



REQUEST FOR QUOTE

Bruker-Alicona InfiniteFocus Microscope System Software Upgrade

FDA-75F40126Q00215

DATE POSTED: June 15, 2026

CLOSE DATE: June 30, 2026, by 1:00PM EST

CLASSIFICATION CODE: 7B22 – IT and Telecom – Compute: Servers (Hardware and Perpetual License Software)

NAICS CODE: 541519 - Other Computer Related Services

SECTION 1 – PRODUCT LIST AND DELIVERY INFORMATION

This is a combined synopsis/solicitation for commercial items prepared in accordance with the Federal Acquisition Regulation (FAR) format, as supplemented with additional information included in this notice. This announcement constitutes the only solicitation; Offers are being requested and a separate written solicitation will not be issued. It is the Government's intent to issue a Firm Fixed Priced Purchase Order in accordance with FAR Part 12.

The solicitation number is **FDA-75F40126Q00215**. This solicitation is issued as a Request for Quote (RFQ). This requirement is being solicited as a total-small business set aside.

The Government is in no way obligated to make an award, nor to pay any costs incurred by the Contractor in preparing and submitting its quote.

1.1 Background

The National Forensic Chemistry Center (NFCC) requires an InfiniteFocus Microscope (IFM) system software upgrade to enable searchability and comparison capabilities, enhancing forensic analysis efficiency.

The IFM system is a non-contact, optical, 3D imaging and measurement system used by NFCC's Trace Examination Section (TES) for surface profilometry and difference analysis measurements, including tablet debossing, punch face embossing, surface abrasion, pit measurements, corroded surface analysis, and pharmaceutical packaging topography and print profiling.

The upgrade will enhance data analysis throughput, enable search and comparison capabilities across datasets, provide sourcing insights to OCI and OII agents, and improve support for suspect counterfeit cases. The FY2017 upgrade significantly impacted data analysis efficiency, and this proposed upgrade builds upon that investment. The upgrade will significantly enhance analysis efficiency through streamlined search and comparison, automated matching, faster data retrieval, improved data organization, and increased productivity.

Additionally, the upgrade is expected to reduce data analysis time, increase cases processed per month for analysts, and achieve accuracy in automated matching. This upgrade will also yield long-term benefits, including improved forensic capabilities, operational efficiency, strategic advantages, financial benefits, and futureproofing. Specifically, it will enhance accuracy and reliability, reduce costs, increase throughput, and ensure scalability and adaptability to future technologies.

The IFM system software upgrade is crucial for maintaining and enhancing the NFCC's forensic analysis capabilities, supporting critical customer needs, and combating counterfeit pharmaceuticals and illicit drugs.

1.2 Objective

The U.S. Food and Drug Administration (FDA), in support of the National Forensic Chemistry Center (NFCC), requires an upgrade to the current **Bruker – Alicona IFM G5 Systems**.

1.3 Product List

CLIN	Product Number	Labor and Services	Qty	Price	Extended Price
001	BA-14389	Alicona Control ServerSF	1		
002	BA-SSO-0185	Travel Expenses Region 2_A	1		
003	BA-SSO-0157	Analysis Software License	1		
004	BA-SSO-0109	Installation & Training	1		
005		FCC IT Server Installation	1		
006		FCC IT Client Installation	1		
Total					

1.4 Technical Requirements

The contractor shall provide all resources necessary to accomplish the tasks and deliverables described in this statement of work, including the hardware system requirements which are the minimum

requirements. Equivalent requirements that differ from these minimum requirements must be justified by the proposing vendor and evaluated by the NFCC prior to purchase.

Hardware

The system shall include the ability to be used by the NFCC current Alicona InfiniteFocus Microscope (IFM) G5 database:

- Minimum computer(s) requirements: Operating System:
 - Windows 11 64bit
 - GPU (graphics card): NVidia required. RAM: 16GB
 - Hard Disk: 1 TB
- The software license must include:
 - Per attached quote:
 - Offline MetMaX (Unlimited) software included. See quote for full detail.
 - Analysis Searchability Software License included.

Software

The NFCC requires a software upgrade for the IFM G5 system to enable advanced searchability and management of a 3D dataset library exceeding 500GB of data. To maintain the integrity of our historical metrology data, the software must natively support proprietary Alicona data structures. This is a system requirement because only the original equipment manufacturer's (OEM) upgraded software can guarantee non-destructive indexing of existing datasets while ensuring seamless, real-time integration with the IFM G5 hardware. Failure to utilize the OEM software would result in a loss of metrological traceability and require a costly, high-risk migration of the entire NFCC digital library of 3D datasets."

The list below defines the "Must-Haves" for the software to perform the required task.

1) Native Compatibility with IFM G5 Proprietary Formats

The software must provide full, native read/write/search support for the Bruker Alicona proprietary 3D dataset formats (e.g., .al3d, .met, and associated metadata). It must interact directly with the IFM G5's existing sensor calibrations and optical encoders without the need for data conversion.

2) High-Volume Library Indexing (Terabyte-Scale)

The software must be capable of indexing and querying a terabyte-sized digital library of 3D datasets.

Requirement: The indexing process must allow for "Search-in-Place" capabilities, where users can query historical NFCC datasets based on metadata (date, operator, difference analysis measurements, roughness parameters, or batch ID) without having to load individual massive files into active memory.

3) Non-Destructive Data Integrity

The software must utilize a Read-Only indexing protocol when accessing the current NFCC digital library of 3D datasets.

Requirement: The search, upload, or transfer processes must not alter the original timestamp, file structure, or metrological traceability of existing 3D datasets.

4) Seamless Dataset Ingestion and Expansion

The platform must allow for the seamless background "uploading" or cataloging of all current NFCC in-house datasets while simultaneously allowing Data-Entry users to add new 3D measurements, specifically difference analysis measurements to the database in real-time.

Key Software Features:

a) Technical Continuity and Data Integrity

The current NFCC digital library of 3D datasets consists of combined data close to a terabyte of high-resolution 3D measurements. Using third-party or non-native software risks data corruption or loss of metrological traceability. Only the Bruker Alicona-upgraded suite (e.g., MetMaX or upgraded Measurement Suite) can guarantee that the 3D point cloud and difference analysis measurements and surface difference measurements calculations remain consistent with the original G5 acquisition parameters.

b) Proprietary Interoperability

The IFM G5 system uses specific Focus Variation algorithms to reconstruct 3D surfaces. Third-party search software cannot "look inside" these proprietary file formats to index specific metrological metadata. To achieve the "searchability" required, the software must be able to parse the specific headers and metadata layers unique to the Alicona architecture.

c) Hardware-Software Synergy

The software upgrade is designed specifically to interface with the G5 hardware controller and optical system. Any other software would lack the necessary drivers to manage the "uninterrupted and continuous" flow of data from the microscope to the dataset library, leading to system downtime.

II. Trade and Service Specifications

- The software system must include annual maintenance for all licenses (upgrade and new licenses)
 - All version of the software upgrades and updates for 12 existing licenses and 3 new licenses
 - Annual maintenance costs for additional licenses purchased during the contract term shall be prorated from the date of purchase to the date of contract renewal
- Phone and Online Remote Support
- The system shall be installed with all necessary files required for installation and start-up
- Current systems have all files updated to bring existing licenses software up to date
- Installation and operational training shall be included
- Training will be provided within 60 days of delivery such that operators may independently operate the system
- The upgrade shall include manuals

1.5 Period of Performance

The anticipated Period of Performance shall be for one (1) twelve-month base year.

Period of Performance	Date
Base Year	From date of award

1.6 Delivery Requirements

The above items shall be delivered according to the above Period of Performance. All items shall be delivered to the FDA COR. The Contractor shall notify the COR via email when the above items are available. All items shall be delivered no later than 30 days after award.

Any physical deliverables will be delivered to the following address:

U.S Food and Drug Administration
National Forensic Chemistry Center
6751 Steger Dr.
Cincinnati, OH 45237

Deliverable	Quantity	Delivery Date
Bruker – Alica control/server and software upgrade	1	No later than 30 days after award
Installation and setup	1	Within 30 days of delivery

1.7 Contract Type

This is a Firm Fixed Price (FFP) purchase order.

SECTION 2 – CONTRACT ADMINISTRATION

2.1 Contract Management

Contracting Officer (CO):
(To be entered at time of award)

Contract Specialist (CS):
Tiffany Gates
Tiffany.Gates@fda.hhs.gov

Contracting Officers Representative (COR):
(To be entered at time of award)

2.2 Contracting Officer's Authority

The ***Contracting Officer (CO)*** is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the RFQ; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract. No statement, whether oral or written, by anyone other than the Contracting Officer, shall be interpreted as modifying the terms and conditions of this award. It is the Contractor's responsibility to contact the CO immediately if there is even the appearance of any technical direction that is or may be outside the scope of the award. The Government will not reimburse the Contractor for any work not authorized by the Contracting Officer, including work outside the scope of the award.

The ***Contracting Officer's Representative (COR)*** is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the contract and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

2.3 Interpretations of Modifications

No oral or written statement of any person and no written statement of anyone other than the CO shall modify or otherwise affect the terms and conditions of this contract. Requests for interpretations, modifications or changes must be made in writing to the CO. The technical point of contact can only respond to technical matters that do not result in a change of scope to this contract.

2.4 Security and Privacy

A. Baseline Security Requirements

1) **Applicability.** The requirements herein apply whether the entire contract or order (hereafter “contract”), or portion thereof, includes either or both of the following:

- a. Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.
- b. Operate a Federal System Containing Information: A Contractor (and/or any subcontractor) will operate a federal system and information technology containing data that supports the HHS mission. In addition to the Federal Acquisition Regulation (FAR) Subpart 2.1 definition of “information technology” (IT), the term as used in this section includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.

2) **Safeguarding Information and Information Systems.** In accordance with the Federal Information Processing Standards Publication (FIPS)199, Standards for Security Categorization of Federal Information and Information Systems, the Contractor (and/or any subcontractor) shall:

- a. Protect government information and information systems in order to ensure:
 - Confidentiality, which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;
 - Integrity, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and
 - Availability, which means ensuring timely and reliable access to and use of information.
- b. Provide security for any Contractor systems, and information contained therein, connected to an FDA network or operated by the Contractor on behalf of FDA regardless of location. In addition, if new or unanticipated threats or hazards are discovered by either the agency or contractor, or if existing safeguards have ceased to function, the discoverer shall immediately, within one (1) hour or less, bring the situation to the attention of the other party. This includes notifying the FDA Systems Management Center (SMC) within one (1) hour of discovery/detection in the event of an information security incident.

- c. Adopt and implement the policies, procedures, controls, and standards required by the HHS/FDA Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the FDA Information Security Program security requirements, outlined in the FDA Information Security and Privacy Policy (IS2P), by contacting the CO/COR or emailing your ISSO.
- d. Comply with the Privacy Act requirements and tailor FAR clauses as needed.

3) **Information Security Categorization.** In accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-60, Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories, Appendix C, and based on information provided by the ISSO or other security representative, the risk level for each Security Objective and the Overall Risk Level, which is the highest watermark of the three factors (Confidentiality, Integrity, and Availability) of the information or information system are the following:

Confidentiality:	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> High
Integrity:	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> High
Availability:	<input checked="" type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High
Overall Risk Level:	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> High

Based on information provided by the Privacy Office, system/data owner, or other privacy representative, it has been determined that this solicitation/contract involves:

☐ No PII ☒ Yes PII

Personally Identifiable Information (PII). Per the OMB Circular A-130, “PII is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual.” Examples of PII include, but are not limited to the following: Social Security number, date and place of birth, mother’s maiden name, biometric records, etc.

PII Confidentiality Impact Level has been determined to be:

☐ Low ☒ Moderate ☐ High

The Privacy Act does not apply.

4) **Controlled Unclassified Information (CUI).** CUI is defined as “information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information.” The Contractor (and/or any subcontractor) must comply with Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR, part 2002) when handling CUI. 32 C.F.R. 2002.4(aa). As implemented the term “handling” refers to “...any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-

using, and disposing of the information.” 81 Fed. Reg. 63323. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, shall be:

- a. marked appropriately;
- b. disclosed to authorized personnel on a Need-To-Know basis;
- c. protected in accordance with NIST SP 800-53, *Security and Privacy Controls for Federal Information Systems and Organizations* applicable baseline if handled by a Contractor system operated on behalf of the agency, or NIST SP 800-171, *Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations* if handled by internal Contractor system; and
- d. returned to FDA control, destroyed when no longer needed, or held until otherwise directed.

Destruction of information and/or data shall be accomplished in accordance with NIST SP 800-88, Guidelines for Media Sanitization and the FDA IS2P Appendix T: Sanitization of Computer-Related Storage Media.

5) Protection of Sensitive Information. For security purposes, information is or may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Contractor (and/or any subcontractor) shall protect all government information that is or may be sensitive in accordance with OMB Memorandum M-06-16, Protection of Sensitive Agency Information by securing it with a FIPS 140-2 validated solution.

Confidentiality and Nondisclosure of Information. Any information provided to the contractor (and/or any subcontractor) by FDA or collected by the contractor on behalf of FDA shall be used only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any FDA records may be made available or disclosed shall be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.

The confidentiality, integrity, and availability of such information shall be protected in accordance with //HHS and FDA policies. Unauthorized disclosure of information will be subject to the HHS/FDA sanction policies and/or governed by the following laws and regulations:

- a. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);
- b. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and
- c. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

6) Internet Protocol Version 6 (IPv6). All procurements using Internet Protocol shall comply with OMB Memorandum M-05-22, Transition Planning for Internet Protocol Version 6 (IPv6).

7) Government Websites. All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent

version of Transport Layer Security (TLS). In addition, HTTPS shall enable HTTP Strict Transport Security (HSTS) to instruct compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that attempt to downgrade connections to plain HTTP. For internal-facing websites, the HTTPS is not required, but it is highly recommended.

8) **Contract Documentation.** The Contractor shall use FDA-provided templates, policies, forms and other agency documents to comply with contract deliverables as appropriate.

9) **Standard for Encryption.** The Contractor (and/or any subcontractor) shall:

- a. Comply with the HHS Standard for Encryption of Computing Devices and Information to prevent unauthorized access to government information.
- b. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with FIPS 140-2 validated encryption solution.
- c. All devices (i.e.: desktops, laptops, mobile devices, etc.) that store, transmit, or process non-public FDA information should utilize FDA-provided or FDA information security authorized devices that meet HHS and FDA-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).
- d. Verify that the encryption solutions in use are compliant with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the COR.
- e. Use the Key Management system on the HHS Personal Identification Verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys. Encryption keys (PIV card) shall be provided to the COR upon request and at the conclusion of the contract. Upon completion of contract, contractor ensures that COR is able to access and read any encrypted data.

10) **Contractor Non-Disclosure Agreement (NDA).** Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract shall complete the FDA non-disclosure agreement (3398 Form), as applicable. A copy of each signed and witnessed NDA shall be submitted to the CO and/or COR prior to performing any work under this acquisition.

11) **Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA)** – The Contractor shall assist the procuring activity representative, program office and the FDA SOP or designee with conducting a PTA for the information system and/or information handled under this contract to determine whether or not a full PIA needs to be completed.

- a. If the results of the PTA show that a full PIA is needed, the Contractor shall assist procuring activity representative, program office and the FDA SOP or designee with completing a PIA for the system or information after completion of the PTA and in

accordance with HHS and FDA policy and OMB M-03-22, Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002. The PTA/PIA must be completed and approved prior to active use and/or collection or processing of PII and is a prerequisite to agency issuance of an authorization to operate (ATO).

- b. The Contractor shall assist the procuring activity representative, program office and the FDA SOP or designee in reviewing and updating the PIA at least every three years throughout the Enterprise Performance Life Cycle (EPLC) /information lifecycle, or when determined by the agency that a review is required based on a major change to the system, or when new types of PII are collected that introduces new or increased privacy risks, whichever comes first.

1.1.1.1 Training

- 12) **Mandatory Training for All Contractor Staff.** All Contractor (and/or any subcontractor) employees assigned to work on this contract shall complete the applicable FDA Contractor Information Security Awareness, Privacy, and Records Management training (provided upon contract award) before performing any work under this contract. Thereafter, the employees shall complete FDA Information Security Awareness, Privacy, and Records Management training at least annually, during the life of this contract. All provided training shall be compliant with HHS and FDA training policies.
- 13) **Role-based Training.** All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role-based training annually commensurate with their role and responsibilities in accordance with HHS and FDA policy and FDA Role-Based Training (RBT) of Personnel with Significant Security Responsibilities Standard Operating Procedures (SOP).
- 14) **Training Records.** The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS and FDA policy. A copy of the training records shall be provided to the CO and/or COR within **30 days** after contract award and **annually** thereafter or upon request.

1.1.1.2 Rules of Behavior

- 15) The Contractor (and/or any subcontractor) shall ensure that all employees performing on the contract comply with the HHS Information Technology General Rules of Behavior.
- 16) All Contractor employees performing on the contract must read and adhere to the Rules of Behavior (ROB) before accessing HHS and FDA data or other information, systems, and/or networks that store/process government information, initially at the beginning of the contract and at least annually thereafter, which may be done as part of annual FDA Information Security Awareness Training. If the training is provided by the contractor, the signed ROB must be provided as a separate deliverable to the CO and/or COR per defined timelines.

1.1.1.3 Incident Response

The Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/FDA SMC /Incident Response Team (IRT) teams within 24 hours, whether the response is positive or negative.

FISMA defines an incident as “an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies.” The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines incidents as events involving cybersecurity and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

A privacy breach is a type of incident and is defined by FISMA as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines a breach as “a suspected or confirmed incident involving PII.”

In the event of a suspected or confirmed incident or breach, the Contractor (and/or any subcontractor) shall:

- 17) Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.
- 18) NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor shall send FDA approved notifications to affected individuals as directed by FDA’s SOP.
- 19) Report all suspected and confirmed information security and privacy incidents and breaches to the FDA Systems Management Center, COR, CO, and other stakeholders, (Recommend adding the FDA Senior Official for Privacy with contact information and either defining or deleting “other stakeholders.”) including incidents involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour of discovery/detection, and consistent with the applicable FDA and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contract information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor shall:
 - a. cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;
 - b. not include any sensitive information in the subject or body of any reporting e-mail; and
 - c. encrypt sensitive information in attachments to email, media, etc.
- 20) Comply with OMB M-17-12, *Preparing for and Responding to a Breach of Personally Identifiable Information* and HHS and FDA incident response policies when handling PII breaches.
- 21) Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event

information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to contractor facilities during a breach/incident investigation demand.

1.1.1.4 Position Sensitivity Designations

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR). The following position sensitivity designation levels apply to this solicitation/contract: *[See the FDA Security Article, entitled Contractor Personnel Security Clearance Standards and Residency Requirements for the Position Risk Designation Tier(s) (i.e., 1, 2, and/or 4”) that apply to this award.]*

1.1.1.5 Homeland Security Presidential Directive (HSPD)-12

The Contractor (and/or any subcontractor) and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, *Policy for a Common Identification Standard for Federal Employees and Contractors*; OMB M-05-24; FIPS 201, *Personal Identity Verification (PIV) of Federal Employees and Contractors*; HHS HSPD-12 policy; and *Executive Order 13467, Part 1 §1.2*.

Roster. The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster and any revisions to the roster as a result of staffing changes shall be submitted to the COR and/or CO per the COR or CO’s direction. Any revisions to the roster as a result of staffing changes shall be submitted within a timeline as directed by the COR and/or CO. The COR will notify the Contractor of the appropriate level of investigation required for each staff member.

If the employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate suitability level.

1.1.1.6 Contract Initiation and Expiration

- 22) General Security Requirements. The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the contractor shall follow the FDA EPLC framework and methodology in accordance with the FDA EPLC Project documentation, located here: <http://sharepoint.fda.gov/orgs/DelMgmtSupport/IntakeProc/EPLCv2/SitePages/v2/EPLCHome.aspx>

HHS EA requirements may be located here: <https://www.hhs.gov/about/agencies/asa/ocio/index.html>

- 23) **System Documentation.** Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-64, *Security Considerations in the System Development Life Cycle*, at a minimum,

for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.

- 24) **Sanitization of Government Files and Information.** As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation in accordance with FDA OAGS SMGs to the CO and/or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization and FDA IS2P Appendix T: *Sanitization of Computer-Related Storage Media*
- 25) **Notification.** The Contractor (and/or any subcontractor) shall notify the CO and/or COR as soon as it is known that an employee will stop working under this contract.
- 26) **Contractor Responsibilities Upon Physical Completion of the Contract.** The contractor (and/or any subcontractors) shall return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor shall provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and/or FDA policies.
- 27) The Contractor (and/or any subcontractor) shall coordinate with the COR via email, copying the Contract Specialist, to ensure that the appropriate person performs and documents the actions identified in the FDA eDepart system <http://inside.fda.gov:9003/EmployeeResources/NewEmployee/eDepartDepartureSystem/default.htm> as soon as it is known that an employee will terminate work under this contract within days of the employee's exit from the contract. All documentation shall be made available to the CO and/or COR upon request.

1.1.1.7 Records Management and Retention

The Contractor (and/or any subcontractor) shall maintain all information in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies and schedules and HHS/FDA policies and shall not dispose of any records unless authorized by HHS/FDA.

In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, it shall be documented and reported as an incident in accordance with HHS/FDA policies.

2.4 IPP Invoice Requirements

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/vendors/index.html>
- (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) 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.
- (1) Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov . or phone (866) 973-3131. 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.
 - (2) 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.
 - (3) If your company is already registered to use IPP, you will not be required to re-register.
 - (4) If the Contractors 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 FAR52.216-8 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 contractor 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.

2.5 Payment Terms

Payment terms Net 30 days after government acceptance of the supply item/service. Payments shall not be made more frequently than monthly in arrears. Advance payments will not be made.

SECTION 3 – INSPECTION & ACCEPTANCE

Inspection and acceptance will be at destination in accordance with FAR clause 52.212-4(a). In accordance with FAR 52.212-4(a), the Government has the right either to reject or to require correction of nonconforming supplies. Supplies are nonconforming when they are defective in material or workmanship or are otherwise not in conformity with contract requirements. The Government may reject nonconforming supplies with or without disposition instructions.

The COR will perform inspection and acceptance of all products and services. The performance criteria for these products shall be timely delivery and closure of all activities and deliverables listed above and within the established Period of Performance.

Inspection and acceptance will occur at the place of delivery. Inspection will include verifying all parts were received and warranties and services are in place. The Government will accept goods and services only if they conform to all terms and conditions of this order. The Government will provide written notification of acceptance or rejection within ten (10) business days of receiving the delivery.

The Government will reject non-conforming products and services. The Contractor shall correct any deficiencies within thirty (30) days of when the Government issues the rejection notice. If the Contractor cannot correct the deficiencies within this time frame, the Contractor shall immediately notify the COR or technical POC of the reason for the delay and provide a proposed corrective action plan within ten (10) business days.

All quoter's shall be Authorized reseller and/or servicing agent shall identify and/or provide documentation to confirm their claim as an authorized reseller and/or servicing agent.

All Quoter s quote shall clearly state license number, product description, quantity, price, and period of performance for each product. The quotation shall include and match license number, product description, quantity, and period of performance. Quoter s are advised that should their quotation conflict with or does not clearly reflect the specified product and requirement of this solicitation, their quotation may be deemed as technically unacceptable and may not be considered for award.

Price: Provide a detailed quote for each item/component proposed to the schedule of items. Discounts are highly encouraged.

The Quoter or applicant shall submit all electronic documents for Microsoft Office suite products without the use of macros. If the Quoter or applicant submits documents that contain macros 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 Quoter or applicant to correct the document submission and the Government will not inform the Quoter or applicant that their submission is non-responsive prior to award. It is the Quoter s or applicant's responsibility to ensure all electronic documents are submitted without the use of macros.

• SPECIAL NOTICE AND AGREEMENT REGARDING SOFTWARE EULA/TOS

Computer software and services are often subject to license agreements, referred to as End User License Agreements (EULA), Terms of Service (TOS), or other similar legal instruments or agreements. Many of

these agreements contain indemnification clauses that are inconsistent with Federal law and unenforceable, but which could create a violation of the Anti-Deficiency Act (31 U.S.C. 1341) if agreed to by the Government.

Therefore, by submitting a quotation all Quoter shall agree that the inclusion of any Limitation of Liability, Indemnification, and any other clauses that conflict with Federal law or regulation in any EULA or TOS are NULL AND VOID. The Quoter agrees that any EULA/TOS clauses conflicting with Federal law or regulation and are not agreed to by the Government if included with the submission of a quotation. Additionally, by submission of the quotation the Quoter shall agree to the inclusion of FAR 52.232-39 Unenforceability of Unauthorized Obligations in any resulting contract or order, if awarded.

3.1 The provision at FAR 52.212-1 Instructions to Offerors - Commercial Products and Commercial Services (Oct 2018) applies to this solicitation. The following addenda apply:

It is the Quoter 's responsibility to monitor the Government Point of Entry (GPE) Sam.gov for information relevant to this solicitation, e.g., questions and answers, amendments, etc. An official authorized to bind the Quoter must sign the terms and conditions of the offer. Quoter s that fail to complete the required representations and certifications, or reject the terms and conditions of the solicitation, may be excluded from consideration.

Paragraph (b)(4): Technical Acceptable: Will be determined by review of information submitted by the Quoter which shall provide sufficient technical information for the Government to conclusively determine that the offered supply items meet or exceeds the technical requirements identified above. In addition to identifying brand, item name, and item number of offered products, it is incumbent of Quoter s that they unequivocally demonstrate that offered products meet the requirements herein through the submission of technical specifications, descriptive material, scientific literature, brochures, scientific publications where proposed solution has been used for same or similar purposes, and other information which demonstrates the capability of the offered instrument. Quoters shall address the technical requirements identified above, as well as detailed information on the items in the solicitation. Quoters To quotations must submit technical volume with detailed point-by-point description of how the equal to product meets all the salient characteristics of this solicitation. Equal to Quotations shall be required to operate seamlessly with connecting operating software and/or hardware.

The government is not responsible for locating or securing any information which is not identified in the proposal however the Government reserves the right to obtain information for use in the evaluation from any and all sources including sources outside of the Government.

Price: Provide detailed price quote for each item proposed to meet the Schedule of Items. Include the firm's Unique Entity Identifier (UEI) number with quote. The option year periods will not be funded at time of award. If exercised, funding will be obligated individually each year for the option period exercised via contract modification; the option periods shall be priced accordingly.

All Quoters shall submit a complete pricing for all products listed in this RFQ. Partial or Incomplete quotes may not be considered for award.

All Quoters providing quotations shall (include any shipping and taxes) in the overall cost to the Government.

Quoters shall certify their quotes to be valid for 60 days.

3.2 The provision at 52.212-2 Evaluation-Commercial Products and Commercial Services (OCT 2014) is applicable to this solicitation. The following addenda apply:

The Government shall 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 should 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.

SECTION 4 – FAR / HHSAR: PROVISIONS & CLAUSES

FAR Provision 52.252-1 Provisions Incorporated by Reference (Feb 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The Quoter is cautioned that the listed provisions may include blocks that must be Completed by the Quoter and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the Quoter may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es): <https://www.acquisition.gov/far/> and <http://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html>

FAR Provision:

FAR 52.204-7 System for Award Management-Registration (April 2026)

FAR 52.204-90 Offeror Identification (April 2026)

HHSAR Provision:

HHSAR 352.239-73 Electronic and Information Technology Accessibility (Dec 2015)

FAR 52.252-2: Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address:

<https://www.acquisition.gov/browse/index/far>

Far Clause:

52.203-19: Prohibition on Requiring Certain Internal Confidentiality Agreements (Jan 2017)

52.212-4: Contract Terms and Conditions-Commercial Products and Commercial Services (Nov 2023)

52.227-19: Commercial Computer Software License (Dec 2007)

52.232-39: Unenforceability of Unauthorized Obligations (Jun 2013)

52.232-40: Providing Accelerated Payment to Small Business Subcontractors (Mar 2023)

52.240-90: Security Prohibitions and Exclusions Representations and Certifications (April 2026)

52.240-91: Security Prohibitions and Exclusions (April 2026)

FAR 52.217-7 Option for Increased Quantity-Separately Priced Line Item (MAR 1989)

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor at any time before the contract expires. Delivery of added items shall continue at the same rate that like items are called for under the contract unless the parties otherwise agree.

FAR 52.217-9 Option to Extend the Term of the Contract (MAR 2000)

- (a) The Government may extend the term of this contract by written notice to the Contractor within any time before the contract expires; provided that the Government gives the Contractor a preliminary written notice of its intent to extend any time before the contract expires. The preliminary notice does not commit the Government to an extension.
- (b) If the Government exercises this option, the extended contract shall be considered to include this option clause.
- (c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed five (5) years. (End of clause)

HHSAR Clauses:**HHSAR 352.222-70 Contractor Cooperation in Equal Employment Opportunity Investigations (Dec 2015)****HHSAR 352.232-71 Electronic Submission of Payment Requests (APR 2026) (RFO DEVIATION)**

- (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 in FAR 32.905(b) and the applicable payment clause included in this contract.
- (b) **Submission instructions.** Except as provided in paragraph (c) of this clause, the Contractor must 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) **Alternate submission procedures.** The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing.
- (d) **Submission of alternate payment procedures authorization.** If alternate payment procedures are authorized, the Contractor must include a copy of the Contracting Officer's written authorization with each payment request. (End of clause)

HHSAR 352.239-74 Electronic and Information Technology Accessibility (Dec 2015)

- (a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the “Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards” set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the “Access Board”) in 36 CFR part 1194. Information about Section 508 is available at <https://www.hhs.gov/web/508> . The complete text of Section 508 Final Provisions can be accessed at <https://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards>.
- (b) The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.
- (c) The Section 508 accessibility standards applicable to this contract are:

- 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.
- Accessibility checklists for various formats are available at the HHS site. Materials that are final items must be compliant with Section 508 at time of delivery, except upon approval of the Contracting Officer or Representative.
- E207 Software (Appendix A, Application and Scoping Requirements)
- Chapter 5 Software (Appendix C, Functional Performance Criteria and Technical Requirements)

(d) In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS website: (<https://www.hhs.gov/web/508>). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(e) If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at <https://www.hhs.gov/web/508> . If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense. (End of clause)

SECTION 5 – QUESTIONS & TIME SUBMISSION

All questions in response to this solicitation shall be submitted on or before **June 22, 2026, by 1:00 PM** Washington DC Local Time. All questions shall be submitted via email to Tiffany Gates, Contracting Specialist, tiffany.gates@fda.hhs.gov

All responsible sources may submit a quote, which if timely received, shall be considered. The quote shall reference solicitation number FDA-75F40126Q00215. The quotes are due by email only to the point of contact listed below on or before **June 30, 2026, by 1:00 PM** Washington DC Local Time.

For information regarding this solicitation, please contact Tiffany Gates email: tiffany.gates@fda.hhs.gov

END OF SOLICITATION