

**Request for Quotation:** FDA\_ 1257261

**Posted Date:** August 11, 2022

**Response Date:** August 18, 2022, 10:00 a.m. Eastern Time.

Interested parties may identify in writing their interest and capability to respond by no later than August 18, 2022, 10:00 a.m. Eastern Time. Please email responses to Elena Tatarov at [Elena.Tatarov@fda.hhs.gov](mailto:Elena.Tatarov@fda.hhs.gov).

Indicate company's SAM.gov Unique Entity ID on the quote. The subject line shall read: *FDA\_1257261 – One (1) Getinge Loading Trolley, one (1) Injector Cart and Accessories 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 - ANALYTICAL LABORATORY INSTRUMENT MANUFACTURING

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 – Getinge 8666 Fixed Height Loading Trolley, Getinge 2-Level Injector Cart and accessories or Equal with one year manufacturer's warranty of equipment, parts and operational services.

### **Background**

The regulatory laboratories of the Food and Drug Administration (FDA), conduct a range of chemical analyses on pharmaceutical products to determine if they meet regulatory requirements. A loading trolley, injector cart and accessories for an existing washer/disinfector system is necessary to complete United States Pharmacopeia analyses on pharmaceutical regulatory samples.

### **Objective**

The Loading Trolley and Injector Cart will allow analysts to securely load dirty/contaminated laboratory glassware for cleaning into an existing washer/disinfector system at the Pacific Southwest Medical Products Laboratory (PSMPL), Irvine, CA.

### **Minimum Requirements**

The contractor shall provide a Getinge 8666 Fixed Height Loading Trolley, Getinge 2-Level Injector Cart and accessories or Equal that will be interfaced to an existing Getinge 8666 Washer-Disinfector. The equipment shall meet or exceed the following requirements:

- I. All Equipment shall:
  - Be compatible with an Getinge 8666 Washer-Disinfector with the model/serial number noted below:

- i. Getinge 8666 Washer-Disinfector Model/Serial Number: S-8666/W50048844
- II. Loading Trolley shall:
  - Be compatible with a 2-level Getinge Injector Cart
  - Be of fixed height and allow for single-end loading
  - Have a maximum capacity load of no less than 165 kg.
- III. 2-Level Injector Cart shall:
  - Be at least 2 levels; with the top levels removable
  - Accommodate at least 4 cassettes
    - i. Be able to accommodate cassettes equipped with two (2) 3x6 injectors and two (2) 4x8 injectors.
- IV. Accessories (Cassettes and Blank Plate) shall:
  - Include 1 (one) - 4x8 glass cassette with holder with the following criteria:
    - i. Have a minimum of thirty-two (32) injectors
    - ii. Accommodate varying sizes of glass flasks ranging from 5-25 milliliters.
  - Include 2 (two) - 3x6 glass cassette with holder that is equipped with multiple injector and holder heights and shall meet the following criteria:
    - i. Have a minimum of sixteen (16) injectors with a holder height no less than 170 mm and an injector height no less than 160 mm
    - ii. Have a minimum of two (2) injectors with a holder height no less than 200 mm and an injector height no less than 197 mm
  - Include 1 (one) - wash cart right blanking plate
    - i. Be compatible with a 2-level Getinge Injector Cart

**The contractor shall ensure the following:**

1. The equipment shall be a newly manufactured unit, not used and refurbished or previously used for demonstration.
  2. FOB Point destination to include inside delivery.
- All equipment shall be warranted for parts and labor for 12 months from the date of formal government acceptance.

**Deliverables or Delivery Schedule**

One (1) Loading Trolley, one (1) Injector Cart and accessories to be interfaced with an existing Washer/Disinfector system for PSMPL, Irvine, CA, meeting or exceeding the requirements stated above shall be delivered, inside delivery required, in accordance with the following:

	Description of Deliverable	Qty	Due Date
1	Getinge 8666 Fixed Height Loading Trolley, Getinge 2-Level Injector Cart and accessories or Equal.	1	Delivery within 90 days after award.
2	Manufacturer's warranty of equipment, parts and operational services.	1	Begins at the delivery and government acceptance through one year.

## **Inspection and Acceptance**

Upon arrival, the shipping container(s) will be inspected for damage. If significant damage is observed, such as a hole going through the container and packing to reach the enclosure itself, it will be rejected. All equipment shall be new, not used or refurbished.

## **Delivery Location and Place of Performance**

POC: To be identified at time of award  
FDA/PSMPL  
19701 Fairchild Rd.  
Irvine, CA 92612

FOB destination

## **Period of Performance**

The period of performance begins the date of contract award. All requirements shall be completed no later than 90 days after contract award.

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)	

**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.ero.c.twai.gov](mailto:ipp.noreply@mail.ero.c.twai.gov). Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to [IPPCustomerSupport@fiscal.treasury.gov](mailto: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 2018-00018, 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](http://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)

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 18th, 2022, 10:00 a.m. Eastern Time. Late submissions may not be evaluated. No phone calls will be accepted. *The subject line shall read: FDA\_ 1257261 – One (1) Getinge Loading Trolley, one (1) Injector Cart and Accessories 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.