

NOTICE TO THE PUBLIC

HPLC Post-Column Derivatization Instrument, (FDA-1257523)

This is a combined synopsis/solicitation for commercial items prepared in accordance with the format in FAR 12.6. This announcement constitutes the only solicitation, and a written solicitation will not be issued.

This requirement is "Subject to the Availability of Funds" The Following FAR Clause applies: AVAILABILITY OF FUNDS (52.232-18) (APR 1984)

This synopsis, NAICS code 334516, identified as REQ#1257523 is to notify contractors that the government intends to issue a Purchase Order in accordance with FAR Part 13.106 for the following specifications, under the simplified acquisition procedures.

Background

The FDA (Food and Drug Administration), Northeast Food and Feed Laboratory (NFFL), Chemistry laboratory analyzes a wide variety of regulatory samples across numerous program areas. Additionally, the laboratory often requires the development and verification of methodology to detect contaminants in a wide variety of regulated commodities. NFFL is seeking to bring the AOAC paralytic shellfish poisoning method online, which requires this piece of equipment.

Purpose

The post-column reactor will be used to bring the AOAC/ISSC PSP method online.

Scope

NFFL requires services only from an Equipment Manufacturer trained technician capable of providing new equipment and installation of this system.

The contractor shall provide the requirements described in this Statement of Work (SOW).

1. Minimum Performance Requirements

1. The purchase includes the instrument
2. Shall have the approximate dimensions: depth: 42 cm; height 45 cm; width: 22 cm
3. Shall have a heater reactor that controls at $\pm 0.4^{\circ}\text{C}$ from 10°C above ambient to 130°C
4. Shall have a reaction coil can withstand 600 psi

5. Shall have a reagent pump adjustable from 0.05 mL to 2.00 mL/minute
6. Shall have a flow accuracy ~3%
7. Shall have a flow precision ~0.5%
8. Shall have an approximate weight: 11.5 kg
9. Shall have an one liter capacity pressurized reagent reservoir is standard.
10. Shall uses inert gas to maintain inert conditions
11. Shall have a post-column reactor can work on all

HPLC systems Trade and Service Specifications

1. The instrument must be a newly manufactured unit, not used and refurbished or previously used for demonstration.
2. FOB Point destination to include inside delivery and clean-up of area after installation.
3. The entire system must be warranted for parts and labor for 12 months from the date of formal government acceptance. The vendor must also be capable of servicing the instrument through the covered warranty period. The system must include at least a one (1) year warranty and shall include at a minimum: coverage on all non-consumable items and parts supplied including base instrument, factory- certified replacement parts, engineer labor and travel costs. Any equipment repair and maintenance work shall be performed by an OEM-trained engineer. This factory-trained engineer shall have (verified by the OEM) the following: 1) access to OEM factory telephone support; 2) access to the most current OEM factory training for both hardware and software components; and 3) access to all current OEM factory parts, not build-to-order parts. The OEM-trained service engineer shall not use salvaged parts from other instruments for performing maintenance and repairs. All parts used in PM and repairs must be guaranteed, factory-tested, OEM quality parts.
4. Instrument operators shall have access to a technical representative call center at no additional charge, for technical assistance and troubleshooting, which is staffed by senior engineers to provide a high level of expertise for troubleshooting the instrument.
5. Any necessary Preventative maintenance (PM) or Repair Services shall be included during the warranty period. This visit shall be inclusive of all parts, labors, travel, consumables, and supplies which are necessary to complete the OEM's suggested PM protocol. Service engineers which perform this service shall be trained by the OEM.
6. Sufficient familiarization training for 3-5 users per delivery onsite location will be provided at time of installation or shortly thereafter (within 30 days), such that operators may independently operate the instrument and with increased familiarity and proficiency. The training shall include manuals and any consumables to be used

- during training.
7. The Contractor shall provide installation qualification with an employee who can provide proof of installation qualification/Operation qualification (IQ/OQ)

Records and Reports

The Contractor shall, commensurate with the completion of each service call (inclusive of warranty service), provide the end-user of the equipment with a copy of a field service report/ticket identifying the equipment name, manufacturer, model number, and serial number of the equipment being serviced/repaired and detailing the reason for the service call, a detailed description of the work performed, the test instruments or other equipment used to affect the repair or otherwise perform the service, the name(s) and contact information of the technician who performed the repair/service, and for information purposes, the on-site hours expended and parts/components replaced. In addition, the Contractor shall provide monthly reports to the FDA PROJECT OFFICER and Contract Specialist, not later than the 5th workday following the end of each month, summarizing all maintenance and repair activities (including warranty work) for the previous month (during months that work is performed).

Deliverables

Table 1. Deliverables / Schedule

HPLC Post Column Derivation System	1	Not later than September 1, 2022

Place of Performance/Shipping Destinations

Food and Drug Administration,
 Northeast Regional Laboratory
 158-15 Liberty Avenue
 Jamaica, NY 11433-1034

The delivery or services must be during regular business hours (Monday – Friday) during the times of 8:00 AM – 4:00 PM Eastern Time, excluding holidays.

Period of Performance

The Anticipated Period of Performance:
September 1, 2022 – August 31, 2023

Inspection and Acceptance

The COR and/or COR designee will perform inspection and acceptance of equipment.

A final inspection and acceptance of all deliverables will be performed by the COR and/or COR designee to ensure the products provided meet the requirements of the Statement of Work (SOW).

Inspection and acceptance will occur at the place of performance and take place within five (5) business days of task being completed. The Government will provide written notification of acceptance or rejection within five (5) business days. Inspection will include review of the deliverables to ensure adequacy.

The Government will accept goods, reports, and services only if they conform to all terms and conditions of the SOW, and satisfy the performance standards developed under this SOW.

The Government will reject non-conforming products and services. The Contractor shall correct any deficiencies within fifteen (15) business days of when the Government issues the rejection notice. If the Contractor cannot correct the deficiencies within this period, the Contractor shall immediately notify the COR of the reason for the delay and provide a proposed corrective action plan within five business days.

Contracting Officer Authority

The Contracting Officer (CO) is the sole person authorized to make or approve any changes in any of the requirements of this order and notwithstanding any provisions contained elsewhere in the order, the said authority remains solely with the CO. In the event the Contractor makes any changes at the direction of any person other than the CO, the change shall be considered to have been made without authority and no adjustment will be made in the delivery order terms and conditions, including price. The CO shall be the only individual authorized to accept nonconforming work, waive any requirement of the order and modify any term or condition of the order. The CO is the only individual who can legally obligate Government funds.

The Contracting Officer's Representative (COR) or Project Officer is not authorized to make any commitments or otherwise obligate the Government or authorize any changes which affect the order price, terms or conditions. The COR/Project Officer is responsible for the technical aspects of the project and serves as technical liaison with the contractor and is responsible for the final inspection and acceptance, and such other responsibilities as may be specified in the order.

Contract Type

Firm-Fixed-Price (FFP). All deliverables shall be clearly identified, complete with clear descriptions; due dates, and at a predetermined, agreed-upon price.

Government Contacts

Contracting Officer: (CO):

Office of Acquisitions Grants and Services

Mary Rose A. Nicol, CO

Phone: 240-402-7606

Email: Maryrose.nicol@fda.hhs.gov

Contracting Office Representative (COR): TBD

Government Holidays

Unless otherwise specified, the Contractor shall perform work Monday through Friday (excluding Federal Holidays) between the hours of 8:00 a.m. and 4:30 p.m. EST. Supplies or services scheduled for delivery on a Federal holiday shall be made the next business day. Workplace is not available on the Government Holidays stated below, or as prescribed by an Executive Order (EO) due to inclement weather.

- New Year's Day
- Martin Luther King Day
- President's Day
- Memorial Day
- Juneteenth National Independence Day
- Independence Day
- Labor Day
- Columbus Day
- Veteran 's Day
- Thanksgiving Day
- Christmas Day

Pricing

Total Price \$_____

Basis of Award

The Government will award a contract resulting from this solicitation to the responsible quoter as a fixed-price contract on the lowest price technically acceptable (LPTA) evaluation method. Award will be made on the basis of the lowest evaluated price

meeting or exceeding the non-cost factor (technical conformance to the requirements of the solicitation). The Quoter's initial quotation shall contain the Quoter's best terms from a price standpoint. Failure to demonstrate meeting any of the requirements will result in a rating of technically unacceptable and will not be considered for award.

In order to facilitate the award process, ALL quotes shall include a statement regarding the terms and conditions herein. Additionally, all quotes shall include price (s); FOB point; a POC (name and telephone number); a statement from the offeror verifying that they are Registered in SAM.gov under NAICS code; 334516_delivery date (delivery date is of the utmost importance); business size; and payment terms. Delivery shall be to FDA.

FDA intends to make an award soon after the response date of this notice and all quotes must be submitted via email to Maryrose.nicol@fdahhs.gov and be received by 5:00 PM (1700) on August 4 , 2022 to the attention of Mary Rose A. Nicol, maryrose.nicol@fda.hhs.gov. Offerors shall ensure the RFQ number is visible in the header of the email.

ALL QUESTIONS REGARDING THIS SYNOPSIS/SOLICIATION MUST BE SUBMITTED IN WRITING NO LATER THAN 5:00 PM (1700) EST August 1, 2022. FAX QUOTES SHALL NOT BE ACCEPTED.