackers.			
2.6 Power-Failure Logic	Software must feature automated recovery routines that log power interruption events in the audit trail and dictate whether a process can resume or must be aborted following a prolonged power outage.			
2.7 Remote Operations	Secure web-based or mobile interface allowing operators to monitor the progress of the fermentation run while off-site. The system must feature an automated alarm notification infrastructure (e.g., SMS, email, or push notifications) to instantly alert operators of parameter deviations, power failures, or containment anomalies.			

3. Training Framework				
Item / Parameter	Specification Required	Comply (Yes)	Comply (No)	Respondent Comments / Reference
3.1 Operational Level Training	Aseptic benchtop setup, micro-probe calibration/handling, autoclave sterilization cycles, and sterile sampling protocols.			

<p>3.2 Technical Level Training</p>	<p>Micro-pump calibration, mass flow controller verification, pressure decay containment testing for glass/steel boundaries, O-ring/gasket replacement, and UPS battery health testing/maintenance.</p>			
<p>3.3 Compliance Level Training</p>	<p>SCADA recipe/gas-mixing management, 21 CFR Part 11 audit trail extraction, and BSL3 emergency "Kill-Recipe" execution (e.g., chemical inactivation protocols).</p>			
<p>3.4 GMP Core Training</p>	<p>Understanding ICH Q8 and Q10 core pillars/process terminology such as Quality by Design (QbD), Critical Quality Attributes (CQA), Critical Process Parameters (CPP), Process Analytical Technology (PAT), and Quality Target Product Profile (QTPP).</p>			

<p>4. Local Compliance & Support Checklist</p>				
<p>Item / Parameter</p>	<p>Specification Required</p>	<p>Comply (Yes)</p>	<p>Comply (No)</p>	<p>Respondent Comments / Reference</p>
<p>4.1 SCM Registration</p>	<p>Active, compliant profile on the National Treasury Central Supplier Database (CSD) and a valid SARS tax clearance status.</p>			

4.2 Warranty & SLA	5-year comprehensive warranty inclusive of all planned preventative maintenance (PM) costs, probe replacements, and calibration to safeguard public expenditure.			
4.3 Spares Security	Initial critical spares (O-rings, seals, replacement probes, exhaust filters) on-site before validation begins; 10-year guarantee on critical BSL3 spares from a regional SA depot within 48 hours.			
4.4 Local Infrastructure	Direct access to a local technical partner or factory-trained engineer capable of responding to the site within 24–48 hours for critical BSL3 failures.			
4.5 Grid Resilience	Compatibility with SA electrical standards (230V @ 50Hz, single-phase). Equipment must feature built-in industrial surge protection and a dedicated PLC/controller UPS capable of maintaining data integrity and control functionality for at least 30 minutes during local grid instability/load shedding.			
4.6 Quality Heritage	ISO 9001 certification and CE/ASME rating for any pressurized modules, paired with a 5–10 year global/local track record supplying benchtop systems to the pharmaceutical, academic, or vaccine sectors.			

3. REQUEST FOR INFORMATION PROCESS

The overall objective of the RFI is to identify what benchtop, high-containment 1L Reusable Fermenter System is available in the market that are aligned with the requirements of OBP.

The RFI process is aimed at soliciting information/solution solutions to:

- Survey the market to identify potential service providers available in the marketplace
- Provide a specification and cost estimation/budget.

4. GENERAL

4.1 CONFIDENTIALITY

OBP shall:

- Use its reasonable endeavours to keep all data and details submitted by responding parties strictly confidential, save to the extent that such data or details are required to be disclosed by applicable law or order of a court of competent jurisdiction; be entitled to disclose all data and details to their officers, employees, agents, advisors and representatives who are involved in the project and the evaluation of the responses; and
- Not be liable for any loss incurred or damage suffered as a result of any disclosure of any information (confidential or otherwise) of the responding party. The responding parties shall not have, and hereby waives, any claim against OBP arising out of the disclosure of any information, confidential or otherwise.

4.2 RESERVATION OF RIGHTS

- OBP reserves the right, to use information submitted in response to this RFI for the purpose of compiling and aggregating data for public release, related to the information submitted, without mentioning / identifying specific parties.
- OBP reserves the right to verify any information contained in a response to this RFI; and OBP reserves the right to cancel or withdraw this RFI as a whole or in part.

4.3 CONTACT INFORMATION AND CLARIFICATIONS

- Interested parties are free to request clarifications from, or engage directly with, the team via email at purchasing@obpvaccines.co.za

5. CLOSING DATE

- The RFI closing date and time is on the **24 of July 2026 @15:00**,
- All bidders MUST register their company (in advance) on the NEW OBP's EProcurement portal, the link can be found on the official OBP website under supply chain.
- Once bidders account registration is approved by the OBP Supply Chain, login credentials will be supplied, whereby bidders will be able to login and apply for opportunities.
- All open opportunities will reflect on the portal for bidders to part take in.
- All required company documents, proposed submissions or additional requirements MUST be uploaded wit you bid application.
- Any additional questions or Queries can be directed via email (purchasing@obpvaccines.co.za) or telephone (012 522 1500), note NO SUBMISSIONS WILL BE ACCEPTED via EMAIL.