

**Entity Name:** South Dakota State Government

**Event Number:** 9229

**Event ID:** 23RFP9229

**Event Name:** Sterile Bioreactor Systems Seeds (4x7.5L)

**Requested By:** Missy Schuetzle

**Created By:** Missy Schuetzle

**Due By Date:** 10/27/2023 05:00 PM Central Time

**Q&A Cutoff Date:** 10/13/2023 10:27 AM Central Time

**Invitation Type:** Invitation Only

**Assigned Commodities:** 495-41 Fermentation Equipment: Chemostats, Chemotaxis Chambers, Fermenters, etc.; 907-40 Engineering Services, Non-Licensed (Not Otherwise Classified)

**Allow Supplier Terms and Conditions:** No

**Public Responses:** No

**Display Awardee:** Display

**Posting Board Status:** Published

**Event Status:** Event Under Review

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**Section #: Name:**

**1 Section 1 - 23RFP9229**

Do not submit responses through ESM Sourcing as this is for informational purposes only. Please download the attached RFP document and follow submittal instructions.

**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 7.5L.

**5 BASIS OF DESIGN**

**5.1 Capacities**

Four bioreactors shall have a working volume of approximately 5L.

**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.

#### 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

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### Terms and Conditions

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#### ESM Sourcing Terms

None

#### General Terms and Conditions

None

#### Event Specific Terms and Conditions

See attached RFP Document