NOTICE TO THE PUBLIC

UV/PDA Detector

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#114000 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 Northeast Medical Products Laboratory (NMPL) performs regulatory methods that utilize Mass Spectrometer (MS) to confirm the identity of active ingredients and impurities. It is often necessary to quantitate the ingredients by Ultraviolet (UV) detection for improved precision. Acquisition of UV data on using a Photodiode Array Detector (PDA) provides additional advantages. It allows the selection of the optimum wavelength for UV detection. For products with multiple ingredients and different optimum wavelengths, the PDA can be configured to simultaneously collect data at multiple wavelengths. The PDA also allows acquisition of UV spectra which can be compared to the reference standard to further confirm the identity of the active ingredients and impurities. NMPL does not have a PDA detector connected in line with the HPLC/MS used in analysis of regulatory samples. NMPL seeks to procure a PDA detector compatible with an existing HPLC to expand its capability to perform regulatory methods requiring concurrent UV and MS detection.

Objective

The Northeast Medical Products Laboratory (NMPL) needs an Ultraviolet/Photodiode Array Detector (UV/PDA) connected in line with an existing LC/MS system. Addition of the UV/PDA will expand the capability of the equipment to allow simultaneous acquisition of Mass Spectra data and Ultraviolet spectra. This will allow for more accurate compound confirmation and when quantitation is required, it can be performed by UV which can provide a high level of precision. The addition of a UV/PDA detector will allow the laboratory to perform regulatory analytical methods requiring compound confirmation by MS and quantitation by UV.

Scope

The Contractor shall provide all resources necessary to accomplish the tasks and deliverables described in this Statement of Work (SOW). The Contractor shall provide a Photodiode Array Detector compatible with an existing Ultimate 3000 Binary Analytical Liquid Chromatography system to the Northeast Medical Products Laboratory.

REQUIREMENTS

MINIMUM SALIENT CHARACTERISTICS

All the following are minimum requirements:

- Shall be compatible with an existing Liquid Chromatography (LC) system connected to Mass Spectrometer
- Shall be capable of acquiring 3-D full spectral data in the UV-Visible region of 190 – 800 nm
- Shall have the capability of extraction of up to 8 channels of single wavelength data from 3-D data
- Shall be capable of data acquisition speed of up to 200 Hz
- Shall have a wide linear range up to 2.0Au
- Shall be equipped with built in holmium oxide filter for performing wavelength verification and self-calibration.
- Shall be capable of spectral resolution of 1nm
- Shall be capable of noise of less than 10 µAu and drift rate less than 500 µAu/h
- Shall be equipped with a flow cell compatible with conventional HPLC and Ultra High-Pressure Liquid Chromatography (UHPLC) analytical applications
- Shall be 21 CFR Part 11 compliant
- Shall have a minimum of one-year warranty

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 trouble-shooting, 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 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 that the 5th work day 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

Ultraviolet/PDA Detector	1	Not later than September 30, 2022
Familiarization Training	1	Within two weeks after Government acceptance of instrument
Service Reports	Varies	Not later that the 5th work day following the end of each month, (during any months during which

		warranty work is performed)

Shipping Destination

POC: To Be Identified at time of award
Food and Drug Administration,
Northeast Medical Products 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, excluding holidays.

Period of Performance

The period of performance begins the date of contract award execution.

The anticipated Period of Performance is as follows:

Base Period: September 1, 2022 – August 31, 2023

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
Michael Gemmill
Email: Michael.Gemmill@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.

January (New Year's Day)
January (Martin Luther King Day)
February (President's Day)
May (Memorial Day)
June (Juneteenth)
July (Independence Day)
September (Labor Day)
October (Columbus Day)
November (Veterans Day)
November (Thanksgiving Day)
December (Christmas Day

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 Michael.Gemmill@fda.hhs.gov and be received by 5:00 PM (1700) on , August 4,2022 to the attention of Michael Gemmill. 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) on , August 4,2022. FAX QUOTES SHALL NOT BE ACCEPTED.