Advance Contract Award Notice (ACAN)

23-58197

Bench-top, single-use chromatography system and 140-200mm ID columns

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 a bench-top chromatography system (equivalent: AKTA Pilot 600s™), a single-use Chromatography system (equivalent: AKTA ready gradient™), and four new chromatography columns (equivalent: AxiChrom™): two 140mm and two 200mm internal diameter (ID).

HHT requires the chromatography systems and columns to increase the downstream purification capacity and for the development of purification process of recombinant proteins, viruses, virus like particles expressed in various production platforms like microbial, mammalian, and insect cell expression systems.

The chromatography systems require an automated unattended purification process using multiple outlets to collect different fractions to achieve highest purity while the columns require intelligent packing which enables the automated column packing with existing chromatography systems.

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 product/equipment/system (as appropriate) meets the following requirements:

Minimum requirements for the bench top Chromatography System:

3.1 Be of modular design and must ensures that functionality can be added or removed as per the user requirement changes.

3.2 The system must be able to operate up to 20 cm internal diameter chromatography column with column volume of up to 9L.

3.3 Must have two metering type piston pumps for buffers (equilibration, wash, elution, strip, sanitization, column packing buffer etc.) /samples (Clarified cell culture fluid, cell lysate, periplasmic extract etc.) with operating flow rate range of 0.1 to 1200ml/min.

3.4 Must be capable of running the gradient from 0% to 100%B (100% to 0%A) within flow rate of 4 to 600ml/min.

3.5 The tubing connectors must be O-rings or welding free to avoid the risk of contamination.

3.6 Must have 0 to 20 bar of operating pressure range.

3.7 Must have 12 inlets for buffers/samples selection with an option to increase it up to 15 when required.

3.8 Must have 9 outlets to be able to collect the purified product (Monoclonal antibody, peptide, enzyme, virus, Virus like particles etc.) in different fractions to achieve better purity and maximum recovery with an option to increase it up to 15 when required.

3.9 Must have a column valve with capacity to connect 2 columns and run them in Up-flow, down flow, serial and by-pass mode.

3.10 The column valve must have integrated pre and post column pressure sensors to be able to monitor column pressures and able to calculate differential pressure across the column (delta P).

3.11 Column valve must have a dedicated port for Intelligent column packing of columns like Axichrome and IndEx.

3.12 Must have multi-wavelength UV detector (190 to 700 nanometer), monitor minimum three simultaneous wavelength and must use the Xenon flash lamp (does not generate heat).

3.13 Must have pH valve with integrated pH electrode with a pH reading range of 1-14.

3.14 Must have a conductivity monitor with integrated temperature sensor to correct the variation in conductivity due to temperature variations with reading range of 0.01-999 mS/cm.

3.15 Include all required software to operate the systems and compatible with Windows 10 or higher.

3.16 The software must have the programmed phases that can be quickly drag and drop create a purification method for automated runs in daily operations.

Minimum requirements for the single-use Chromatography System:

3.17 Be a single use liquid chromatography hardware and must operate with ready to use, disposable flow paths.

3.18 The system must be able to operate up to 45 cm internal diameter chromatography column with column volume of up to 50L.

3.19 Must have two pumps for buffer (equilibration, wash, elution, strip, sanitization, column packing buffer etc.) /samples (Clarified cell culture fluid, cell lysate, periplasmic extract etc.) pumping on to the column with operating flow rate range from 3 L/hour to 510 L/hour.

3.20 Must have at least 4 bar of operating pressure capacity.

3.21 The single use flow kit must have the following sensors,

- 3.21.1 Flowmeter with capacity of up to 510 L/hours with an accuracy of ± 5% actual value at flow ≥ 40 L/hour and ± 10% actual value at flow ≤ 40 L/hour.
- 3.21.2 Pressure sensor with a range of 0-5 bar with accuracy of ± 0.02 bar.
- 3.21.3 Conductivity sensor with a range of 0-150 mS/cm with an accuracy of ± 5% full scale.
- 3.21.4 Temperature sensor with a range of 2 ^{0}C to 40 ^{0}C with an accuracy of ± 3 ^{0}C.
- 3.21.5 UV sensor with a range of 0.01 – 1.0 Absorbance Unit (AU) with AU linearity of ± 5%.
- 3.21.6 pH sensor with a range of pH 2-12 with an accuracy of ± 0.2.

3.22 The flow kit must have 6 inlets for buffers/samples and one inlet for running the system in gradient mode.

3.23 The flow kit must have 6 outlets to be able to collect the product in different fraction to achieve maximum recovery and purity.

3.24 The flow kit must have an air trap to prevent the air being pumped on to the column.

3.25 Include all required software to operate the systems and compatible with Windows 10 or higher.

Chromatography columns must have the following specification;

3.26 The Chromatography columns must have Specification mentioned in the table below;

Column	1	2
Internal Diameter (mm)	140	200
Minimum Bed height (mm)	100	100
Maximum bed height (mm)	300	300
Minimum Bed Volume (L)	1.54	3.14
Maximum Bed Volume (L)	4.62	9.42
Packing Pressure (bar)	8	6
Operating Pressure (bar)	6	5

3.27 The column tubes must be made of Borosilicate glass.

3.28 The adapter movement must be by hydraulic pressure.

3.29 The columns must support automated packing methods of our existing chromatography systems. (Intelligent packing).

3.30 The columns must have mechanical lock to keep the adapter at set bed height.

3.31 The columns must have rotating pivot stand for easy emptying, safer operation, and convenient access to bed supports and O-rings

3.32 The columns must be able to operate with temperature range of 2 – 30 ^{o}C

3.33 The columns must have 20µm stainless steel bed support.

The interested supplier must guarantee delivery of product instructions/guides, installation, on-site training, and initial testing of the chromatography systems and columns and be fully compatible with the existing Cytiva systems.

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* (CCOFTA)
- *Canada-Honduras Free Trade Agreement* (CHFTA)
- *Canada-Korea Free Trade Agreement* (CKFTA)
- *Canada-Panama Free Trade Agreement* (CPAFTA)
- *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

The pre-identified supplier is Global Life Sciences Solutions. Due to commonality and compatibility with existing equipment, the preidentified supplier, Global Life Sciences Solutions Canada ULC, is the only one able to distribute Cytiva equipment in Canada.

NRC' s HHT research center already owns multiple ÄKTA chromatography systems and different size AxiChrom chromatography columns. The system to be purchased must also be an ÄKTA for reason of interoperability with existing systems and software. The AKTA Pilot 600s, AKTA Ready Gradient and Chromatography columns manufactured by Cytiva meet all the requirements and are fully compatible with existing systems and will integrate seamlessly into our production-like environment, thus allowing for repeatability of

processes, column packing processes and commonality of the Operating System (O/S), parts and hardware configurations, interchangeability and data transfer.

HHT develops the purification process/technology and transfers them to Contract Manufacturing Organizations (CMO) for GMP productions. Biologics Manufacturing Center (BMC) and Clinical Trial Manufacturing Facility (CTMF) will act as future CMOs and they have exact same chromatography system (AKTA ready gradient) so by having the same system in both R&D team and NRC manufacturing team (CTMF) make purification process transfer seamless and reduces the risk of process failure at manufacturing scale.

Cytiva is also the owner of the UnicornTM software. The UnicornTM software allows users to design chromatography steps based on parameters defined by the user and to automatically create methods and execute them with the system. The software has the programmed phases that can be quickly drag and drop to create a purification method for automated runs in daily operations. The software also enables programming with flow velocity in column volumes per hour (CV/h) and normalization of UV signal. This possibility makes scaling and transfer of methods as well as data comparison easier.

AxiChrom chromatography columns supports the intelligent packing which enables the automated column packing by using predefined packing parameters with existing chromatography systems. The ability to reproduce the column packing at manufacturing scale is critical to achieve the product quality that matches the product release criteria and AxiChrom columns by packed with predefined intelligent packing methods are capable to reproduced the desired column packing.

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

Cytiva is the manufacturer (OEM) of the proposed systems and products and owns the associated intellectual property (IP).

The Crown will have software right of use and own IP generated through NRC's research using the equipment.

11. Period of the proposed contract or delivery date

NRC expects the equipment to be delivered within the month of March 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 January 3, 2024 at 2:00PM EST.

15. Inquiries and submission of statements of capabilities

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