

**Request for Quotation:** FDA\_ 1256896

**Posted Date:** August 12, 2022

**Response Date:** August 19, 2022, 10:00 a.m. Eastern Time.

Interested parties may identify in writing their interest and capability to respond by no later than August 19, 2022, 10:00 a.m. Eastern Time. Please email responses to Elena Tatarov at Elena.Tatarov@fda.hhs.gov. No phone calls will be accepted. Indicate company's SAM.gov Unique Entity ID on the quote. The subject line shall read: *FDA\_ 1256896 – Stereomicroscope System with Camera and Software*

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: 333314

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 – FDA\_ 1256896 – Stereomicroscope System with Camera and Software

**Background:**

The U.S. FDA, San Juan Laboratory in the Office of Regulatory Science, Office of Medical Products, Tobacco, and Specialty Laboratory Operations is a Pharma Specialty Laboratory. Details of the pharmacopeial products can be observed and documented using a stereomicroscope equipped with a camera and software to demonstrate compliance with the Pharmacopeial standards. The San Juan Laboratory uses product observations and documentation of those observations as a part of routine regulatory sample analyses.

**Objectives:**

To acquire a stereomicroscope with a camera and software to document compliance or anomalies in pharmacopeial products. A stereomicroscope will improve the visual clarity, three-dimensional imaging, measurement, and photo documentation for regulatory samples and allow the laboratory to share those observations easily and clearly with our customers.

**Requirements:**

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 stereomicroscope with compatible camera, software, and the additional components, accessories, and services to meet the requirements below.

**Minimum Performance Requirements**

The Contractor shall provide the following minimum requirements:

- a. The stereomicroscope, camera and software shall meet or exceed the following specifications:
  - i. **Stereomicroscope with common main optical objective shall meet the following requirements:**
    - i. Photo port
    - ii. Binocular head with phototube
      - 1. Eye tubes inclines at 20°
      - 2. Interpupillary adjustment of 51-75mm
      - 3. Eye piece accepts 26mm diameter reticle
      - 4. Eyecup
      - 5. Apochromat Objective WD 60mm
    - iii. Focusing eyepieces
    - iv. Minimum zoom 1-8x
    - v. Minimum multiplication range 10x to 80x
    - vi. Manual magnification changer
    - vii. Transmitted LED illumination
      - 1. Brightfield
      - 2. Darkfield
      - 3. Oblique
    - viii. Reflected LED illumination
      - 1. Dual gooseneck guides with focusing lenses
    - ix. Track Stand with fine and coarse focusing
    - x. C Mount adapter for camera connection
    - xi. ProLux LED pipes
    - xii. Apochromat objectives
    - xiii. Transillumination base for BF/DF
      - 1. Includes 120mm glass stage plate
    - xiv. 350mm column with manual coarse and fine focus drive
    - xv. Dust Cover
  - ii. **Digital Camera shall meet the following requirements:**
    - i. Back lit camera sensor
    - ii. Minimum resolution 1920 x 1080 pixels/2mp
    - iii. Minimum capture resolution 3840 x 2160/8mp
    - iv. Pixel size 1.85um x 1.85um
    - v. Minimum quantum efficiency 57%
    - vi. Minimum dynamic range 65 db
    - vii. 1920 x 1080 live image at 30 fps

- viii. Record video at 1920 x 1080 at 30 fps
- ix. Minimum 10-bit/16-bit color depth
- x. C Mount adapter 0.5x

iii. **Advanced Software shall meet the following requirements:**

- i. Image management exposure, gain, white balance, grey scale, monochrome
- ii. Still image capture
- iii. Video capture
- iv. Time lapse/Image series
- v. Measurement in Live mode, line, angle, freeform and radius
- vi. Grid scaling and crosshair in lime mode
  - 1. Ability to calibrate the grid scale
- vii. Z-stacking
- viii. Extended depth of Focus
- ix. Multi-focus
- x. Image Switching
- xi. Panorama
- xii. Multi-fluorescence image overlays
- xiii. Multi-channel fluorescence
- xiv. Annotation
  - 1. Text
  - 2. Arrow
  - 3. Marking
- xv. Histogram in live mode
- xvi. Image comparison
  - 1. Side by side mode

iv. **Shipping to Inside the Facility**

v. **Warranty Minimum 1 year**

**The contractor shall ensure the following:**

- Equipment shall be newly manufactured, not used, refurbished, or previously used for demonstration.
- Provide a minimum of a one-year manufacturing warranty for all manufactured equipment and parts. The warranty shall be included with the equipment and not separately priced. The warranty 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 original equipment manufacturer (OEM) trained engineer. The 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.
- Provide access to a technical representative call center, Monday through Friday, at no additional charge, for technical assistance and troubleshooting. The contractor shall ensure that the call center is staffed by senior engineers to provide a high level of expertise for troubleshooting the instrument.

- Provide inside delivery, disposing pallets, boxes, and any associated garbage, and unpacking the equipment and inventory of parts with a lab representative.
- Inside delivery and shipping charges shall be included.

**Documentation Requirements:**

- Qualification Documentation
- Instrument Manuals

**Repair Service and Documentation:**

- The Contractor shall repair or replace any part or parts under the warranty that prove to be defective at no additional charge to the Government.
- For repairs that fall under the warranty, the Contractor shall plan for the fastest delivery for parts and will schedule service upon receipt of parts within 72 business hours (3 days) upon COR approval.
- All replacement parts shall be from the original manufacturer and will be installed to the original manufacturers’ specifications.
- At the completion of any warranty service and contracted services, the contractor shall provide a written service report to the SJNL COR. This report shall clearly indicate the date of the service, the type of service performed the model and serial number(s) of the equipment serviced, the name of the field service technician, a brief description of the service performed and copy of the calibration certificate of any reference material used.

**Deliverable Table:**

<b>Deliverable</b>	<b>Quantity</b>	<b>Due Date</b>
Stereomicroscope and Required Accessories	1	Within 60 days after date of award
Digital Camera for the Stereomicroscope	1	Within 60 days after date of award
Imaging Software	1	Within 60 days after date of award
Instrument Manuals	1	Within 60 days after date of award

**Inspection and Acceptance:**

The COR will perform inspection and acceptance of equipment.

A final inspection and acceptance of all deliverables will be performed by the COR 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 (5) business days.

**Place of Performance:**

Food and Drug Administration  
San Juan Laboratory  
466 Fernández Juncos Ave.  
San Juan, PR. 00901-3223

COR: Donna LaGarde  
[donna.lagarde@fda.hhs.gov](mailto:donna.lagarde@fda.hhs.gov)  
787-729-8730

FOB destination

Vendor shall call the COR at least 48 hours prior to delivery. Unless otherwise specified, deliveries shall be made inside to the Delivery Point specified above, Monday through Friday (excluding Government Holidays see below between the hours of 8:00 a.m. and 4:00 p.m. in accordance with the delivery location time zone (Atlantic Standard Time). Supplies or services scheduled for delivery on a Government holiday shall be made the next business day. Delivery must be **inside** the laboratory facility. The San Juan Laboratory has no equipment to assist transporting the equipment from the delivery truck to inside the building. **The contractor is responsible for planning and transporting the equipment to inside the building. The laboratory does not have a holding area; therefore, the contractor is responsible for inside delivery.**

**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 inside delivered no later than 60 days after date of award.

**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-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)

52.219-28, 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
- 52.232-40 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)
- E206 Hardware (Appendix A, Application and Scoping Requirements)
- E207 Software (Appendix A, Application and Scoping Requirements)
- Chapter 4 Hardware (Appendix C, Functional Performance Criteria and Technical Requirements)
- Chapter 5 Software (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](mailto:Elena.Tatarov@fda.hhs.gov) for the RFQ no later than August 19th, 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\_ 1256896 – Stereomicroscope System with Camera and Software*

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 offeror's 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. 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 as well as demonstrate the ability to meet the solicitation requirements. If the contractor fails to demonstrate the solicitation requirements than it will be deemed technically unacceptable. 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.