

Request for Quotation: FDA_ 1257087

Posted Date: August 23, 2022

Response Date: August 30, 2022, 10:00 a.m. Eastern Time.

Interested parties may identify in writing their interest and capability to respond by no later than August 30, 2022, 10:00 a.m. Eastern Time. Please email responses to Elena Tatarov at Elena.Tatarov@fda.hhs.gov.

Indicate company's SAM.gov Unique Entity ID on the quote. The subject line shall read: *FDA_ 1257087 – Type 1 Ultrapure Water Purification System or Equal*

This announcement constitutes the only solicitation; quotes are being requested and a written solicitation will not be issued. This requirement is being issued in conjunction with FAR Part 13 Simplified Acquisition Procedures. This solicitation is issued as a Request for Quote (RFQ).

NAICS Code: 334516

Line Item Structure: The following is a contract line item number(s), quantities, and units of measure, (including option(s), if applicable):

Line Item 0001 – *Type 1 Ultrapure Water Purification System or Equal*

Background

The Pesticides group within the Kansas City Laboratory needs a benchtop point-of-use water purification system to provide high quality Type 1 ultrapure water for use in Total Diet Study sample analysis for Glyphosate and Related Residues in Food on LC-MS instruments. The use of the highest quality water possible is critical for low level glyphosate analysis. The sensitivity of this method increased approximately tenfold when the mobile phase was prepared using ultrapure water from a point of use water purification system instead of LC-MS grade bottled water.

Purpose

The water purification system shall connect to the existing DI water supply and provide Type 1 ultrapure water at the point-of-use in the laboratory.

Requirements

The contractor shall provide and install a Type 1 Ultrapure Water Purification System or Equal, a complete water purification system capable of producing and dispensing Type 1 ultrapure water at the point-of-use in the laboratory from existing DI feed water. The system shall meet or exceed the following requirements:

- The control, operation and monitoring of the system shall be integrated within a built-in graphic interface.
- Provide adjustable flow rate dispensing, volumetric dispensing, and available dispense reports.
- Include a in-line resistivity cell, with a 0.01 cm^{-1} low cell constant and a 0.1°C sensitive thermistor, to continuously monitor the resistivity value of the produced water.
- Include a built-in TOC monitor with a range of 0.5 – 999.9 and precision passing USP & EP suitability tests.

Water Specifications/Requirements:

- Resistivity at 25°C : $18.2 \text{ M}\Omega\cdot\text{cm}$
- TOC: $\leq 2 \text{ ppb}$ ($\mu\text{g/L}$)
- Particles: No particles with size $> 0.22 \mu\text{m}$
- Bacteria: $< 0.01 \text{ CFU/mL}$
- Pyrogens: $< 0.001 \text{ EU/mL}$
- Flow Rate: $0.05 - 2 \text{ L/min}$

System Specifications/Requirements (Production Unit):

- Dimensions (H x W x D): $\leq 20'' \times 12'' \times 15''$
- Operating weight: $\leq 20 \text{ kg}$
- Electrical power source voltage: 120 V
- Electrical power frequency: $50 - 60 \text{ Hz}$ at $\pm 2\text{Hz}$

The contractor shall ensure the following:

1. Provide familiarity of all the features of the new system.
2. Include system operations, calibrations, and basic preventative maintenance procedures. This shall take place upon system installation.
3. The instrument shall be a newly manufactured unit, not used and refurbished or previously used for demonstration.
4. FOB destination to include inside delivery and clean-up of area after installation.
5. The entire system shall be warranted for parts and labor for 12 months from the date of formal government acceptance.
6. 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.
7. The Government must be able to expect routine customer service and technical support to be available from the vendor during its lifecycle (assumed 10 years).

8. Instrument to be delivered no later than 60 days after issuance of deliver order.

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 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.

Deliverables:

Deliverable	Quantity	Delivery Date
Water Purification System, Type 1 Ultrapure Water or Equal that meets or exceeds minimum technical specifications.	1	Within 60 days of award
Installation including initial consumables.	1	Within 30 days of delivery
Familiarization of the main features, operation, and basic maintenance.	1	Within 30 days of delivery
Corrective action to fix the system under any failures during warranty.	1	After occurrence and request due to a fault.

Shipping:

US Food & Drug Administration
Kansas City Laboratory
10749 West 84th Terr
Lenexa KS, 66214

FOB destination

Instrument to be delivered no later than 60 days after issuance of deliver order.

Vendor shall contact Government Points of Contact (to be provided at time of award) at a minimum of 48-hours prior to arrival.

Delivery will be accepted during regular business hours (Monday-Friday) during the times of 8:00 AM – 4:00 PM Pacific Time.

Workplace is not available on the Government Holidays stated below, or as prescribed by an Executive Order (EO) due to inclement weather.

Government Holidays

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

When contractor representatives arrive on site to deliver / install equipment, they will need to provide proper U.S. photo identification to check-in with the Federal Protective Service (FPS) Security Guards in order to enter the building. The vendor representatives will receive an "Escort Required" temporary badge, which shall be worn at all times in the building and will remain escorted by lab personnel during their visit. If vendors need to enter the laboratory, safety glasses must be worn. When their work is complete, the contractor representatives will provide the lab personnel a work order or service receipt detailing the requirements of the visit. The contractor representatives will check-out with the same FPS Security Guards, turning in their temporary badge. Tobacco, of any form, and e-cigarettes are not permitted on Federal Property, in Federal Buildings or parking lots.

Packing, Marking and Shipping

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and contractor name. The contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

Inspection and Acceptance

The Project Officer will perform inspection and acceptance of equipment, installation and services to be provided. The Project Officer – to be determined upon contract award - is the authorized representative of the Contracting Officer.

Period of Performance

The period of performance begins the date of contract award and continues for one year from the date of formal government acceptance. Instrument to be delivered no later than 60 days after issuance of deliver order.

Type of Contract: Firm-Fixed-Price (FFP); The Government anticipates issuing a firm fixed-price purchase order.

Set Aside: N/A

FDA Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP) (Jan 2022)

(a) All Invoice submissions for goods and or services must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP).

<http://www.ipp.gov/contractors/index.htm>

(b) Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract, or the clause 52.212-4 Contract Terms and Conditions – Commercial Items included in commercial items contracts. The IPP website address is: <https://www.ipp.gov>.

(c) -----

(1) The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 – 5 business days of the contract award for new contracts or date of modification for existing contracts.

(2) Registration emails are sent via email from ipp.noreply@mail.eroct.wai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.

(3) The Contractor POC will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.

(4) If your company is already registered to use IPP, you will not be required to re-register.

(5) If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

(d) Invoices that include time and materials or labor hours Line Items must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).

(e) Invoices that include cost-reimbursement Line Items must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts.

(1) At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.

- Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category.
- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirect)- show rate, base and total amount.
- Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant.
- Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed.
- Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor.
- Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
- Fee – amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

(f) Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:

(1) list of all invoices submitted to date under the subject award, including the following:

- invoice number, amount, & date submitted
- corresponding payment amount & date received
- total amount of all payments received to date under the subject contract or order
- and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance.

(g) Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.

(h) If the services are rejected for failure to conform to the technical requirements of the task order, or any other contractually legitimate reason, the Contractor shall not be paid, or shall be paid an amount negotiated by the CO.

(i) Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.

(j) The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.

(k) Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.

(END OF CLAUSE)

FAR / HHSAR Clauses:

I. The provision at 52.212-1, Instructions to Offerors – Commercial DEVIATION 2018-O0018, applies to this acquisition. The following addenda have been attached to this provision:

In addition to the requirements set for the in FAR 52.212-1, all offers responding to this solicitation must provide their business size in relation to the NAICS code contained in this solicitation and shall identify any socioeconomic categories to which they belong.

II. Evaluation Criteria - The specific evaluation criteria to be used are as follows: Lowest price technically acceptable (LPTA).

III. Offerors shall include a completed copy of the provision at FAR 52.212-3 (with its Alternate I), Offeror Representations with its offer.

IV. The clause at 52.212-4, Contract Terms and Conditions - Commercial Items, applies to this acquisition. The following addenda have been attached to this clause – Not Applicable

V. The clause at 52.212-5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders - Commercial Items applies to this acquisition. The following additional FAR clauses cited in this clause are applicable:

52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Oct 2018)

52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Oct 2015)

52.211-6 Brand Name or Equal. (Aug 1999)

52.219-28, Post Award Small Business Program Representation (Nov 2020)

52.222-3, Convict Labor (June 2003)

52.222-19, Child Labor-Cooperation with Authorities and Remedies (Jan 2020)

- 52.222-21, Prohibition of Segregated Facilities (Apr 2015)
- 52.222-26, Equal Opportunity (Sept 2016)
- 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020)
- 52.222-50, Combating Trafficking in Persons (Oct 2020)
- 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020)
- 52.225-13, Restrictions on Certain Foreign Purchases (June 2008)
- 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct 2018)
- 52.204-7 System for Award Management (Oct 2018)
- 52.204-13 System for Award Management Maintenance (Oct 2018)
- 52.204-16 Commercial and Government Entity Code Reporting (Aug 2020)
- 52.204-18 Commercial and Government Entity Code Maintenance (Aug 2020)
- 52.204-24 Representations Regarding Certain Telecommunications and Video Surveillance Services or Equipment (Aug 2019)
- 52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment
- 52.204-26 Covered Telecommunications Equipment or Services-Representation
- 52.211-6 Brand Name or Equal.(Aug 1999)
- 52.232-40 Providing Accelerated Payments to Small Business Subcontractors (Dec 2013)
- 352.239-73 Electronic and Information Technology Accessibility Notice (Dec 2015)
- 352.239-74 Electronic and Information Technology Accessibility (Dec 2015)
- 352.232-71 Electronic Submission of Payment Requests (FEB 2022)
- (a) Definitions. As used in this clause—
Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), “Content of Invoices” and the applicable Payment clause included in this contract.
- (b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.
- (c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.
- (d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(END OF CLAUSE)

VII. This acquisition is rated under the Defense Priorities and Allocations System (DPAS) as N/A

VIII. The following notes apply to this announcement: N/A

Section 508 Requirements

The following standards are applicable for this requirement:

- Must meet WCAG 2.0 A and AA
- E101.2 Equivalent Facilitation (Appendix A, Application and Scoping Requirements)
- E203 Access to Functionality (Appendix A, Application and Scoping Requirements)
- E204 Functional Performance Criteria (Appendix A, Application and Scoping Requirements)
- E205 Electronic Content (Appendix A, Application and Scoping Requirements)
- E208 Support Documentation and Services (Appendix A, Application and Scoping Requirements)
- Chapter 6 Support Documentation and Services (Appendix C, Functional Performance Criteria and Technical Requirements)
- 302 Functional Performance Criteria (Appendix C, Functional Performance Criteria and Technical Requirements)
- E206 Hardware (Appendix A, Application and Scoping Requirements)
- Chapter 4 Hardware (Appendix C, Functional Performance Criteria and Technical Requirements)

Electronic content must be accessible to HHS acceptance criteria. Checklist for various formats are available at <https://www.hhs.gov/web/section-508/accessibility-checklists/index.html>, or from the Section 508 Coordinator listed at <https://www.hhs.gov/web/section-508/additional-resources/section-508-contacts/index.html>. Materials that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Representative.

Instructions to Offeror for Proposal Submission

FAR 52.212-1 Instructions to Offerors—Commercial Items (Jun 2020)

PROPOSAL SUBMISSION FORMAT:

The solicitation does not commit the Government to pay any cost for the preparation and submission of a quote or proposal. It is also advised that the Contracting Officer (CO) is the only individual who can legally commit and obligate the Government to the expenditure of public funds in connection with the proposed acquisition.

QUOTES DUE: All quotes are due, electronically via email to Elena.Tatarov@fda.hhs.gov for the RFQ no later than August 30, 2022, 10:00 a.m. Eastern Time. Late submissions may not be evaluated.

The subject line shall read: *FDA_ 1257087 – Type 1 Ultrapure Water Purification System or Equal*

The offeror or applicant shall submit all electronic documents for Microsoft Office suite products

without the use of “macros”. When submitting proposals via email, DO NOT include.exe, mso, or any other executable file types that could potentially trigger email security protections (i.e., email blocks, quarantine). If the offeror or applicant submits documents that contain macros, macro referenced files, and/or executable files, the Government will not be able to view or open such documents and the submission will be considered non-responsive to the solicitation. No additional time will be given to an offeror or applicant to correct the document submission and the Government will not inform the offeror or applicant that their submission is non-responsive prior to award. It is the offerors or applicant’s responsibility to ensure all electronic documents are submitted without the use of macros.

Basis for Award/Evaluation Criteria

The Government shall award a firm fixed price contract resulting from this solicitation to the responsible Quoter using the lowest price, technically acceptable (LPTA) evaluation method. For or Equal quotes, the contractor shall provide a line-by-line narrative demonstrating that they meet each salient characteristics. If narrative not provided it will deem technically unacceptable. The Government intends to evaluate quotes and award an order without discussions. Quoters' initial quote should contain the Quoters’ best terms from a price standpoint. The Government requests the Contractor to provide discounts off their established pricing for each line item. The Government reserves the right to conduct discussions if later determined by the Contracting Officer to be necessary.