

NOTICE TO THE PUBLIC

Nitrogen Generator with Compressor for DART-TD-MS

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#113601 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 Forensic Chemistry Center in The Office of Regulatory Affairs/Office of Regulatory Science/Medical Products, Tobacco and Specialty Labs (ORA/ORS/OMPTSLO) requires the purchase of a nitrogen generator with compressor in support of the FDA’s proposed increased package inspections for opioid products, drugs, and other FDA regulated products at International Mail Facilities (IMFs) and Express Courier Hubs (ECHs). This generator will be utilized to provide high purity nitrogen to the DART-TD-QDa mass spectrometer instrument at the satellite laboratory that will be stationed at the Miami IMF. The generator will prevent the need to purchase nitrogen gas cylinders.

Objective

The Forensic Chemistry Center (FCC) has developed a “toolkit” of analytical instruments capable of rapidly screening both bulk substances and solid dosage forms for active pharmaceutical ingredients (APIs), including opioids. A mass spectrometer instrument (DART-TD-QDa) is currently deployed at the Chicago IMF mobile laboratory and is being used to screen incoming parcels that contain unapproved products with potentially dangerous APIs. The DART-TD-QDa instrument requires ultra-high purity nitrogen for operation, and it utilizes a nitrogen generator. A second satellite laboratory is being installed at the Miami IMF and the same instrumentation is required for continuous and seamless operations among all the satellite laboratories.

Scope

The Forensic Chemistry Center (ORA/ORS/MPTSLO/FCC) requires the purchase of one nitrogen generator system with an integrated compressor. The system must meet or exceed the following requirements:

REQUIREMENTS

MINIMUM SALIENT CHARACTERISTICS

All the following are minimum requirements:

- The system shall be completely self-contained, requiring no external source of compressed air.
- The system shall be able to operate using a standard 110V electrical outlet.
- The system shall include an integrated air compressor.
- The system shall be capable of providing ultra-high purity nitrogen at flow rates up to 3 L/min
- The system shall utilize molecular sieve purification capable of self-regeneration.
- The system shall provide nitrogen at a purity of 99.9995%.
- The system shall be able to be installed as a free-standing unit, with a footprint no larger than 17 inches x 17 inches and a standing height no larger than 50 inches.
- The system shall be capable of a max outlet pressure of 80 psi.
- The system shall weigh less than 200 lbs.
- The system shall be capable of providing nitrogen gas on-demand.

Trade and Service Specifications

- The instrument shall be delivered with all necessary supplies and accessories required for installation and start-up.
- The instrument shall be a newly manufactured unit, not used and refurbished or previously used for demonstration.
- The instrument shall include at least a one (1) year warranty on the entire instrument, except for maintenance parts, operating supplies, and expendable components.

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/repared 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 COR and /or COR designee, 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).

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

<u>Deliverable</u>	<u>Quantit y</u>	<u>Delivery Date</u>
<u>Nitrogen Generator with Integrated Compressor</u>	<u>1</u>	<u>No later than 30 days after award.</u>

PLACE OF PERFORMANCE

One nitrogen generator with integrated compressor to be delivered to:

FDA Office
11698 NW25th Street
Miami, FL USA 33172
POC: To be determined

PERIOD OF PERFORMANCE

The Period of Performance begins the date of contract award execution and continues for one year (or longer depending on how long the OEM offered warranty period is) from the date of formal government acceptance. Instrument to be delivered no later than 30 days after contract award.

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.