July 27, 2021

Public notice of a proposed contract action less than $25,000.00

Notice of Intent to Sole Source
Remcom Inc.
FDA_1241592

The Food and Drug Administration (FDA) intends to award a Sole Source firm-fixed price purchase order to Remcom Inc., 315 S. Allen Street, Ste. 416, State College, PA 16801. In accordance with FAR Part 13.106-1(b), (b) Soliciting from a single source. (1) For purchases not exceeding the simplified acquisition threshold. (i) Contracting officers may solicit from one source if the contracting officer determines that the circumstances of the contract action deem only one source reasonably available (e.g., urgency, exclusive licensing agreements, brand-name or industrial mobilization).

The purpose of this notice is to inform the public that the Food and Drug Administration (FDA) anticipates issuing a purchase order.

MINIMUM REQUIREMENTS:

Specific Tasks/Deliverables

The Food and Drug Administration requires maintenance services (hotline and upgrade support) on our two XFDTD licenses with GPU acceleration options.

The vendor will supply online and phone support for the resolution of technical questions that the end user may encounter during the period of service. The vendor will supply any periodic updates and bug fixes that are released during the period of service.

This notice is not a request for competitive proposals. However, any party that believes it can meet this requirement as stated herein may submit a written capability statement that clearly supports and demonstrates their ability to perform the requirement.

Capability statements must be received by the response date and time of this notice. Submissions will be reviewed to determine if they can meet the requirement. A determination by the Government to compete this proposed contract based upon responses to this notice is solely within the discretion of the Government.

It is anticipated that an award will be issued to Remcom within approximately ten (10) days after the date of this notice unless the Government determines that any other organization has the capability to meet this requirement.

Response Date: August 2, 2021 by 5:00PM Eastern Time. Please email responses to Kimberly Pennix at kimberly.pennix@fda.hhs.gov. No phone calls will be accepted.

STATEMENT OF NEED
OSEL Procurement Request Form
Remcom Yearly Maintenance and Support
March 31, 2021

1. BACKGROUND

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable, and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health. CDRH assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

The Office of Science and Engineering Laboratories (OSEL) supports the CDRH mission of protecting and promoting public health. OSEL undertakes the highest quality science to provide our customers with the best methods, tools and expertise to:

- Ensure readiness for emerging and innovative medical technologies
- Develop appropriate evaluation strategies and testing standards
- Create accessible and understandable public health information
- Deliver timely and accurate decisions for products across their life cycle

The Division of Biomedical Physics (DBP) investigates gender-based differences in cardiac resynchronization therapy for pacemakers, development of phantoms (physical models) to assess the measurement of eye disease by optical imaging systems, evaluation and improvement of electrode reliability in neural prosthetics used to control artificial limbs, and computational modeling of active and passive implants to determine if unsafe levels of heating arise during a patient's exposure to magnetic resonance imaging (MRI) systems. These serve the Center's mission of advancing regulatory science, facilitating consistent and efficient regulatory pathways, and assuring continued access to safe, effective, and high-quality medical devices.

Specifically, DBP focuses on device issues that involve:

- Biomedical and tissue optics
- Biophysics and electrophysiology
- Electrical engineering
- Functional device performance and human factors, and
- Wireless communication and electromagnetic interference and compatibility

The Electromagnetics and Wireless Laboratory (EMW) in the FDA's DBP is, among other things, responsible for analyzing the exposure of people – patients, medical care providers and the public – to sources of electromagnetic radiation. XFDTD is a computational modeling software suite that is used to calculate and visualize the behavior of three-dimensional (3D) models of medical devices and people when they are exposed to electromagnetic (EM) fields. Under the FDA's guidance, the DBP uses XFDTD's primary tools to analyze computer simulations using high resolution models of the human body. XFDTD is used extensively in numerous investigations which include:

- Magnetic Resonance Imaging (MRI) safety
- Electromagnetic compatibility (EMC)
- Human exposure to electromagnetic fields from sources such as cell phones, metal detectors, and Radio Frequency Identification (RFID)
- Radio frequency ablation safety and effectiveness
- Hyperthermia safety and effectiveness

The CDRH/OSEL/DBP owns two XFDTD licenses, and continued software upgrades and technical support are essential for the continuation of these investigations. The objective of this requisition is to obtain hotline and upgrade support for our two XFDTD licenses.

2. STATEMENT OF BUSINESS NEEDS

Item: The FDA is looking to purchase maintenance services (hotline and upgrade support) on two XFDTD licenses with graphics processing unit (GPU) acceleration options.

Technical support shall be included in the cost of the license. A representative sample of technical support includes following services:

- Provide expert advice and best practice recommendations on how to use the software
- Participate in Root cause identification
- Provide 1:1 training support on specific problems
- Resolve user access problems: login issues and password resets
- Maintain a list of users
- Assign permission rights
- Troubleshoot issues
- Track volume of calls
- Maintain an issue log
- Track the time it takes to resolve issues
- Issue customer satisfaction surveys

The Contractor shall also provide Software upgrade license and support or the equivalent solution that meets the following salient characteristics:

- The Contractor shall provide product roadmap and upgrade path to the latest version available
- Program updates, fixes, security alerts, critical patch updates, and configuration-specific updated recommendations.
- Include upgraded scripts
- Include major product and technology releases, including but not limited to general
- Include maintenance releases, selected functionality releases, and documentation updates
- Include assistance with service requests 24 hours per day, 7 days a week, including the ability to log service requests online.

NOTE to Contractor: Before the contract is awarded, we are required to get Pre-Approval of all the IT Hardware and/or Software-Firmware-Freeware from the FDA Chief Information Officer (CIO). For IT Hardware, this includes any device that process or stores data or controlled by data (computers/data switches, etc ..) but does not include passive hardware (rack, network cables, power supplies/cords). This will require the applicable contractor to provide a complete list of Hardware and/or Software-Firmware-Freeware that the contractor will use in fulfilling this contract.

This list will need to include:

- IT hardware: Manufacture, nomenclature and model number
- Software (all types): Manufacture, nomenclature and version number

Item(s) rejected by the CIO will need to be changed and the replacement item(s) would need to go through the same approval process.
Deliverables will conform to 36 CFR Part 1194.41, "Information, Documentation and Support," and 36 CFR Part 1194.24 "Video and Multimedia Products" which are of particular importance with regard to all written, graphical or broadcast, video materials or products produced for HHS (to include training). 36 CFR Part 1194.41 outlines the requirements supporting services for products accommodating the communication needs of end-users with disabilities. The deliverables will be provided in Microsoft Word and Adobe PDF formats and compatible with versions currently used at FDA. C.A. Section 508.
This language is applicable to Statements of Work (SOW) or Performance Work Statements (PWS) generated by the Department of Health and Human Services (HHS) that require a contractor or consultant to (1) produce content in any format that could be placed on a Department-owned or Department-funded Web site; or (2) write, create or produce any communications materials intended for public or internal use; to include reports, documents, charts, posters, presentations (such as Microsoft PowerPoint) or video material that could be placed on a Department-owned or Department-funded Web site.

3. CONTRACT TYPE

Firm-Fixed Price

4. ASSEMBLY AND DELIVERY REQUIRMENTS

This quote from Contractor shall include costs of the following services:

The vendor shall supply online and phone support for the resolution of technical questions that the end user may encounter during the period of service. The vendor will supply any periodic updates and bug fixes that are released during the period of service.

The contractor shall provide remote technical support by phone, email, and online Monday through Friday, from 8 a.m. to 5:30 p.m. on federal workdays.

5. PERIOD OF PERFORMANCE

License Type: This is a perpetual license allowing the FDA to use the program indefinitely.
1-year technical support and maintenance: Not to exceed 12 months. The contract's Period of Performance shall be August 9th, 2021 to August 8th, 2022.

The Contractor shall be required to provide technical services on FDA's campus if necessary and upon request.

6. PLACE OF PERFORMANCE

U.S. Food and Drug Administration's
Attention: Joshua Guag
U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Science and Engineering Laboratories (OSEL)
Division of Biomedical Physics
10903 New Hampshire Ave
Building 62, Room 1131
Silver Spring, MD 20993
Phone Number: 301-796-3638
Email: Joshua.guag@fda.hhs.gov

7. SECTION 508 STANDARDS

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) requires Federal agencies to purchase information and communication technologies (ICT) that meet specific accessibility standards. This law helps to ensure that federal employees with disabilities have access to, and use of, the information and data they need to do their jobs. Furthermore, this law ensures that members of the public with disabilities have the ability to access government information and services.

There are three regulations addressing the requirements detailed in Section 508. The Section 508 technical and functional standards are codified at 36 CFR Part 1194 and may be accessed through the Access Board's Web site at http://www.access-board.gov. The second regulation issued to implement Section 508 is the Federal Acquisition Regulation (FAR). FAR Part 39.2 requires that agency acquisitions of Electronic and Information Technology (EIT) comply with the Access Board's standards. The entire FAR is found at Chapter 1 of the Code of Federal Register (CFR) Title 48, located at http://www.acquisition.gov. The FAR rule implementing Section 508 can be found at http://www.section508.gov. The third applicable regulation is the HHS Acquisition Regulation (HHSAR).

Regardless of format, all Web content or communications materials produced for publication on or delivery via HHS Web sites - including text, audio or video - must conform to applicable Section 508 standards to allow federal employees and members of the public with disabilities to access information that is comparable to information provided to persons without disabilities. All contractors (including subcontractors) or consultants responsible for preparing or posting content intended for use on an HHS-funded or HHS-managed Web site must comply with applicable Section 508 accessibility standards, and where applicable, those set forth in the referenced policy or standards documents below. Remediation of any materials that do not comply with the applicable provisions of 36 CFR Part 1194 as set forth in the SOW, shall be the responsibility of the contractor or consultant retained to produce the Web-suitable content or communications material.

Unless an agency exception to this requirement exists, the Contractor must conform to applicable Section 508 standards and must apply best practices associated with Section 508 compliance during the application design, development, and testing phases. The Contractor shall utilize FDA approved tools to verify the compliance with the Section 508 standards and ensure the delivery of the fully compliant products.

The following Section 508 provisions apply to the content or communications material identified in this SON:

- 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/making-files-accessible/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.

8. SOURCE

Remcom Inc. is the developer and only distributor of XFDTD. Remcom is the only possible source for XFDTD maintenance and technical support.
Justin Newton
Remcom, Inc.
315 S. Allen Street, Suite 416
State College, PA 16801
Phone: (814) 861-1308
www.remcom.com
justin.newton@remcom.com

9. POINTS OF CONTACT

Program Point of Contact

Joshua Guag
U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Science and Engineering Laboratories (OSEL)
Division of Biomedical Physics
10903 New Hampshire Ave
Building 62, Room 1131
Silver Spring, MD 20993
Phone Number: 301-796-3638
Email: Joshua.guag@fda.hhs.gov

Contract Officer Representative (COR)

Cedric Hanley
FDA/CDRH/OM/DAS
Acquisition Program Specialist
10903 New Hampshire Avenue
Silver Spring, M.D. 20903
Phone: 301.796.2794
Email: cedric.hanley@fda.hhs.gov