STATEMENT OF WORK

Ion Source to Interface Nanoflow LC and High- Resolution MS for the Food and Drug Administration, (FDA-1254843)

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#1254703 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 Animal, Drug Research Center has successfully developed and applied a wide-scope screening method for veterinary drugs and other contaminants using the Q-Exactive High Field (HF) Orbitrap instruments. This method development work is in support of the Chemotherapeutics in Aquaculture Program (PAC 04018). Several LIBs and peer reviewed papers have been published. We have started to investigate coupling the HRMS to nanoflow LC. The use of this type of LC system with Q-Exactive HF HRMS for veterinary drug and pesticide residue analyses has been described in the literature. The primary advantage of using nanoflow LC is more sensitive analyte detection. This allows for faster sample cleanup (dilution of extract) and less matrix effects.

As part of FMD81 process in FY2019, the nanoflow LC and a "Nanoflex" ion source were purchased. Although initial work was promising (showing significant increases in MS sensitivity), there were problems maintaining a stable MS spray and tight connections with nanoflow LC columns. These issues hindered progress on the project and did not seem promising for future use in a regulatory laboratory. In addition, some consumable parts for the Nanoflex source have been unavailable. There has recently put more effort into improving options for more rugged ion sources including the Thermo "EasySpray". This source is designed to be more amenable to production laboratories with more easily exchangeable nanoflow LC columns and matching spray needles.

This request is for a Thermo EasySpray ion source to effectively interface the Q-Exactive High Resolution MS and nanoflow LC systems already in our laboratory.

Objective

To purchase a rugged electrospray source to interface high resolution mass spectrometer to nanoflow liquid chromatograph

Scope

Thermo EasySpray Ion Source Kit

System Requirements

The Contractor shall provide instrumentation with identical technical specifications and functional features as the Thermo EasySpray Ion Kit. Services shall include delivery of the instrumentation to the laboratories as specified, as well as on-site installation instruction, familiarization, and standard equipment warranties.

Technical Specifications for Ion Source

- Ion source must be compatible with instrumenation already in use including
  - Thermo Q-Exactive High Field High Resolution Mass Spectrometer
  - Thermo EASY n1200 Nanoflow liquid chromatograph
- Ion source must be capable of interfacing with nanoflow columns (50-75 µm ID)with integrated spray tips using finger-tight connections up to 1000 bar
- Variable column positioning options with camera to view spray stability
- Column temperature control (30-60 °C in 5 °C increments) with display

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. Sufficient familiarization training 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.

Records and Reports

The Contractor shall, commensurate with the completion of each service call relating to the first year warranty, provide the end-user of the equipment with a copy of the field corrective service report identifying the equipment name, manufacturer, model number, and serial number of the equipment being repaired and detailing the reason for the warranty call, a detailed description of the work performed. The parts and the test equipment used to repair the system shall be on the report. This will include the name (s) and contact information of the engineer who performed the repair, and for information purposes, the on-site hours expended, and parts/components replaced.

Section 508 Compliance

The Contractor shall be familiar with Section 508 requirements as described at http://www.section508.gov/ in order to ensure that documents generated as part of the tasks are fully Section 508-accessible using the available COTS tools. Each order will identify the standards applicable to that order.

Deliverables

Deliverable	Quantity	Delivery Date
Easy Spray Ion Source Kit	1	ASAP after Purchase Order
Familiarization of the new main features, operation, and basic maintenance.	1	Upon completion of the initial Qualification
Corrective action to fix the system under any failures during warranty	1	After occurrence and request due to a fault.

Shipping Destinations:

Food and Drug Administration – POC Sherri Turnipseed
Denver Federal Center
6th and Kipling
Building 20 Entrance W10
Denver, CO 80225

Period of Performance:

The period of performance shall be 12- month from the date of award which includes a 12-month warranty period.

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.

10. 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.

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 Maryrose.nicol@fdahhs.gov and be received by 5:00 PM (1700) on , July 7, 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 July 5, 2022. FAX QUOTES SHALL NOT BE ACCEPTED.