COMBINED SYNOPSIS/SOLICITATION FOR BRAND NAME OR EQUAL COMSOL MULTIPHYSICS SINGLE USER LICENSE
SOLICITATION NUMBER: FDA-20-SOL- 1231199

GENERAL INFORMATION

This is a combined synopsis/solicitation for commercial items prepared in accordance with the Federal Acquisition Regulation (FAR) format in Subpart 12.6, as supplemented with additional information included in this notice. This announcement constitutes the only solicitation; quotes are being requested and a written solicitation will not be issued. In accordance with FAR 13.106-1(b) this is a sole source requirement.

The solicitation number is **FDA-20-SOL- 1231199**.

The associated North American Industry Classification System (NAICS) Code is 511210 Software Publishers; Small Business Size Standard in millions of dollars is $38.5.

SUPPLIES OR SERVICES AND PRICES/COSTS

The US Food & Drug Administration (FDA) intends to issue a Commercial Item Firm Fixed-Price purchase order that meets the following specifications below. Please submit all quotes to be valid until September 30, 2020.

Item	Description	Qty	Unit Price	Amount
1	Brand Name or Equal COMSOL Multiphysics, Single User CPU-locked License (CPU), for one (1) computer. This is a perpetual license.	1		
2	Brand Name or Equal AC/DC Module for use with COMSOL Multiphysics, Single User CPU- locked License (CPU), for one (1) computer. This is a perpetual license.	1		

DESCRIPTION OF REQUIREMENT

Background

The Division of Biomedical Physics needs to acquire a newer version of the multiphysics modeling software and electromagnetic simulation module used to generate three dimensional models of the electric field distribution generated by stimulus electrode current pulses from electrodes across the tissue layers of the retina.

Project Objective: Procure new base multiphysics modeling and mesh generation program with features (add-ons) needed to support simulation with alternating current/direct current (AC/DC) electromagnetics. For modeling the electric field distribution on the retina generated by stimulus electrodes, the base multiphysics modeling program must be able to generate 3- dimensional mesh models of layered tissues, and generate movies of the simulated voltages on the tissue during pulsing. The support electromagnetics module must have the ability to model current

pulses by the electrodes, and be able estimate tissue heating. Other modules can be added later expanding capability.

Technical Requirements:

Note: To be considered equivalent, the software package must possess the following salient characteristics for the needed functionality:

- Base program to develop 3-dimensional meshed models of solids
- Base program has ability to generate movies of simulations in time
- Modules allow modeling AC or DC current pulses generated by electrodes
- Modules allow modeling electric fields (V) or electrical currents (I)
- Modules also have ability to model magnetic fields
- Modules allow estimate of heat transfer into tissue or solid
- Other modules can be added later to add modeling capabilities

Warranty

Warranty: 1-Years Parts and Labor or better

Deliverables and Delivery Requirement

The Contractor shall deliver the item and quantities ordered within 30 days of award. All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and contractor's name. The Contractor shall guarantee that all required materials shall be delivered in immediate new, usable and acceptable condition.

US FDA CDRH DBP
10903 New Hampshire Ave
Attention: Ethan Cohen
10903 New Hampshire
Avenue WO62 Rm 1204
Silver Spring, Maryland 20993
PH: 301-796-2485
Fax: 301-796-9927
Email: ethan.cohen@fda.hhs.gov

Inspection and Acceptance

The Contracting Officer's Representative (COR) designated in the order, will inspect and accept the goods delivered. Inspections and acceptance will occur at the place of delivery. Inspection will include testing of the deliverables to ensure they work. The Government will accept deliverables only if they conform to all terms and conditions of the contract, and satisfy the performance standards detailed within this SOW. The Government will provide written notification of acceptance or rejection within seven (7) business days of receiving the delivery.

The Government will reject non-conforming deliverables/products. The Contractor shall correct any deficiencies within seven (7) calendar days of when the Government issues the rejection notice. If the Contractor cannot correct the deficiencies within the time frame, the Contractor shall immediately notify the COR of the reason for the delay and provide a proposed corrective action plan within ten (10) business days.

Period of Performance

One year from the date of award.

Points of Contact

Program Manager (PM):
Ethan Cohen
US FDA CDRH DBP
10903 New Hampshire Avenue
WO62 RM 1204
Silver Spring, Maryland 20993
PH: 301-796-2485
Fax: 301-796-9927
Email: ethan.cohen@fda.hhs.gov

Contracting Officer's Representative (COR):
Derrick Johnson
US FDA CDRH
10903 New Hampshire Avenue
WO62 RM 4237
Silver Spring, Maryland, 20993
PH: 301-796-5348
Fax: 301-796-9926
Email: Derrick.Johnson@fda.hhs.gov

Contracting Officer's Authority

The Contracting Officer (CO) is the sole person authorized to make or approve any changes in any of the requirements of this order and notwithstanding any provisions contained elsewhere in the order, the said authority remains solely with the CO. In the event the Contractor makes any changes at the direction of any person other than the CO, the change shall be considered to have been made without authority and no adjustment will be made in the order terms and conditions, including price. The CO shall be the only individual authorized to accept nonconforming work, waive any requirement of the order and modify any term or condition of the order. The CO is the only individual who can legally obligate Government funds.

The Contracting Officer's Representative (COR) or Project Officer is not authorized to make any commitments or otherwise obligate the Government or authorize any changes which affect the order price, terms or conditions. The COR/Project Officer is responsible for the technical aspects of the project and serves as technical liaison with the Contractor and is responsible for the final inspection and acceptance, and such other responsibilities as may be specified in the order.

ISSO - FDA Security and Privacy Language for IT Procurements

ISSO Section: 6, Other IT Procurements

B. Information Technology Application Design, Development, or Support

1) The Contractor (and/or any subcontractor) shall ensure IT applications designed and developed for end users (including mobile applications and software licenses) run in the standard user context without requiring elevated administrative privileges.

2) The Contractor (and/or any subcontractor) shall follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.

3) The Contractor (and/or any subcontractor) shall ensure that computer software developed on behalf of HHS/FDA or tailored from an open-source product, is fully functional and operates correctly on systems configured in accordance with government policy and federal configuration standards. The contractor shall test applicable products and versions with all relevant and current updates and patches updated prior to installing in the HHS/FDA environment. No sensitive data shall be used during software testing.

4) The Contractor (and/or any subcontractor) shall protect information that is deemed sensitive from unauthorized disclosure to persons, organizations, or subcontractors who do not have a need to know the information. Information which, either alone or when compared with other reasonably-available information, is deemed sensitive or proprietary by HHS/FDA shall be protected as instructed in accordance with the magnitude of the loss or harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the data. This language also applies to all subcontractors that are performing under this contract.

Invoice Submission

FDA Three-Way Match Invoicing Procedures

A. The contractor shall submit all invoices to:

U.S. FOOD AND DRUG ADMINISTRATION
Attn: Vendor Payments
Division of Payment Services
10903 New Hampshire Ave
WO32 - Second Floor
MAIL HUB 2145
Silver Spring, MD 20993-0002
301-827-3742
FDAVendorPaymentsTeam@fda.hhs.gov

*** Acceptable methods of delivery include: E-mail (preferred) and Standard Mail. Provide a copy marked courtesy to the Technical Point of Contact (TPOC). The TPOC is identified above.

B. Invoices submitted under this contract must comply with the requirements set forth in FAR Clauses 52.232-25 (Prompt Payment) and 52.232-33 (Payment by Electronic Funds Transfer - System for Award Management) and/or other applicable FAR clauses specified herein. To

constitute a proper invoice, the invoice must be submitted on company letterhead and include each of the following:

(i) Name and address of the contractor;

(ii) Invoice date and invoice number;

(iii) Contract/Order number (including a reference to any base award for Indefinite-Delivery/Indefinite-Quantity Contracts or Blanket Purchase Agreements);

(iv) Description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed, including:

(a) period of performance for which costs are claimed;
(b) itemized travel costs, including origin and destination;
(c) any other supporting information necessary to clarify questionable expenditures;
(d) the contractor shall include the award item number for each description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed;

(v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on government bill of lading;

(vi) Terms of any discount for prompt payment offered (Prompt Payment terms other than NET 30);

(vii) Name and address of official to whom payment is to be sent (must be the same as that in the purchase order/award, or in a proper notice of assignment)

(viii) Name, title, and phone number of person to notify in event of defective invoice;

(ix) Taxpayer Identification Number (TIN);

(x) banking routing transit number of the financial institution receiving payment for Electronic funds transfer (EFT);

(xi) Name and telephone number of the FDA Contracting Officer Representative (COR) or other Program Center/Office point of contact, as referenced on the award;

(xii) For all Inspections, Time-and-Materials and Labor-Hour Awards, 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:

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

(1) invoice number, amount, & date submitted
(2) corresponding payment amount & date received

(b) total amount of all payments received to date under the subject contract or order
(c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance;

(xiii) Any other information or documentation required by the award.

C. An electronic invoice is acceptable if submitted in adobe acrobat (PDF) format. All items listed in (i) through (xiii) of this clause must be included in the electronic invoice. Electronic invoices must be on company letterhead and must contain no ink changes and be legible for printing.

D. Questions regarding invoice payments should be directed to the 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.

Section 508 Standard Compliance

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.

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) requires Federal agencies to purchase electronic and information technologies (EIT) 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 or PWS, shall be the responsibility of the contractor or consultant retained to produce the Web-suitable content or communications material.
The following Section 508 provisions apply to the content or communications material identified in this SOW or PWS:

- Subpart B, 1194.21 - Software Applications and Operating Systems
- Subpart C, 1194.31 - Functional Performance Criteria
- Subpart D, 1194.41 - Information, Documentation, and Support

Clauses

The following FAR Clauses are applicable to this task order. Where they do not appear in full text, the clauses are incorporated by reference. The full text of the FAR can be viewed at: https://www.acquisition.gov/

52.204-23-Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018)
52.212-4 Contract Terms and Conditions—Commercial Items (Jan 2017)
52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items (Jan 2018)
52.227-19 – Commercial Computer Software License (Dec 2007)
52.232-39 – Unenforceability of Unauthorized Obligations (Jun 2013)
52.232-33 Payment by Electronic Funds Transfer— System for Award Management (Jul 2013) (31 U.S.C. 3332)
52.232-40 Providing Accelerated Payments to Small Business Subcontractors (Dec 2013)

The following HHSAR Clauses are applicable to this task order. Where they do not appear in full text, the clauses are incorporated by reference. The full text of the HHSAR can be viewed

at: https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html

352.202-1 Definitions (January 2006)
352.203-70 Anti-lobbying (January 2006)
352.224-70 Privacy Act (January 2006)
352.222-70 Contractor Cooperation in Equal Employment Opportunity Investigations (January 2010)
352.231-71 Pricing of Adjustments (January 2001)
352.239-70 Standard for Security Configurations (January 2010)
352.239-71 Standard for Encryption Language (January 2010)
352.239-73 Electronic and Information Technology Accessibility (January 2010)

Provisions

52.252-1 – Solicitation 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 offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror 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 address
https://www.acquisition.gov/far/current/html/FARTOCP52.html#wp372482

52.209-11 Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law
52.211-6 Brand Name or Equal (Aug 1999)
52.212-1 Instructions to Offerors—Commercial Items (Jan 2017)
52.212-2 Evaluation—Commercial Items (Oct 2014)
52.212-3 Offeror Representations and Certifications-Commercial Items (Nov 2017)

352.239-73 Electronic and Information Technology Accessibility Notice (December 18, 2015)

Instructions to Quoters and Evaluation Criteria

The Government intends to award a firm-fixed price purchase order resulting from this solicitation to the responsible offeror whose offer conforming to the solicitation will be most advantageous to the Government, price and other factors considered. Contractor selection will be based on the lowest price technically acceptable (LPTA) offer that can “meet or exceed” the requirements stated in this solicitation. The Government reserves the right to award without discussions. The following factors shall be used to evaluate offers:

1. Technical Features Meeting/Exceeding Salient Requirements (Brand Name or Equal)

2. Total Price (all CLINs shall be priced)

All responsible vendors are encouraged to submit a response to this notice by no later than 2:00pm EST Friday, July 10, 2020. FDA will consider all responses received prior to the closing date of this notice and will use responses to determine whether it is necessary to use full and open competition for this requirement. For further information or to submit a response please contact Contract Specialist Peter Lee by email at Peter.Lee@FDA.HHS.GOV.