

**STERILE BIOREACTOR SYSTEMS SEEDS (4X40L)**

**USER REQUIREMENT SPECIFICATIONS**

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**U.S. DEPARTMENT OF COMMERCE**

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**APPROVED**

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## **2 SCOPE**

The project will include several skid-mounted sterile bioreactor systems to perform as seed vessels for larger systems. This document defines the requirements and deliverables for four of these systems. It describes overall requirements that must be met to produce the specific equipment requested. This document covers the procurement and delivery of the systems, with no required installation.

This URS is the input document for the:

- Equipment procurement purposes
- Equipment sizing
- Functional and technical specifications

## **3 BACKGROUND**

Dakota Bioworx is a research facility for the development of high-quality bioproducts. Several bioreactor systems of different sizes will be installed to enable customers to scale up their processes. These customers will be able to generate data and/or small volumes of fermentation broth and/or finished product.

## **4 PROCESS DESCRIPTION**

Several separate sterile bioreactor systems will be installed, with plans to add capacity as required in the future. The bioreactor skids will be stand-alone or twin units equipped with their own dedicated control and monitoring systems. Each skid will include an agitation system, aeration system, exhaust system, and temperature and pressure control. Each will be SIP and CIP cleanable or be appropriately sterilized via autoclave. These systems will be commercial grade systems that are easily configurable to handle a wide variety of process requirements. This document specifically covers four systems with reactor volumes of approximately 40L.

## 5 BASIS OF DESIGN

### 5.1 Capacities

Four bioreactors shall have a working volume of approximately 30L.

### 5.2 Skidded Construction

Each system will be mounted on a skid. Piping for steam, air, and water will be located on the skid, as well as any and supporting equipment. The control system and associated wiring will also be mounted on the skid. These vessels **may also be assembled in multi-vessel skids** as twin units so long as the SCADA allows for individual unit control.

### 5.3 Health, Safety and Environment (HSE)

The bioreactors will satisfy appropriate conformity assessment procedures and the controls shall carry the UL marking. Selected unit shall be constructed per the current ASME BPE standard. The units will be designed to protect users from hot surfaces. Pressure relief safety valves or rupture disks shall be vented to a safe location.

### 5.4 Operation, personnel and automation

The fermentation systems will be fully automated as standalone units such that operations personnel will not need to attend to them once they are started and operating. An ethernet connection for SCADA interface for batch reporting shall be provided.

### 5.5 Materials of Construction

All materials of construction must be compatible with ambient and hot water for injection (WFI), and typical chemical cleanings agents such as phosphoric acid, potassium hydroxide, and sodium hydroxide up to 3%. Piping specifications, including all gasket and valve seat material must align with current ASME-BPE standards, where applicable.

### 5.6 Reliability & maintenance

The fermentation systems will be designed to operate routinely during 24 / 7 / 365 operations. All wear parts shall be easily accessible and replaced on a regular maintenance schedule. Wear parts like gaskets shall be stock items that can be ordered and delivered in a timely manner.

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## **6 ABBREVIATIONS, ACRONYMS & DEFINITIONS**

<b>Acronyms</b>	<b>Description</b>
ASME BPE	American Society of Mechanical Engineers Bio-Processing Equipment
CIP	Clean In Place
HMI	Human Machine Interface
NEMA	National Electrical Manufacturers Association
OPT	Optional Attribute
P&ID	Piping & Instrumentation Diagram
PLC	Programable Logic Controller
REQ	Required Attribute
SCADA	Supervisory Control and Data Acquisition
SIP	Sterilization In Place
UL	Underwriters Laboratories
URS	User Requirements Specification
WFI	Water for Injection

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## 7 USER REQUIREMENT SPECIFICATIONS

URS TABLE – Sterile Fermentation Systems		
Designation	Description	Type
URS-F1	The four fermenter working volumes shall be approximately 30L with a total volume of approximately 40L.	REQ
URS-F2	The four fermenters must be skid mounted and mobile as either individual units or two twin skids.	REQ
URS-F3	Aspect ratio for the fermenters shall be approximately 3:1 (height:width).	REQ
URS-F4	ASME/CE certification is required.	REQ
URS-F5	The agitators shall be Rushton impellers.	REQ
URS-F6	The system must be capable of an oxygen transfer rate of > 300 mmol O <sub>2</sub> /L/hr.	REQ
URS-F7	Tank baffles shall be removable and made of 316L stainless steel or similar quality material.	REQ
URS-F8	Interior surface finishes shall be mechanically polished to 20 Ra.	REQ
URS-F9	Vessel design pressure shall be 40 psig and full vacuum.	REQ
URS-F10	Vessel jacket design pressure shall be 50 psig and full vacuum.	REQ
URS-F11	Vessels and their jackets shall both have design temperatures of 300° F.	REQ
URS-F12	Connections shall be sanitary.	REQ
URS-F13	All electrical enclosures shall carry a NEMA 4 rating.	REQ
URS-F14	Vessel temperature control will be accomplished automatically via tank jacket.	REQ
URS-F15	Each fermentation system should be supplied mounted on a steel frame skid. The skid shall be an open, modular design that can facilitate the addition of standard options at any time.	REQ
URS-F16	Power shall be provided to the skid via a single point 220V or 480V, 3-phase/ 60Hz connection.	REQ
URS-F17	The SCADA shall be accessible remotely over the institute network.	REQ
URS-F18	The operator interface shall be via HMI and offer password protection with operator, supervisor, and administrator levels of access.	REQ
URS-F19	The operator interface shall include a recipe function to save, load, or delete process recipes.	REQ
URS-F20	Full system documentation shall be provided, including instruction and maintenance manuals, safety instructions, P&ID, and dimensional drawings.	REQ
URS-F21	Control system documentation shall be provided, including specifications, wiring overview, circuit diagram, arrangement drawing, terminal connection diagram,	REQ
URS-F22	The head plate removal system shall be motorized or spring assisted.	REQ
URS-F23	System validation documentation (SAT, IQ, OQ) must be provided by manufacturer.	REQ
URS-F24	Manufacturer must offer US-based factory trained service engineers to assist with installation and training as needed.	REQ

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<b>URS TABLE – Sterile Fermentation Systems</b>		
<b>Designation</b>	<b>Description</b>	<b>Type</b>
URS-F25	Manufacturer must maintain US-based storage location for spare parts.	REQ
URS-F26	The sanitary piping skid design and program must enable automated cleaning in conjunction with a 3 <sup>rd</sup> party CIP system	REQ
URS-F27	Auto pressure control, including pressure transmitter and pressure control valve, with ability to monitor pressure in SCADA	OPT
URS-F28	Single inlet filter w/ temperature indicator	OPT
URS-F29	Single exhaust filter w/ temperature indicator	OPT
URS-F30	Exhaust condenser for SIP	OPT
URS-F31	Load cells for direct measurement of the vessel volume	OPT
URS-F32	Two gas mixing with a thermal mass flow meter	OPT
URS-F33	Auto flow control	OPT
URS-F34	Overlay valve	OPT
URS-F35	5 addition valves	OPT
URS-F36	SIP housing	OPT
URS-F37	Dual ph/DO ISM transmitter option	OPT
URS-F38	120 mm optical ISM DO option	OPT
URS-F39	120 mm ISM pH option	OPT
URS-F40	High & high-high foam sensor	OPT
URS-F41	Glycol cooling option via second heat exchanger	OPT
URS-F42	Sample valve	OPT
URS-F43	Pump box, including four fixed speed peristaltic pumps with pulse width modulation	OPT
URS-F44	Electropolish option to guarantee finish of 15 Ra or less	OPT
URS-F45	Low seal pressure switch for bottom-drive impeller	OPT
URS-F46	SCADA package	OPT
URS-F47	Startup assistance	OPT
URS-F48	Dual exhaust filter	OPT
URS-F49	Sterile sampling kit	OPT
URS-F50	Pro ext ethernet switch	OPT
URS-F51	Aux 4-20 mA outputs	OPT
URS-F52	3" sight glass on head plate	OPT
URS-F53	Water prefilter/regulator kit	OPT
URS-F54	Utility steam prefilter/regulator kit	OPT
URS-F55	Process steam prefilter/regulator kit	OPT
URS-F56	Instrument air prefilter/regulator kit	OPT
URS-F57	Preventative Maintenance Kit	OPT
URS-F58	Spare parts Kit	OPT

**END OF SPECIFICATION**

## 8 SELECTION CRITERIA

Vendors will be evaluated based on the following criteria:

<b>Evaluation Criteria</b>		
<b>Description</b>	<b>Ranking</b>	<b>Weight</b>
<b>Mandatory Technical Requirements</b> A review of your proposal to determine adherence with the REQ specifications and technical requirements.	1-10	30%
<b>Proposal Pricing</b> Review of your proposal in relation to the services offered in the proposal. Proposals will be evaluated against competing proposals for cost effectiveness. Proposals will be evaluated to be reasonable and appropriate.	1-10	20%
<b>Technical Response</b> The technical response in your proposal portrays knowledge, experience, and professionalism. Relevant product features and/or specifications are available with your equipment other than those mandatory specifications allotted above.	1-10	10%
<b>Lead Time</b> A review of your product's lead time to meet business objectives.	1-10	15%
<b>Product Warranty</b> The available warranty, in scope, duration, and value, proposed with your product.	1-10	5%
<b>Experience and Demonstrated Results</b> Our evaluation will include a review of your history, your experience as it relates to the requirements within this RFP, evidence of past performance, quality and relevance of past work, references, and related items.	1-10	20%

## 9 RETURN BIDS TO

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## **10 OTHER PROVISIONS**

Must meet 200 CFR buy America Provision • Title 49 Subtitle B Chapter VI [Part 661](#)

Federal Participation Disclosure – “This project will be partially funded with Federal funds from the United States Department of Commerce, Economic Development Administration and therefore is subject to the Federal laws and regulations associated with that program.”

Must meet Federal Contract provision 200 CFR Title 2 subtitle A Chapter II [Part 200](#)

### **1.1 CERTIFICATION RELATING TO PROHIBITED ENTITY**

For contractors, vendors, suppliers, or subcontractors who enter into a contract with the State of South Dakota by submitting a response to this solicitation or agreeing to contract with the State, the bidder or offeror certifies and agrees that the following information is correct:

The bidder or offeror, in preparing its response or offer or in considering proposals submitted from qualified, potential vendors, suppliers, and subcontractors, or in the solicitation, selection, or commercial treatment of any vendor, supplier, or subcontractor, is not an entity, regardless of its principal place of business, that is ultimately owned or controlled, directly or indirectly, by a foreign national, a foreign parent entity, or foreign government from China, Iran, North Korea, Russia, Cuba, or Venezuela, as defined by SDCL 5-18A. It is understood and agreed that, if this certification is false, such false certification will constitute grounds for the State to reject the bid or response submitted by the bidder or offeror on this project and terminate any contract awarded based on the bid or response. The successful bidder or offeror further agrees to provide immediate written notice to the contracting executive branch agency if during the term of the contract it no longer complies with this certification and agrees such noncompliance may be grounds for contract termination.

### **1.2 RESTRICTION OF BOYCOTT OF ISRAEL**

For contractors, vendors, suppliers, or subcontractors with five (5) or more employees who enter into a contract with the State of South Dakota that involves the expenditure of one hundred thousand dollars (\$100,000) or more, by submitting a response to this solicitation or agreeing to contract with the State, the bidder or offeror certifies and agrees that the following information is correct:

The bidder or offeror, in preparing its response or offer or in considering proposals submitted from qualified, potential vendors, suppliers, and subcontractors, or in the solicitation, selection, or commercial treatment of any vendor, supplier, or subcontractor, has not refused to transact business activities,

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has not terminated business activities, and has not taken other similar actions intended to limit its commercial relations, related to the subject matter of the bid or offer, with a person or entity on the basis of Israeli national origin, or residence or incorporation in Israel or its territories, with the specific intent to accomplish a boycott or divestment of Israel in a discriminatory manner. It is understood and agreed that, if this certification is false, such false certification will constitute grounds for the State to reject the bid or response submitted by the bidder or offeror on this project and terminate any contract awarded based on the bid or response. The successful bidder or offeror further agrees to provide immediate written notice to the contracting executive branch agency if during the term of the contract it no longer complies with this certification and agrees such noncompliance may be grounds for contract termination.

### **1.3 CERTIFICATION OF NO STATE LEGISLATOR INTEREST**

Offeror (i) understands neither a state legislator nor a business in which a state legislator has an ownership interest may be directly or indirectly interested in any contract with the State that was authorized by any law passed during the term for which that legislator was elected, or within one year thereafter, and (ii) has read South Dakota Constitution Article 3, Section 12 and has had the opportunity to seek independent legal advice on the applicability of that provision to any Agreement entered into as a result of this RFP. By signing an Agreement pursuant to this RFP, Offeror hereby certifies that the Agreement is not made in violation of the South Dakota Constitution Article 3, Section 12.