NOTICE TO THE PUBLIC

Gas Chromatography Mass Spectrometry (GCMS) and GCMS with Headspace Sampler, (FDA-1255269)

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#1255269 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 Food and Drug Administration (FDA) field laboratories perform analyses requiring the use of GCMS and GCMS with headspace Sampler. The methodology used by the Agency for the determination of impurities in hand sanitizer samples collected as a response to the COVID-19 pandemic requires use of GCMS technology. As the Agency continues to monitor the quality of hand sanitizers and other products, the laboratories require the use of GCMS for detection and confirmation of known and unknown impurities. For many types of samples, the GCMS needs to be equipped with a Headspace sampler. Having a GCMS equipped with a Headspace Sampler allows the lab to perform pharmaceutical residual solvents analysis of Active Pharmaceutical Ingredients (API) and drug products.

Purpose

The FDA PHARMA laboratories need to acquire GCMS and GCMS equipped with Headspace Sampler in order to have the capability of analyzing drug samples requiring GCMS methods of analysis. For the detection and confirmation of known and unknown impurities in hand sanitizers and other regulatory samples, it is imperative that the FDA Pharma Laboratories are equipped with GCMS instrumentation.

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) a GCMS system to the San Juan Laboratory (SJN), and
(b) a GCMS configured with a Headspace Sampler to the Northeast Medical Products Laboratory (NMPL),

I. Requirements:

Minimum Technical Requirements**:**

GCMS

- GC shall be equipped with Flame Ionizing Detector (FID) optimized for capillary columns
- Split/splitless GC inlet shall be capable of electronic control of carrier gas pressure, flow, and velocity. Inlet shall have pressure capability of up to 100 psi
- The Mass Selective Detector (MSD) shall be equipped with an inert Electron Impact (EI) source and self-cleaning jet
- The MSD shall be capable of a mass range of 2 to 1050 m/z (mass/charge)
- The MSD shall be capable of scan speed of greater than 20,000 Da/s and sensitivity of greater than or equal to 10 femtograms (fg)
- The system shall have a connected liquid autoinjector with a choice of injection modes to match sample volume and viscosity
- The autoinjector sample tray shall have a minimum capacity of 100 vials
- The system shall be equipped with the latest NIST MS Library
- The system shall be equipped with software that allow for qualitative and quantitative analyses.

GCMS with Headspace Sampler

- GC shall be equipped with Flame Ionizing Detector (FID) optimized for capillary columns
- Split/splitless GC inlet shall be capable of electronic control of carrier gas pressure, flow, and velocity. Inlet shall have pressure capability of up to 100 psi
- The Mass Selective Detector (MSD) shall be equipped with an inert Electron Impact (EI) source and self-cleaning jet
- The MSD shall be capable of a mass range of 2 to 1050 m/z (mass/charge)
- The MSD shall be capable of scan speed of greater than 20,000 Da/s and sensitivity of greater than or equal to 10 femtograms (fg)
- The system shall have a connected liquid autoinjector with a choice of injection modes to match sample volume and viscosity
- The autoinjector sample tray shall have a minimum capacity of 100 vials
- The system shall be equipped with the latest NIST MS Library
- The system shall be equipped with software that allow for qualitative and quantitative analyses.
- **The Headspace Sampler** shall be integrated with the GC to allow a single interface for control of both components.
- The Headspace Sampler shall be capable of electronic control of carrier gas pressure, flow and velocity.
- The Headspace Sampler shall be capable of performing leak test on individual vials during vial pressurization to ensure vials are properly capped.
- The Headspace Sampler shall be able to accommodate different vial sizes in the same run.
- The Headspace Sampler shall have a minimum capacity of 40 vials.
- The Headspace Sampler shall be equipped with a 1 mL sample loop.

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 one-year 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

GCMS and GCMS with Headspace Sampler	1 each	Not later than August 1, 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
1) For GCMS
Donna LaGarde
Food and Drug Administration,
466 Ave Fernandez Juncos
San Juan, PR 0901-3225

Puerto Rico

2) For GCMS with Headspace Sampler
Phyllis Wilson
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: 08/1/2022 – 07/31/2023, which includes a 1-year 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.

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 20, 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 18, 2022. FAX QUOTES SHALL NOT BE ACCEPTED.