

NOTICE TO THE PUBLIC

Two (2) water polishing systems for The Forensic Chemistry Center in The Office of Regulatory Affairs/Office of Regulatory Science/Medical Products, Food and Drug Administration, (FDA-1257413)

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#1257125 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 water polishing system for the FCC to support FDA’s proposed increased inspections for opioid products, drugs, and other FDA regulated products collected at International Mail Facilities (IMFs) and Express Courier Hubs (ECHs). This water polishing system will be utilized to provide purified water for use in varying sample analyses and with instrumentation deployed in the opioid and IMF labs. The water polishing system will prevent microbial contaminants and reduce particulates coming from the distilled water source.

Objective

The Forensic Chemistry Center (FCC) requires two (2) direct water polishing systems, each capable of delivering 2 L/minute of purified water with a resistivity $\geq 18 \text{ M}\Omega$ and a Total Organic Carbon (TOC) of $\leq 5 \text{ ppb}$ from a pre-treated feed water supply. The required systems include an on-line UV treatment to reduce microbial contamination and a 0.22-micron filter to reduce particulates. Additionally, the systems provide remote volumetric dispensing control. The required systems will be installed in the new IMF and opioid labs deployed at the FCC to maintain purified water for continuous sample analyses and operations.

Scope

The Forensic Chemistry Center (ORA/ORS/MPTSLO/FCC) requires the purchase of two water polishing systems. The system must meet or exceed the following requirements.

REQUIREMENTS

MINIMUM SALIENT CHARACTERISTICS

All the following are minimum requirements:

- The system shall be capable of supplying water to meet ASTM Type I specifications.
- The system shall be capable of supplying water with a resistivity $\geq 18 \text{ M}\Omega$.
- The system shall be capable of supplying water with a total organic carbon content (TOC) $\leq 5 \text{ ppb}$.
- The system shall be capable of supplying water with a particulate load of < 1 particulate ($> 22 \text{ micron}$)/mL.
- The system shall be capable of supplying water meeting the preceding requirements at a rate of 2 L/minute .
- The system shall have connections to feed into the pre-treated feed water supply.
- The system shall include a feed water pressure regulator.
- The system shall include both ion-exchange and organic-scavenging resins.
- The system shall include a UV treatment for the photo-oxidative reduction of TOC contaminants.
- The system shall monitor the resistivity of the product water.
- The system shall monitor TOC of the product water.
- The system shall display an alert/notification when resistivity and/or TOC values fall below acceptable limits.
- The system shall include a particle filtration step to eliminate particulates $\geq 0.22 \text{ microns}$.
- The system shall include volumetric dispensing control.
- The system base unit must have a footprint of $\leq 400 \text{ mm}$ wide and deep and a height $\leq 600 \text{ mm}$.
- The remote dispensing unit must have a footprint of $\leq 300 \text{ mm}$ (on a side) and be capable of being located up to 2.9 m from the base unit and include a recirculation loop.
- The remote dispensing unit must include a graphic display (including current resistivity and TOC measurements).
- The system must operate on standard 110 V current at $50\text{-}60 \text{ Hz}$.

Trade and Service Specifications

- The system shall be delivered with all necessary supplies and accessories required for installation and start-up.
- The system shall be a newly manufactured unit, not used and refurbished or previously used for demonstration.
- The delivered systems should include one set of hard copy installation and service manuals; and preloaded firmware required to operate and control the water purification system.

- The system shall include at least a one (1) year warranty on the entire system, except for maintenance parts, operating supplies, and expendable components.

Records and Reports

The Contractor shall, at the completion of each service call or maintenance repair (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, description of the work performed, the parts cleaned and/or replaced, the results of the instrument related tests to confirm its operation status, 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.

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
Water Polishing System	2	No later than 30 days after award.

PLACE OF PERFORMANCE

Two (2) water polishing systems to be delivered to and located at the following laboratory:

- 1) Forensic Chemistry Center
 U.S Food and Drug Administration
 6751 Steger Drive
 Cincinnati, OH 45237
 POC: Renee Easter
 (513) 679-2700 Ext. 2302
 Renee.easter@fda.hhs.gov

PERIOD OF PERFORMANCE

The Period of Performance begins the date of contract award execution and continues for one with a 12-month warranty period) from the date of formal government acceptance. The System 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

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 29, 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 26, 2022. FAX QUOTES SHALL NOT BE ACCEPTED.

