Advance Contract Award Notice (ACAN)

23-58179

Single-Use Bioreactor with a 50L working volume

1. Advance Contract Award Notice (ACAN)

An ACAN is a public notice indicating to the supplier community that a department or agency intends to award a contract for goods, services or construction to a pre-identified supplier, thereby allowing other suppliers to signal their interest in bidding, by submitting a statement of capabilities. If no supplier submits a statement of capabilities that meets the requirements set out in the ACAN, on or before the closing date stated in the ACAN, the contracting officer may then proceed with the award to the pre-identified supplier.

2. Definition of the requirement

- The National Research Council (NRC) Human Health Therapeutics has a requirement for the supply of 1 Single-Use Bioreactor controller with a 50L working volume. The bioreactor controller must be able to operate single-use bioreactor suitable for cell culture in suspension for the production of various biologics, including recombinant proteins, viral vector and vaccines. The bioreactor controller must be able to monitor and control critical parameters for cell culture such as dissolved oxygen, agitation rate, dissolved oxygen level, pH and temperature. It must be fully compatible with single-use bioreactor bags that allow for sterile cell culture in suspension without any contaminations. These bags must be designed in accordance to the current Good Manufacturing Practices for biologics, i.e. bags that are pre-sterilized via gamma irradiation and that present minimized risks for leachable and extractable compounds impacting either the cells or the product's quality.
- To coordinate with the existing equipment, the bioreactor controller needs to be able to operate the exact same single-use bioreactor that will be used in its Clinical Trial Manufacturing Center facility: same material in contact with the cells, same geometry and design to assure a similarity in performance from an hydrodynamic perspective (shear stress, mixing, gassing, etc.), and similar operation and setup procedure to facilitate cross-training and technology transfer between the R&D and the GMP team. Given these constraints, the National Research Council have selected to acquire a XDR-50 bioreactor controller (Cytiva 29744027) or equivalent, suitable for the use of XDR-50 single-use bioreactor development bags (Cytiva 888-0356-C) or equivalent.
- The equipment that NRC desire to acquire must include the following component:

- One bioreactor controller where the single-use bioreactor bag is installed and the various parameters (temperature, agitation, dissolved oxygen, pH, pressure, gassing, pumping) are measured and controlled
- One Human-Machine Interface (HMI) where the bioreactor operator can see the various control parameter values, see the trends and change the setpoints / control strategy loops
- One external Temperature control unit, if needed, to adjust the water temperature in the temperature control jacket of the bioreactor
- 2 dissolved oxygen and 2 pH probes
- 2 single-use bioreactor bags to perform initial tests on the equipment following installation, including probes inserts
- Any external pumps, if needed, to fit the pumping requirements
- 24 months warranty

3. Criteria for assessment of the Statement of Capabilities (Minimum Essential Requirements)

- Any interested supplier must demonstrate by way of a statement of capabilities that its 50L single-use bioreactor controller meets the following requirements:
  - Capacity to cultivate cells in XDR-50 single-use bioreactor bags from Cytiva (888-0356-C) or equivalent, to assure comparability and compatibility with existing equipment from the NRC Clinical Trial Manufacturing Center suite.
    1. Same material in contact with the cells and the product
    2. Exact same bioreactor design than in the Clinical Trial Manufacturing Facility Center (NRC): bag dimensions, impeller & sparger positioning, probe positioning, impeller & sparger design, mass flow and pump sizing
    3. Same method for bag installation, setup and operation to allow for single procedure to be used across the R&D and the manufacturing team
  - Same user interface than in the X-platform (Cytiva) to facilitate cross-training of the bioreactor operation between the R&D and the manufacturing team
  - Capability to cultivate suspension mammalian cells in a sterile, controlled environment, with the ability to control the following parameters to specific setpoints
    1. Temperature
    2. Pressure
    3. Agitation rate
    4. Dissolved oxygen
    5. pH
    6. Dissolved CO2 (as an option)

7. Gassing rate (both headspace and sparging rate)
8. Pumping rate (alkali solution for pH control, feed rate)
9. Weight / level via the use of integrated or external pumps

- OPC UA/DA communication to integrate the equipment into the NRC R&D SCADA software

4. Applicability of the trade agreement(s) to the procurement

This procurement is subject to the following trade agreement(s)

- *Canadian Free Trade Agreement* (CFTA)
- Revised *World Trade Organization - Agreement on Government Procurement* (WTO-AGP)
- *Canada-European Union Comprehensive Economic and Trade Agreement* (CETA)
- *Comprehensive and Progressive Agreement for Trans-Pacific Partnership* (CPTPP)
- *Canada-Chile Free Trade Agreement* (CCFTA)
- *Canada-Colombia Free Trade Agreement*
- *Canada-Honduras Free Trade Agreement*
- *Canada-Korea Free Trade Agreement*
- *Canada-Panama Free Trade Agreement*
- *Canada-Peru Free Trade Agreement* (CPFTA)
- *Canada-United Kingdom Trade Continuity Agreement* (Canada-UK TCA)
- *Canada-Ukraine Free Trade Agreement* (CUFTA)

5. Set-aside under the Procurement Strategy for Aboriginal Business.

Not applicable

6. Comprehensive Land Claims Agreement(s)

Not applicable

7. Justification for the Pre-Identified Supplier

- Due to commonality and compatibility with existing equipment, the pre-identified supplier, Global Life Sciences Solutions Canada ULC, is the only one able to distribute Cytiva equipment in Canada. The Cytiva XDR-50 bioreactor controller is the only equipment that can operate the XDR-50 single-use bioreactor bags, which, as stated above, comply to the following constraints

1. Same material in contact with the cells and the product than the bioreactors used in the manufacturing suite
2. Exact same bioreactor design than in the Clinical Trial Manufacturing Center facility (NRC): bag dimensions, impeller & sparger positioning, probe positioning, impeller & sparger design, mass flow and pump sizing
3. Same method for bag installation, setup and operation to allow for single procedure to be used across the R&D and the manufacturing team

- The rationale behind this procurement is to provide the NRC R&D team with a 50L bioreactor controller that will be used to transfer cell culture processes from the NRC R&D team to the NRC manufacturing team seamlessly, reducing the risk of failures in the manufacturing process to a minimum. Because of the very nature of the mammalian cells, which are extremely sensitive to the external conditions, using the same single-use bioreactor bags is the only way to guarantee reproducibility between the two teams. Cells are very sensitive to the chemical environment (bioreactor material) and to the physical environment (hydrodynamic constraints created by the bioreactor geometry and design). Since it is impossible to predict the impact of these changes on the outcome of the cell culture process, the NRC will need to use the same equipment in both teams to eliminate these risks to a minimum.

8. Government Contracts Regulations Exception(s)

The following exception(s) to the *Government Contracts Regulations* is *(are)* invoked for this procurement under subsection (d) - "only one person is capable of performing the work".

9. Exclusions and/or Limited Tendering Reasons

The following exclusion(s) and/or limited tendering reasons are invoked under the:

a. Canadian Free Trade Agreement (CFTA) – Article 513 (1) (b) (iii): due to an absence of competition for technical reasons;
b. World Trade Organization - Agreement on Government Procurement (WTO-AGP) – Article XIII (b) (iii): due to an absence of competition for technical reasons;

c. Canada-European Union Comprehensive Economic and Trade Agreement (CETA) – Article 19.12 (b) (iii): due to an absence of competition for technical reasons;
d. Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) – Article 15.10 (2) (b) (iii): due to an absence of competition for technical reasons;
e. Canada-Chile Free Trade Agreement (CCFTA) – Article Kbis-16 (2) (c): necessary to protect intellectual property;
f. Canada-Colombia Free Trade Agreement – Article 1409 (1) (b) (iii): due to an absence of competition for technical reasons;
g. Canada-Honduras Free Trade Agreement – Article 17.11 (2) (b) (iii): due to an absence of competition for technical reasons;
h. Canada-Korea Free Trade Agreement – referencing the WTO Protocol Amending the GPA, Article XIII (1) (b) (iii): due to an absence of competition for technical reasons;
i. Canada-Panama Free Trade Agreement – Article 16.10 (1) (b) (iii): because of the absence of competition for technical reasons;
j. Canada-Peru Free Trade Agreement (CPFTA) –Article 1409 (1) (b) (iii): due to an absence of competition for technical reasons;
k. Canada-Ukraine Free Trade Agreement (CUFTA) – Annex 10-6 (2) (a): any form of preference, including set asides, to benefit micro, small and medium enterprises; and
l. Canada-United Kingdom Trade Continuity Agreement: refer to CETA as the provisions of CETA are incorporated by reference into and made part of this Agreement. (CETA) Article 19.12 (b) (iii).

10. Ownership of Intellectual Property

Not Applicable

11. Period of the proposed contract or delivery date

NRC is expecting the equipment to be delivered within the month of April 2024, based on the date of the contract.

12. Name and address of the pre-identified supplier

Global Life Sciences Solutions Canada ULC
250 Howe Street, Suite 1400-C
Vancouver, BC
V6C 3S7

13. Suppliers' right to submit a statement of capabilities

Suppliers who consider themselves fully qualified and available to provide the

goods, services or construction services described in the ACAN may submit a statement of capabilities in writing to the contact person identified in this notice on or before the closing date of this notice. The statement of capabilities must clearly demonstrate how the supplier meets the advertised requirements.

14. Closing date for a submission of a statement of capabilities

The closing date and time for accepting statements of capabilities is December 15, 2023 at 2:00PM EST.

15. Inquiries and submission of statements of capabilities

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Organization: National Research Council Canada

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