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Event Name: Sterile Bioreactor Systems
Requested By: Missy Schuetzle
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Allow Supplier Terms and Conditions: No
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Section #: Name:

1 Section 1 - 23RFP8663

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1 SCOPE

The project will include several skid-mounted sterile bioreactor systems. This document defines the requirements and deliverables for six 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

2 BACKGROUND

The Dakota Bioproducts Innovation Institute 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.

3 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 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. These systems will be commercial grade systems that are easily configurable to handle a wide variety of process requirements. This document specifically covers six systems with reactor volumes of approximately:

- 200 L – qty 2
- 50 L – qty 4

4 Basis of Design

4.1 Capacities

Six skids are covered in this specification, each with its own bioreactor. Two bioreactors shall have a working volume of approximately 200 L. Four bioreactors shall have a working volume of approximately 50 L.

4.2 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.

4.3 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.

4.4 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.

4.5 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.

4.6 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.

Terms and Conditions

ESM Sourcing Terms

None

General Terms and Conditions

None

Event Specific Terms and Conditions

See attached RFP Document