

Subject: FDA Analysis and Evaluation Support

Solicitation Number: FDA1071398

PART 1 – DESCRIPTION

THIS IS A COMBINED SYNOPSIS/SOLICITATION FOR COMMERCIAL ITEMS PREPARED IN ACCORDANCE WITH THE FORMAT IN FAR SUBPART 12.6-STREAMLINED PROCEDURES FOR EVALUATION AND SOLICITATION FOR COMMERCIAL ITEMS-AS SUPPLEMENTED WITH ADDITIONAL INFORMATION INCLUDED IN THIS NOTICE. THIS ANNOUNCEMENT CONSTITUTES THE ONLY SOLICITATION; QUOTATIONS ARE BEING REQUESTED, AND A WRITTEN SOLICITATION DOCUMENT WILL NOT BE ISSUED. THIS SOLICITATION IS BEING ISSUED USING FAR PART 15 PROCEDURES.

This solicitation is a Request for Quote (RFQ). The solicitation document and incorporated provisions and clauses are those in effect through Federal Acquisition Circular 05-44.

The associated North American Industrial Classification System (NAICS) code for this procurement is 541690.

This is an RFQ for scientific consulting support and analysis. The requirement is for full and open competition multiple award as a result of this combined synopsis/solicitation that will include the terms and conditions that are set in PART 3. There will be a maximum of three (3) awardees.

PART 2 – SUPPLIES OR SERVICES AND PRICES/COSTS

2. DESCRIPTION OF SUPPLIES & SERVICES

- 2.1. The FDA has a requirement for expert consultants to perform analytical, evaluation and technical assistance tasks to the FDA.
- 2.2. Contract Type
 - 2.2.1. IDIQ contract vehicle with the issuance of Labor Hours or Fixed-Price task orders.
- 2.3. Pricing Terms
 - 2.3.1. Supply fully burdened hourly rates for the labor categories. The Offeror may propose additional labor categories provided that their inclusion is justified. Additional instructions regarding the pricing format are in PART 11.
- 2.4. Minimum Amount Commitment
 - 2.4.1. The IDIQ contract includes an initial obligation of funds in the amount of \$10,000.00 to each awardee to cover the minimum order guarantee over the 5 year ordering period.
- 2.5. Maximum Contract Ceiling
 - 2.5.1. This is a Multiple Award; IDIQ Contract will have an overall ceiling price of \$9.2 Million. The maximum aggregate dollar value of the task orders awarded to all Contractors can not exceed the established contract ceiling.

	Fully Burdened Hourly Rates				
Labor Categories	Year 1	Year 2	Year 3	Year 4	Year 5
Project Manager I	\$	\$	\$	\$	\$
Project Manager II	\$	\$	\$	\$	\$
Systems Analyst	\$	\$	\$	\$	\$
Mid Level Analyst	\$	\$	\$	\$	\$
Sr. Analyst	\$	\$	\$	\$	\$
Statistician	\$	\$	\$	\$	\$
Technical Writer	\$	\$	\$	\$	\$

PART 3 – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

OBJECTIVES

FDA's objective is to engage expert consultants to perform specific analytic, evaluation and technical assistance tasks to support timely and efficient performance of activities supporting the human drug programs. This includes programs and activities reauthorized or established under the FDA Amendments Act (FDAAA) of 2007. This contract is to provide technical assistance to support, evaluate and improve FDA/CDER programs and processes, including new processes undertaken to implement FDAAA.

3. Technical Requirements:

3.1. Technical Approach

- 3.1.1. The contractor shall furnish the personnel, services, facilities, except as provided in the schedule, required for or incident to the performance of the work as described below. The contractor shall be prepared to develop a response to individual requests for task order proposals as set forth in PART 3.1.3 below. This will be a task order type contract extending for a five year ordering period.
- 3.1.2. This contract will be used for awarding tasks for analytic studies (e.g. - methodology development, testing and implementation) and process development initiatives (e.g. - modification and optimization, testing and implementation support) and technical assistance. The scope of this contract includes all aspects of data identification/ analysis and modeling and program evaluation studies determined to be necessary to support FDA drug programs.
- 3.1.3. The contractor shall specify the methods it will employ to accomplish the key tasks of each task order. The contractor shall perform the following tasks:
 - 3.1.3.1. Provide technical assistance in identifying, developing, enhancing, applying, validating or otherwise evaluating, and implementing advanced analytic methods to address the specific issues, challenges, and objectives outlined for each task.
 - 3.1.3.2. Develop a study design and plan, applying principles and methods that include, but are not limited to, advanced statistical methods including both Classical and Bayesian statistics, statistical process control, operations research, risk analysis, sensor systems and signal processing, artificial intelligence, modeling and simulation, and other mathematical, statistical or engineering methods as appropriate for each task.
 - 3.1.3.3. Conduct sophisticated modeling and analysis, or develop new methods and models, applying principles and methods that include, but are not limited to, advanced statistics including both Classical and Bayesian statistics, statistical process control, operations research, risk analysis, sensor systems and signal processing, artificial intelligence, modeling and simulation, and other mathematical, statistical or engineering methods as appropriate for each task.
 - 3.1.3.4. Develop data identification and access plans that include the kinds, and availability of, data necessary to complete the specified analytic task and related evaluation.
 - 3.1.3.5. Conduct survey and analysis of existing literature and other sources of information relevant to identified characteristics of information, decision-making, operations issues, regulatory activities, system performance, or other factors pertinent to the specified task.
 - 3.1.3.6. Conduct reviews of relevant primary data, focusing on information characteristics of the data, including non-clinical and clinical data collected in clinical studies, if required for the specific task.
 - 3.1.3.7. Depending on the focus of the specified task, identify and analyze potential advantages and disadvantages of existing/proposed methods for data extraction, signal

- detection, pattern recognition, application of optimal estimation theory, statistical process/quality control, or other specified methods, to specified regulatory activities.
- 3.1.3.8. Provide regular briefings to the agency on draft deliverables and findings, e.g., following literature reviews, proposed approaches to analysis, the findings of conducted analyses, and other tasks, to obtain agency input.
- 3.1.3.9. Provide technical assistance to support not only the development and evaluation of the potential application of these advanced methods, but also support the piloting and full-scale implementation of these methods in FDA regulatory operations, as appropriate, and required by FDA for a given task.
- 3.1.3.10. Develop an evaluation study design and plan including retrospective and prospective analyses and comparisons of performance as appropriate for each task.
- 3.1.3.11. Develop draft reports and final letters and other documents per agency-specified requirements.
- 3.1.3.12. Analyze program parameters as appropriate (e.g., time to agency response versus time frames prescribed in FDAAA) using FDA data systems.
- 3.1.3.13. Evaluate implementation procedures and corresponding training programs using performance metrics.
- 3.1.3.14. Evaluate the system impact of changes in agency processes, including the resource impact and value of changes to FDA and applicants.
- 3.1.3.15. Provide routine briefings to designated FDA/CDER staff on the progress of work under specified task orders, analysis findings, and other contract deliverables.

3.2. General examples of tasks include the following:

- 3.2.1. Develop and apply advanced mathematical approaches to analysis of data related to drug safety and effectiveness from all available sources at each stage of the drug life cycle.
- 3.2.2. Apply new signal detection technologies and methodologies to safety analysis and post-market observational data.
- 3.2.3. Apply engineering and systems dynamics approaches to problem-solving, safety issue prioritization, workload management, and other regulatory operations issues.
- 3.2.4. Develop and apply advanced pattern-recognition algorithms to enhance post-market safety surveillance and signal detection, including analysis of patterns of medical care associated with safe use versus safety problems.
- 3.2.5. Develop and apply algorithms for analysis of health care delivery system and drug product design features associated with safe use versus safety problems.
- 3.2.6. Identify, assess and evaluate available data on the supply chain, manufacture, and quality assurance of imported drug ingredients, intermediates, and finished drug products, to improve understanding of commercial trends, enable risk-based prioritization of oversight and surveillance activities, including development of portable analytical technology to rapidly screen suspicious imported ingredients.
- 3.2.7. Identify or develop risk assessment and management tools to facilitate reviews, inspections related to the implementation of new process and analytical technologies.
- 3.2.8. Improve quality of data sources on post-market product defects, and algorithms to detect emerging risks. Analyze data on product defects and adverse events to facilitate development of cause/effect relationships which may reveal common manufacturing failure modes and product defects that are ultimately linked to adverse events. Develop risk models and feed the acquired information into risk models to enhance the scientific basis for review and inspection decisions related to product safety/quality risk mitigation decisions, and prioritize oversight activities.
- 3.2.9. Develop standardized decision-making approaches for regulatory review work processes.
- 3.2.10. Conduct process evaluation and make recommendations to support the re-design of relevant supporting operational systems across CDER.

- 3.2.11. Create and implement a CDER specific repository designed for ease of access to regulatory history and decision-making tools and information.
- 3.2.12. Develop training materials for FDA staff to ensure that staff have a full understanding, proficiency and confidence in the application and interpretation of the data and findings resulting from application of the advanced methods and models developed under a given contractor task.

3.3. Task Order Placement Procedures

- 3.3.1. When contractual services are required within the scope of the contract arises, the FDA will issue a Request for Task Order Proposal (RTOP). Pursuant to the fair opportunity requirements of PAR 16.505, FDA will provide all contract holder fair opportunity to compete for each task order. The process for awarding task orders will be as follows:
 - 3.3.1.1. FDA will issue an RTOP via email. The RTOP will include a SOW, the period of performance, the anticipated order type (Labor Hour or Firm Fixed Price) and any special terms and conditions applicable to the task order.
 - 3.3.1.2. Unless otherwise specified in the RTOP, all proposals are due 10 calendar days after the issuance of the RTOP.
 - 3.3.1.3. Contractors have three days in which to submit any questions about the RTOP.
 - 3.3.1.4. The Contractors shall submit proposals via email. Each proposal shall include a description of the Contractor's approach to the task; a schedule of deliverables, resumes of any key personnel proposed and price build up. The price build up should include the labor categories to be utilized, the number of hours in each labor category, extended pricing for each labor category and a bottom line price/ceiling.
 - 3.3.1.5. FDA will evaluate the responses and award the task order to the vendor whose proposal represents the best value to the FDA, technical and price factors considered. FDA will consider the following technical factors: technical approach; whether the labor mix is appropriate; whether the level of effort is suitable, and whether any key personnel proposed have the requisite experience.
 - 3.3.1.6. Each task order issued shall contain the following information: Task Order Number, Task Order Date, Accounting/Appropriation data, SOW, Deliverables, Price/Ceiling, Period of Performance, Delivery Instructions, and Special Terms/Conditions Unique to the Task Order.
- 3.3.2. The Contracting Officer is the only person authorized to place task orders.
- 3.3.3. The Contractor shall not commence work on a task order until it is fully executed by a Contracting Officer or the Contracting Officer has been given a verbal order to proceed to the Contractor. If any performance difficulties are anticipated or arise due to the terms and conditions of the task order, the Contractor shall promptly notify the Contracting Officer. Each task order shall be treated, for purposes of payment and expenditure, as an independent document.

3.4. Orders Under Multiple Award Contracts - Fair Opportunity

- 3.4.1. Each IDIQ Contract awardee will be afforded a fair opportunity to compete for all task orders within the awarded labor category exceeding \$3,000 unless one of the following statutory exceptions applies (See FAR 16.505 (b)(2)):
 - 3.4.1.1. The agency need for the supplies or services is so urgent that providing a fair opportunity would result in unacceptable delays.
 - 3.4.1.2. Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.
 - 3.4.1.3. The order must be issued on a sole-source basis in the interest of economy and efficiency because it is a logical follow-on to an order already issued under the

- 3.4.1.4. It is necessary to place an order to satisfy a minimum guarantee.
- 3.4.2. Selection criteria for task order awards will be based on a “best value” evaluation with the final award decision made by the Contracting Officer (CO). The CO will consider technical content, personnel skills/experience/past performance, and cost/price in making each task order award.
- 3.4.3. The Contractor shall establish and execute the technical approach, organize resources, and establish and execute management controls to ensure the cost, performance, and schedule requirements of each task order are met.
- 3.4.4. The Contractor shall provide continuous oversight and tracking of the cost, schedule, and performance status of the individually tasked efforts. The Contractor shall adhere to the reporting requirements in Part 4, paragraph 4.6 Reports/Deliverables.
- 3.4.5. The designated FDA Task Order Ombudsman is Russ Abbott.

3.5. Staffing and Key Personnel

- 3.5.1.1. The key personnel for this contract will be designated at the Task Order level. The Contractor shall comply with the terms of HHSAR Clause 352.270-5, incorporated into PART 9.3 of this contract.
- 3.5.1.2. Labor Categories are as follows:

Project Manager I	
Task Responsibility	* Provides analysis, assessment, technical or business area expertise * Proficient or unique knowledge in areas including, but not limited to process evaluation, analysis functions, biostatistics, finance, accounting, information technology, software capability, research and analysis, or other program support fields. * Possesses complex understanding of federal business practices and ability to analyze, evaluate and implement systems or processes. * Leads teams and supervises employees that will process business requirements, to include, but not limited to, analysis, evaluation and implementation of projects, programs or processes. * Plans, designs, and conducts studies to include risk analysis, contingency planning and feasibility studies. * Creates high-quality presentations and reports. * Strong analytical and critical-thinking skills. * Works directly with Project Manager and Sr. Managers. * Proficiency in MS Office including: Word, Excel, PowerPoint, and Outlook.
Years of Experience	Minimum Experience: Must have 5+ years of experience or 9 plus years of experience without a degree. May substitute MS degree for 2 years of experience. Requires knowledge of techniques and tools of analysis, for example, modeling and simulation, operations research techniques, functional decomposition, surveys, business process reengineering, and policy analysis.

Project Manager II	
Task Responsibility	* Manages a team of professionals in providing a wide range of services. * Manages assigned projects within scope and budget. * Responsible for all aspects of project performance (e.g. - technical, contractual, administrative, financial, etc). * Provides leadership to the project team, ensures conformance to performance requirements. * Knowledgeable and possesses direct experience with the evaluation of operational requirements relative to specific field of expertise required within the program guidance and review process. * Able to multi-task and prioritize work assignments with minimal supervision. * Proficiency in MS Office including: Word, Excel, PowerPoint, and Outlook.
Years of Experience	Minimum Experience: Must have at least 5+ years of relevant work experience and an undergraduate degree in a management field. PMP certification preferred.
Systems Analyst	
Task Responsibility	* Provides analysis and research to specific projects. Conducts analysis of complex business processes and data processing requirements to develop functional requirements documents. * Understands systems development lifecycle and is capable of developing testing plans and conducting acceptance testing for new systems. * Possesses basic knowledge in specialized technical fields. * Supports managers on a variety of tasks and projects to meet project deadlines * Analyzes data and presents data in reports. * Assist in the development of documents and reports. * Maintain databases and contact information. * Responsible for collecting, analyzing and interpreting data. * Knowledge of Web development programming tools, including HTML.
Years of Experience	Minimum Experience: Must have at least 5+ years of relevant work experience and an undergraduate degree in software development, information technology, computer science, operations research science, and/or systems analysis.
Mid Level Analyst	
Task Responsibility	* Provides knowledge and experience relevant in management consulting, facilitation, survey, analysis, and related activities. Applies intermediate knowledge of the subject matter to analyze and solve problems in areas including but not limited to finance, accounting, information technology, human resources, contracting/procurement, research and analysis, or other program support fields. * Assists in leading teams with business requirements and analysis, evaluation and implementation of systems or processes. * Plans, designs, and conducts studies to include risk analyses, contingency planning and feasibility studies. * Assist in presentations and creating budgets and complex spreadsheets * Analyzes data and presents data in reports. * Assist in the development of documents and reports.
Years of Experience	Minimum Experience: Must have at least 5+ years of relevant work experience and an undergraduate degree in a related field such as operations research. PMP certification preferred.

Senior Analyst	
Task Responsibility	* Experience relevant in management consulting, facilitation, survey, analysis, process improvement, benchmarking, quality systems and related activities. * Applies intermediate knowledge of the subject matter to analyze and solve problems in relevant areas as specified in task orders. * Assists in leading teams with business requirements and analysis, evaluation and implementation of systems or processes. * Plans, designs, and conducts studies to include risk analyses, contingency planning and feasibility studies. * Leads in the development of presentations and reports. * Analyzes data and presents data in reports.
Years of Experience	Minimum Experience: Must have at least 7+ years of relevant work experience and an undergraduate degree in a related field. PMP certification preferred.
Statistician	
Task Responsibility	* Designs methodology, oversight of data collection efforts, prepares descriptive and analytical reports, documents, and presentations. * Experience in statistical analysis of survey and results. Applies standard sampling techniques to results to determine statistical significance. Creates and validates reports and results.
Years of Experience	Minimum Experience: Must have at least 5+ years of relevant work experience and an undergraduate degree in various software applications. Master's degree preferred in Statistics, Mathematics, Operations Research, Business Management, or other related scientific, technical, or organizational discipline, or equivalent years of experience.
Technical Writer	
Task Responsibility	* Responsible for documentation design, technical materials, manuals, reports, and presentations. * Tasks may include technical writing/editing, editorial consultation, graphics, proofreading, or overall documentation review. Works with project manager to define documentation content and specifications and high attention to detail. * Produces high quality deliverables, reports, and presentations for senior leadership review. * Performs editing to ensure document organization and quality.
Years of Experience	Minimum Experience: Must have at least 5+ years of relevant work experience and an undergraduate degree in a related field such as technical writing. PMP certification preferred.

PART 4 – DELIVERABLES

- Deliverables shall be specified at the Task Order level.

PART 5 – INSPECTION AND ACCEPTANCE

- The Contracting Officer's Technical Representative (COTR) will perform inspection and acceptance of materials and services to be provided.
 - For the purpose of this part, (COTR – to be determined upon contract award) is the authorized representative of the Contracting Officer.
 - Inspection and acceptance will be performed at: the locations identified in Part 6. Acceptance is communicated in writing unless otherwise indicated in writing by the Contracting Officer or the COTR within 30 days of receipt.

PART 6 – DELIVERIES OR PERFORMANCE

6. DELIVERIES

- 6.1.1. Satisfactory performance of this contract shall be deemed to occur upon performance of the work described in the Statement of Work in PART 3 of this contract and upon delivery and acceptance by the Contracting Officer, or the COTR, of the services, plans and reports required at the dates specified within PART 3 of this contract.
- 6.1.2. Deliveries of the reports are to be sent via email to the COTR's address listed below:

Name.lastname@fda.hhs.gov

6.2. PERIOD OF PERFORMANCE

- 6.2.1. The period of performance for this contract vehicle shall be the effective date of contract for a five year ordering period.

6.3. PLACE OF PERFORMANCE

- 6.3.1. The place of performance for this contract shall be at the contractor's site.

PART 7 – CONTRACT ADMINISTRATION DATA

7. CONTRACTING OFFICERS TECHNICAL REPRESENTATIVE (COTR)

- 7.1. The following COTR will represent the Government for the purpose of this contract: (To be determined upon contract award)
 - 7.1.1. The COTR 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 Statement of Work 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.
 - 7.1.2. The Contracting Officer 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.
 - 7.1.3. The contact information for the Contracting Officer is:

David Kordel
5630 Fishers Lane
Rockville, MD 20857
David.kordel@fda.hhs.gov

7.2. INVOICE SUBMISSION

- 7.2.1. In accordance with clause 52.232-33 all payments made under this contract shall be made using electronic funds transfer through the Automated Clearing House (ACH). The Contractor shall provide the following information to the Food and Drug Administration no later than 14 days prior to submission of the first invoice:
 - A. The contractor shall submit all invoices to all addresses in the manner specified below:
 - (I) One original to the Contracting Officer:

U.S. Food and Drug Administration
Office of Acquisitions and Grants Services
ATTN: David Kordel, Contracting Officer
5630 Fishers Lane
Room 2095, HFA-500
Rockville, MD 20857
E-mail: david.kordel@fda.hhs.gov

*** Acceptable methods of delivery include: mail, hand delivery and email***

(II) One copy to the contracting officer technical representative (COTR), clearly marked "Courtesy Copy Only":

U.S. Food and Drug Administration
ATTN: [INSERT NAME], COTR
10903 NEW HAMPSHIRE AVENUE
ROOM XXXX
Silver Spring, MD 20993
Email: xxxx.xxxx@fda.hhs.gov

*** Acceptable methods of delivery include: mail, hand delivery and email***

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 – Central Contractor Registration) 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) Purchase order/award number;
- (IV) Description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed, including:
 - (a) Period of performance for high costs claimed;
 - (b) Itemized travel costs, including origin and destination;
 - (c) Any other supporting information necessary to clarify questionable expenditures;
- (V) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped to Government bill of lading;
- (VI) Terms of any discount for prompt payment offered;
- (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 the person to notify in the event of a defective invoice;
- (IX) Taxpayer identification number (TIN);
- (X) Electronic funds transfer (EFT) banking information, including routing transit number of the financial institution receiving payment and the number of the account into which funds are to be deposited;
- (XI) Name and telephone number of the FDA Contracting Officer Technical Representative (COTR), as referenced on the purchase order;
- (XII) Any other information or documentation required by the purchase order/award.
- (XIII) Contractor is ☐ is not ☐ 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, and date submitted

- (2) Corresponding payment amount and 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.

C. An electronic invoice is acceptable if in Adobe Acrobat (PDF) format. All items listed in (I) through (XII) 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 FDA Payment Office at:

FDA/OC/OA/OFO/OFS
ATTN: Division of Payment Services
12345 Parklawn Drive, HFA-720
Rockville, MD 20857
301.827.3742 OR 866.807.3742
fdavendorpaymentsteam@fda.gov

7.2.2. Final payments will occur upon verification by the FDA Project Officer and the FDA Technical Advisor, noting successful integration and proper functionality of the laboratory equipment.

7.2.3. Payment will be made after acceptance and receipt of a proper invoice, and in accordance with the pricing matrix described in Pricing Terms.

7.2.3.1. Payment will be made on a task order basis in accordance with the pricing matrix.

7.3. GOVERNMENT FURNISHED PROPERTY

7.3.1.1. FDA will provide any Government Furnished Property that the Contractor will need to perform at the Task Order level.

7.4. SECTION 508

7.4.1.1. Pursuant to the HHSAR clause at 352.270-19 incorporated into PART 3 of the underlying contract, the following Section 508 standards apply at the Task Order level:

- 7.4.1.1.1. Software applications and operating systems
- 7.4.1.1.2. Web-based intranet and internet information and applications
- 7.4.1.1.3. Functional performance criteria
- 7.4.1.1.4. Information, documentation, and support

PART 8 – SPECIAL CONTRACT REQUIREMENTS

- **Reserved**

PART 9 – CONTRACT CLAUSES

9. FAR CLAUSES INCORPORATED BY REFERENCE

9.1. 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: www.acquisition.gov/far/index.html

52.212-4(i) Contract Terms and Conditions-Commercial Items (Jun 2010)
(ii) Alternate I (Oct 2008) of 52.212-4
52.216-24, Limitation of Government Liability (Apr 1984)
52.216-31, Time and Materials/Labor Hours Proposal Requirements – Commercial Items Acquisition (Feb 2007)
52.233-3, Protest After Award (Aug 1996)

9.2. FAR CLAUSES BY FULL TEXT

52.212-5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders - Commercial Items.
As prescribed in 12.301(b)(4), insert the following clause:

Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items (Jul 2010)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) [52.222-50](#), Combating Trafficking in Persons (Feb 2009) ([22 U.S.C. 7104\(g\)](#)).

Alternate I (Aug 2007) of [52.222-50](#) ([22 U.S.C. 7104\(g\)](#)).

(2) [52.233-3](#), Protest After Award (AUG 1996) ([31 U.S.C. 3553](#)).

(3) [52.233-4](#), Applicable Law for Breach of Contract Claim (OCT 2004) (Pub. L. 108-77, 108-78).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

___ (1) [52.203-6](#), Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) ([41 U.S.C. 253g](#) and [10 U.S.C. 2402](#)).

___ (2) [52.203-13](#), Contractor Code of Business Ethics and Conduct (Apr 2010) (Pub. L. 110-252, Title VI, Chapter 1 ([41 U.S.C. 251 note](#))).

___ (3) [52.203-15](#), Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (June 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

___ (4) [52.204-11](#), American Recovery and Reinvestment Act—Reporting Requirements (Jul 2010) (Pub. L. 111-5).

___ (5) [52.219-3](#), Notice of Total HUBZone Set-Aside (Jan 1999) ([15 U.S.C. 657a](#)).

___ (6) [52.219-4](#), Notice of Price Evaluation Preference for HUBZone Small Business Concerns (JULY 2005) (if the offeror elects to waive the preference, it shall so indicate in its offer) ([15 U.S.C. 657a](#)).

___ (7) [Reserved]

___ (8)(i) [52.219-6](#), Notice of Total Small Business Set-Aside (June 2003) ([15 U.S.C. 644](#)).

___ (ii) Alternate I (Oct 1995) of [52.219-6](#).

___ (iii) Alternate II (Mar 2004) of [52.219-6](#).

___ (9)(i) [52.219-7](#), Notice of Partial Small Business Set-Aside (June 2003) ([15 U.S.C. 644](#)).

___ (ii) Alternate I (Oct 1995) of [52.219-7](#).

___ (iii) Alternate II (Mar 2004) of [52.219-7](#).

___ (10) [52.219-8](#), Utilization of Small Business Concerns (May 2004) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)).

___ X (11)(i) [52.219-9](#), Small Business Subcontracting Plan (Apr 2008) ([15 U.S.C. 637\(d\)\(4\)](#)).

___ (ii) Alternate I (Oct 2001) of [52.219-9](#).

___ (iii) Alternate II (Oct 2001) of [52.219-9](#).

___ (12) [52.219-14](#), Limitations on Subcontracting (Dec 1996) ([15 U.S.C. 637\(a\)\(14\)](#)).

___ (13) [52.219-16](#), Liquidated Damages - Subcontracting Plan (Jan 1999) ([15 U.S.C. 637\(d\)\(4\)\(F\)\(i\)](#)).

___ (14)(i) [52.219-23](#), Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (OCT 2008) ([10 U.S.C. 2323](#)) (if the offeror elects to waive the adjustment, it shall so indicate in its offer).

___ (ii) Alternate I (June 2003) of [52.219-23](#).

___ (15) [52.219-25](#), Small Disadvantaged Business Participation Program - Disadvantaged Status and Reporting (Apr 2008) (Pub. L. 103-355, section 7102, and [10 U.S.C. 2323](#)).

___ (16) [52.219-26](#), Small Disadvantaged Business Participation Program— Incentive Subcontracting (Oct 2000) (Pub. L. 103-355, section 7102, and [10 U.S.C. 2323](#)).

___ (17) [52.219-27](#), Notice of Total Service-Disabled Veteran-Owned Small Business Set-Aside (May 2004) ([15 U.S.C. 657 f](#)).

___ X (18) [52.219-28](#), Post Award Small Business Program Re-representation (Apr 2009) ([15 U.S.C. 632\(a\)\(2\)](#)).

___ X (19) [52.222-3](#), Convict Labor (June 2003) (E.O. 11755).

___ X (20) [52.222-19](#), Child Labor—Cooperation with Authorities and Remedies (Jul 2010) (E.O. 13126).

___ X (21) [52.222-21](#), Prohibition of Segregated Facilities (Feb 1999).

___ X (22) [52.222-26](#), Equal Opportunity (Mar 2007) (E.O. 11246).

___ X (23) [52.222-35](#), Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Sept 2006) ([38 U.S.C. 4212](#)).

___X (24) [52.222-36](#), Affirmative Action for Workers with Disabilities (Jun 1998) ([29 U.S.C. 793](#)).
 ___X (25) [52.222-37](#), Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Sept 2006) ([38 U.S.C. 4212](#)).
 ___X (26) [52.222-54](#), Employment Eligibility Verification (JAN 2009). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in [22.1803](#).)
 ___ (27)(i) [52.223-9](#), Estimate of Percentage of Recovered Material Content for EPA-Designated Items (May 2008) ([42 U.S.C. 6962\(c\)\(3\)\(A\)\(ii\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
 ___ (ii) Alternate I (May 2008) of [52.223-9](#) ([42 U.S.C. 6962\(i\)\(2\)\(C\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
 ___ (28) [52.223-15](#), Energy Efficiency in Energy-Consuming Products (DEC 2007) ([42 U.S.C. 8259b](#)).
 ___ (29)(i) [52.223-16](#), IEEE 1680 Standard for the Environmental Assessment of Personal Computer Products (DEC 2007) (E.O. 13423).
 ___ (ii) Alternate I (DEC 2007) of [52.223-16](#).
 ___X (30) [52.225-1](#), Buy American Act - Supplies (Feb 2009) ([41 U.S.C. 10a-10d](#)).
 ___ (31)(i) [52.225-3](#), Buy American Act - Free Trade Agreements - Israeli Trade Act (June 2009) ([41 U.S.C. 10a-10d](#), [19 U.S.C. 3301](#) note, [19 U.S.C. 2112](#) note, [19 U.S.C. 3805](#) note, Pub. L. 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, and 110-138).
 ___ (ii) Alternate I (Jan 2004) of [52.225-3](#).
 ___ (iii) Alternate II (Jan 2004) of [52.225-3](#).
 ___ (32) [52.225-5](#), Trade Agreements (AUG 2009) ([19 U.S.C. 2501](#), *et seq.*, [19 U.S.C. 3301](#) note).
 ___X (33) [52.225-13](#), Restrictions on Certain Foreign Purchases (June 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
 ___ (34) [52.226-4](#), Notice of Disaster or Emergency Area Set-Aside (Nov 2007) ([42 U.S.C. 5150](#)).
 ___ (35) [52.226-5](#), Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) ([42 U.S.C. 5150](#)).
 ___ (36) [52.232-29](#), Terms for Financing of Purchases of Commercial Items (Feb 2002) ([41 U.S.C. 255\(f\)](#), [10 U.S.C. 2307\(f\)](#)).
 ___ (37) [52.232-30](#), Installment Payments for Commercial Items (Oct 1995) ([41 U.S.C. 255\(f\)](#), [10 U.S.C. 2307\(f\)](#)).
 ___X (38) [52.232-33](#), Payment by Electronic Funds Transfer - Central Contractor Registration (Oct 2003) ([31 U.S.C. 3332](#)).
 ___ (39) [52.232-34](#), Payment by Electronic Funds Transfer - Other than Central Contractor Registration (May 1999) ([31 U.S.C. 3332](#)).
 ___ (40) [52.232-36](#), Payment by Third Party (Feb 2010) ([31 U.S.C. 3332](#)).
 ___ (41) [52.239-1](#), Privacy or Security Safeguards (Aug 1996) ([5 U.S.C. 552a](#)).
 ___ (42)(i) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) ([46 U.S.C. Appx. 1241\(b\)](#) and [10 U.S.C. 2631](#)).
 ___ (ii) Alternate I (Apr 2003) of [52.247-64](#).
 (c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:
 ___ (1) [52.222-41](#), Service Contract Act of 1965 (Nov 2007) ([41 U.S.C. 351](#), *et seq.*).
 ___ (2) [52.222-42](#), Statement of Equivalent Rates for Federal Hires (May 1989) ([29 U.S.C. 206](#) and [41 U.S.C. 351](#), *et seq.*).
 ___ (3) [52.222-43](#), Fair Labor Standards Act and Service Contract Act - Price Adjustment (Multiple Year and Option Contracts) (Sep 2009) ([29 U.S.C. 206](#) and [41 U.S.C. 351](#), *et seq.*).
 ___ (4) [52.222-44](#), Fair Labor Standards Act and Service Contract Act - Price Adjustment (Sep 2009) ([29 U.S.C. 206](#) and [41 U.S.C. 351](#), *et seq.*).
 ___ (5) [52.222-51](#), Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment - Requirements (Nov 2007) ([41 U.S.C. 351](#), *et seq.*).
 ___ (6) [52.222-53](#), Exemption from Application of the Service Contract Act to Contracts for Certain Services - Requirements (Feb 2009) ([41 U.S.C. 351](#), *et seq.*).
 ___ (7) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (Mar 2009) (Pub. L. 110-247).
 ___ (8) [52.237-11](#), Accepting and Dispensing of \$1 Coin (Sept 2008) ([31 U.S.C. 5112\(p\)\(1\)](#)).
 (d) *Comptroller General Examination of Record*. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at [52.215-2](#), Audit and Records - Negotiation.
 (1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.
 (2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR [Subpart 4.7](#), Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause -

(i) [52.203-13](#), Contractor Code of Business Ethics and Conduct (Apr 2010) (Pub. L. 110-252, Title VI, Chapter 1 ([41 U.S.C. 251 note](#))).

(ii) [52.219-8](#), Utilization of Small Business Concerns (May 2004) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$550,000 (\$1,000,000 for construction of any public facility), the subcontractor must include [52.219-8](#) in lower tier subcontracts that offer subcontracting opportunities.

(iii) [Reserved]

(iv) [52.222-26](#), Equal Opportunity (Mar 2007) (E.O. 11246).

(v) [52.222-35](#), Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Sept 2006) ([38 U.S.C. 4212](#)).

(vi) [52.222-36](#), Affirmative Action for Workers with Disabilities (June 1998) ([29 U.S.C. 793](#)).

(vii) [Reserved]

(viii) [52.222-41](#), Service Contract Act of 1965 (Nov 2007) ([41 U.S.C. 351](#), *et seq.*).

(ix) [52.222-50](#), Combating Trafficking in Persons (Feb 2009) ([22 U.S.C. 7104\(g\)](#)).

Alternate I (Aug 2007) of [52.222-50](#) ([22 U.S.C. 7104\(g\)](#)).

(x) [52.222-51](#), Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (Nov 2007) ([41 U.S.C. 351](#), *et seq.*).

(xi) [52.222-53](#), Exemption from Application of the Service Contract Act to Contracts for Certain Services-Requirements (Feb 2009) ([41 U.S.C. 351](#), *et seq.*).

(xii) [52.222-54](#), Employment Eligibility Verification (JAN 2009).

(xiii) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (Mar 2009) (Pub. L. 110-247). Flow down required in accordance with paragraph (e) of FAR clause [52.226-6](#).

(xiv) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) ([46 U.S.C. Appx. 1241\(b\)](#) and [10 U.S.C. 2631](#)). Flow down required in accordance with paragraph (d) of FAR clause [52.247-64](#).

(2) While not required, the contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

52.217-8 Option to Extend Services (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within the term of the contract.

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; provided that the Government gives the Contractor a preliminary written notice of its intent 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 5 years.

52.216-18, Ordering (Oct 1995)

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from 2010 through 2015.

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) If mailed, a delivery order or task order is considered “issued” when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

52.216-19, Order Limitations (Oct 1995)

(a) Minimum order. When the Government requires supplies or services covered by this contract in an amount of less than \$10,000.00, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) Maximum order. The Contractor is not obligated to honor—

(1) Any order for a single item in excess of \$9 million dollars;

(2) Any order for a combination of items in excess of \$9 million dollars; or

(3) A series of orders from the same ordering office within 2 days that together call for quantities exceeding the limitation in paragraph (b)(1) or (2) of this section.

(c) If this is a requirements contract (i.e., includes the Requirements clause at subsection [52.216-21](#) of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) of this section.

(d) Notwithstanding paragraphs (b) and (c) of this section, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within 2 days after issuance, with written notice stating the Contractor’s intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

52.216-20, Definite Quantity (Oct 1995)

(a) This is a definite-quantity, indefinite-delivery contract for the supplies or services specified, and effective for the period stated, in the Schedule.

(b) The Government shall order the quantity of supplies or services specified in the Schedule, and the Contractor shall furnish them when ordered. Delivery or performance shall be at locations designated in orders issued in accordance with the Ordering clause and the Schedule.

(c) Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.

(d) Any order issued during the effective period of this contract and not completed within that time shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor’s and Government’s rights and obligations with respect to that order to the same extent as if the order were completed during the contract’s effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after 2015.

9.3. HHSAR CLAUSES INCORPORATED BY REFERENCE

This contract incorporates one or more clauses by reference, noted in Title 48, Federal Acquisition Regulations System, 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: <http://www.gpoaccess.gov/cfr/index.html>.

352.202-1, Definitions (Jan 2006)

352.215-70, Late proposals and revisions (Jan 2006)

352.223-70, Safety and health (Jan 2006)

352.224-70, Confidentiality of information (Jan 2006)

352.228-7, Insurance--Liability to third persons (Dec 1991)

352.232-9, Withholding of contract payments (Jan 2006)

352.233-70, Litigation and claims (Jan 2006)

352.242-71, Final decisions on audit findings (Apr 1984)

352.249-14, Excusable delays (Jan 2006)

352.270-1, Accessibility of meetings, conferences, and seminars to persons with disabilities (Jan 2001)

352.270-5, Key Personnel (Jan 2006)

352.270-10, Anti-lobbying (Jan 2006)
352.270-11, Privacy Act (Jan 2006)
352.270-13, Tobacco-free facilities (Jan 2006)
352.270-19, Electronic information and technology accessibility (Jan 2006)

PART 10 – LIST OF ATTACHMENTS

- SBA Subcontracting Form: www.hhs.gov/osdbu/read/SampleSubcontractingPlan.doc

PART 11 – INSTRUCTIONS TO THE OFFERORS

11.1. FAR Provisions Incorporated by Reference

- 11.1.1. This contract incorporates one or more 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. Also, the full text of a clause may be accessed electronically at: www.acquisition.gov/far/index.html:

52.212-1, Instructions to Offerors - Commercial Items (June 2008)

An offeror shall complete only **paragraph (b)** of this provision **if the offeror has completed the annual representations and certifications electronically at <http://orca.bpn.gov>. If an offeror has not completed** the annual representations and certifications electronically at the ORCA website, the offeror shall complete only paragraphs (c) through (m) of this provision.

52.212-3, Offeror Representations and Certifications - Commercial Items (Aug 2009)

11.2. Basic Format

- 11.2.1. The Offeror's quote shall consist of three separate volumes: 1) a technical volume, 2) a cost/price volume and 3) a past performance volume. The technical volume shall consist of four sections: Technical Approach, Representative Resumes, Approach to the Sample Task Order and Relevant Experience.
- 11.2.2. The Technical (Volume 1) and Cost/Price (Volume 2) quotes shall be kept separate from each other. Quotes shall not make reference to pricing data in order that the technical evaluation may be made strictly on the basis of technical merit.
- 11.2.3. The Offeror's email submittal shall contain the appropriate proposal volume in two formats: Word or Excel. Offerors shall not use versions of Microsoft Office products newer than Office 2003.
- 11.2.4. The Offeror shall certify that their attachments have been checked using the latest version of virus detection software and are virus free. The certification shall identify the virus detection software and version used.

11.3. RESPONSE DATES

- 11.3.1. QUESTIONS DEADLINE: All questions shall be submitted via email (david.kordel@fda.hhs.gov) before 4:30 pm (1630) Eastern Time on 20 July 2010.
- 11.3.2. RFQ Due Date: All quotes and revisions shall be submitted via email before 4:30 PM (1630) Eastern Time on 13 August 2010. Offerors shall ensure the RFQ number is visible in the header of the email. FAX QUOTES SHALL NOT BE ACCEPTED.

11.4. Basic Technical Proposal Instructions

11.4.1. The Technical Proposal is limited to 30 pages. The following items are not included in the page limit:

- 11.4.1.1. Cover Sheet;
- 11.4.1.2. A statement from the Offeror verifying that they are CCR Registered under NAICS code 541690;
- 11.4.1.3. Table of Contents;
- 11.4.1.4. Sample Task Order & Pricing (Limited to 18 pages)

11.4.2. All critical information from appendices should be summarized in the technical proposal.

11.4.3. An individual authorized to contractually bind the Offeror shall sign the cover page of the Technical Volume.

11.5. Basic Technical Approach (In descending order of importance)

11.5.1. Section 1: Technical Capability. Instructions - A narrative description of the Offeror's approach to performing the work described in the SOW. The narrative should describe the Offeror's understanding of the project (both from a business and technical standpoint), how the Offeror intends to satisfy the technical requirements. Any risks it foresees in carrying out its approach and mitigation strategies for those risks.

11.5.2. Section 2: Staffing Plan. Instructions - A narrative description of the Offeror's approach to staffing the project. This should include discussion of how it will ensure that it is adequately staffed to start performance within 2 weeks of task order award, how it will have staff "at the ready" for tasks under the sample Task Order.

11.5.3. Section 3: Relevant Experience. Instructions - A narrative description of five (5) examples of experience on current and previous contracts over the past three (3) years which are relevant to this task order in terms of type, scope, complexity, and size. Offerors are encouraged to cite examples of experience that demonstrate the Offeror's ability to overcome difficulties encountered during performance with minimum impact to the program. Relevant experience submissions shall not exceed two pages for each experience provided.

11.5.3.1. In addition to the narrative described above, for each contract provide the following information:

- 11.5.3.1.1. Name of contracting activity (Federal Government agency, local government, commercial customer);
- 11.5.3.1.2. Contract number;
- 11.5.3.1.3. Contract type;
- 11.5.3.1.4. Total contract value;
- 11.5.3.1.5. Contract work (description of experience, degree of involvement, size of the organization, etc.);
- 11.5.3.1.6. Type of analysis/ analytic application;
- 11.5.3.1.7. Contracting Officer contact information (phone, fax, email);
- 11.5.3.1.8. Project Officer/Contracting Officer's Technical Representative contact information (phone, fax, email).

11.5.4. Basic Cost/Price Volume

11.5.4.1. Labor Categories and Rates. Instructions - The pricing data shall be submitted in MS Excel format for verification and evaluation purposes. In addition, all pricing formula, linkages between cells, as well as basis of estimate shall be shown to support

the Offeror's derivation of their proposed pricing. Pasted pricing data shall not be accepted.

11.5.4.2. Pricing for Sample Task Order. Instructions – Pricing data based upon the rates in the base contract.

11.5.4.3. Subcontracting plan, if applicable. Instructions - A completed HHS Subcontracting form, if applicable from the Offeror. The Offeror's approach for any subcontracting possibilities is clearly identified in the form (see PART 10) and that the subcontracting plan is in compliance with FAR 19.704.

11.5.5. Past Performance Volume

11.5.5.1. Past Performance. Instructions - A narrative description the Offeror's overall past performance for the same or similar requirement. Submissions shall not exceed two pages for each experience provided. In addition to the narrative described above, for each contract provide the following information:

11.5.5.1.1. Name of three (3) references (Federal Government agency, local government, commercial customer);

11.5.5.1.2. Contact information (phone, fax, email).

11.5.6. Price Proposal

11.5.6.1. Instructions: The Offeror shall complete a MS Excel Pricing Worksheet. The pricing data meets the requirement set in PART 11.2.2 for the base contract and sample Task Order.

11.5.6.2. The Offeror shall also complete the table in PART 2 to identify the labor categories that it will use to staff work funded under the sample task order.

11.6. Sample Task Order

11.6.1. Section 3: Approach to the Sample Task Order. Instructions - A narrative description of the Offeror's approach for the sample task order. This should describe Quality Systems and Knowledge Management System Benchmarking and how it proposes to manage this task. The offeror shall provide a rationale for its knowledge management systems approach. The offeror shall describe its methodology for managing the task, performance measures it will use to monitor performance, any management tools it will use, how it will ensure quality products are delivered, and how it will communicate with stakeholders.

11.6.2. Background

11.6.2.1. FDA has identified the development and implementation of quality system approaches as a top priority. Knowledge management, including training activities, is a critical element of an effective quality management system. Such a system could also ensure that institutional knowledge from prior regulatory decisions and rationales for past years are captured. In order to support well-informed decision-making in the face of staffing and environmental changes and the increasing complexity of operations, modern tools (e.g., knowledge management system, on-line training) are necessary.

11.6.3. Key Objectives of the Sample Task Order

11.6.3.1. The purpose of this draft project is to understand how quality systems frameworks in environments similar to the FDA are operating and to develop an understanding of the potential utility and applicability of a knowledge management system in the context of a quality management framework. This determination can be enhanced by comparing other organizations (e.g., federal agencies; European

Medicines Agency (EMA) or European member states who have received ISO certifications for drug review programs (e.g., Netherlands, Austria).

11.6.3.2. A knowledge management system could support improved processes in several areas:

- 11.6.3.2.1. Enabling internal communication and collaboration within and across offices;
- 11.6.3.2.2. Driving cultural change from amassing of knowledge to growing of knowledge across the organization
- 11.6.3.2.3. Ensuring that individuals have access to the information they need to accomplish their respective tasks
- 11.6.3.2.4. Documentation of staff technical and regulatory expertise
- 11.6.3.2.5. Facilitating timely external communications with key stakeholder groups, including the public health community, oversight committees, and regulated industry;
- 11.6.3.2.6. Inform staff of existing and new information and knowledge as it is gathered and processed
- 11.6.3.2.7. Document instances and rationales for existing and new precedents as well as justifiable deviations in a decision(s)
- 11.6.3.2.8. Inform staff of evolving regulations, science and technology, including global changes
- 11.6.3.2.9. Reduce the impact of knowledge loss resulting from staff attrition
- 11.6.3.2.10. Enabling consistent, scientifically-sound and defensible decision-making. Were it determined to be needed by Center staff, such a system or tool could serve as a readily-searchable and intuitive repository for past regulatory decision-making;
- 11.6.3.2.11. Serving as a reference guide and training aid for new and current reviewers to reference past regulatory reviews similar to current applications with similar characteristics to understand what types of questions were posited, debates over the merits of various decision-scenarios, and the final decision along with its rationale. The system could also contain all cases of regulatory review precedence and the rationale behind them.

11.6.4. Scope of work of the Sample Task Order

- 11.6.4.1. The contractor shall first perform an internal needs assessment in CDER to determine the need for an intuitive Center-wide knowledge management system. Such a system could support consistent, scientifically-sound and defensible decision-making which could complement other training efforts (e.g., mentoring) for new staff; and to ensure that institutional knowledge is accessible and transferred from experienced staff to continuing staff upon retirement or other discontinuance of service at the Center.
- 11.6.4.2. The contractor shall perform benchmarking of regulatory agencies with profiles similar to that of the FDA that are executing quality management systems.
- 11.6.4.3. The contractor shall perform benchmarking of agencies with similar regulatory mandates to provide an understanding of their knowledge management approaches.
- 11.6.4.4. Additionally, identification of a potential knowledge management tool(s) and quality systems framework will be recommended.

11.6.5. Key Tasks of the Sample Task Order

- 11.6.5.1. The key tasks of the project plan will include the following methods/components:

- 11.6.5.1.1. Conduct internal assessment of knowledge management activities (e.g., precedents documentation efforts in the Offices of Regulatory Policy and Pharmaceutical Science – DARRTS entries)
- 11.6.5.1.2. Perform an assessment to determine needs for knowledge management system (based upon unique needs of review disciplines, internal work processes and interactions, communication needs, and job requirements).
- 11.6.5.1.3. Rank identified needs by mission-criticality and urgency.
- 11.6.5.1.4. If the results of the assessment indicate great need for a knowledge management system, identify what the key characteristics would be for a successful system.
- 11.6.5.1.5. Benchmark comparable regulatory agencies to understand their quality systems frameworks, along with the challenges and advantages of each.
- 11.6.5.1.6. Benchmark comparable regulatory agencies to understand their knowledge management systems, along with the challenges and advantages of each.
- 11.6.5.1.7. Develop recommendations on the most appropriate quality management systems framework, along with recommendations on appropriate knowledge management tool and features (e.g., cataloguing of data and information used as the basis for knowledge) that address mission critical needs.
 - 11.6.5.1.7.1. Propose approach for how to incorporate retrospective consideration and documentation of historical precedents within proposed knowledge management system.
- 11.6.5.1.8. Anticipated hours and labor mixture for the Sample Task Order.

Task to Be Performed	Program Manager	Sr. Analyst	Mid-Analyst	Total Hours
<i>Quality Systems and Knowledge Management System Benchmarking</i>				
1. Conduct internal assessment of knowledge management activities	0.7	7	70	77.7
2. Perform an assessment to determine needs for knowledge management system (based upon unique needs of review disciplines, internal work processes and interactions, communication needs, and job requirements).	4	40	400	444
2a. Rank identified needs by mission-criticality and urgency.				
2b. Identify key characteristics of a successful system.				
3. Benchmark comparable regulatory agencies to understand their quality systems frameworks, along with the challenges and advantages of each	3.2	32	320	355.2
4. Benchmark comparable regulatory agencies to understand their knowledge management systems, along with the challenges and advantages of each	3.2	32	320	355.2
5. Develop recommendations on: most appropriate quality management systems framework; and knowledge management tools and features	1.7	17	170	188.7
5a. Propose approach incorporating retrospective consideration and documentation of historical precedents within proposed knowledge management system				
Subtotal – Number of Total Hours	12.8	128	1280	1420.8

11.6.6. Sample Task Order Period of Performance

- 11.6.6.1. The period of performance shall be a 12 month period of performance.

11.6.7. Sample Task Order Price Proposal

11.6.8. The Offeror shall submit pricing based upon a labor hours vehicle for this sample task order using the fully burdened labor categories in PART 2.

11.6.9. Sample Task Order Deliverables Table

DELIVERABLE	WEEKS AFTER AWARD	FORMAT
1) Kick-Off Meeting	1	MS Powerpoint
2) Meeting with TAG to discuss the draft work plan	2	MS Powerpoint/ MS Visio/ MS Word
3) Final Work Plan	2	MS Powerpoint/MS Visio/MS Word
4) Identify CDER knowledge management efforts within the Center along with the advantages and disadvantages of each system (e.g., expandable, purgeable, etc.)	TBD	
5) Perform an assessment to determine needs for knowledge management system (based upon unique needs of review disciplines, internal work processes and interactions, communication needs, and job requirements). Rank identified needs by mission-criticality and urgency.	TBD	
6) If the results of the assessment indicate great need for a knowledge management system, identify what the key characteristics would be for a successful system.	TBD	
7) Conduct internal assessment of knowledge management activities (e.g., precedents documentation efforts in the Offices of Regulatory Policy and Pharmaceutical Science – DARRTS entries)	TBD	
8) Benchmark comparable regulatory agencies to understand their quality systems frameworks, along with the challenges and advantages of each	TBD	
9) Benchmark comparable regulatory agencies to understand their knowledge management systems, along with the challenges and advantages of each	TBD	
10) Provide recommendations on the most appropriate quality management systems framework, along with recommendations on appropriate knowledge management tool and features (e.g., cataloguing of data and information used as the basis for knowledge) that address mission critical needs. a. Propose approach for how to incorporate retrospective consideration and documentation of historical precedents within proposed knowledge management system	TBD	MS Powerpoint/MS Visio/MS Word
11) Working meetings throughout the contract	TBD	Teleconference/MS Word/MS Powerpoint
12) Weekly Status Reports w/ Action Items	Weekly	Teleconference/ MS Word/Powerpoint
13) Monthly Financial Updates	Monthly	Agency Format
14) General Documentation Support	Throughout the contract	As designated by each deliverable
15) Project Management Support	Throughout the contract	
16) Summary Discussion Forum	TBD	MS Powerpoint

PART 12 – EVALUATION FACTORS FOR AWARD

12. BASIC EVALUATION FACTORS

The offeror's ability to demonstrate/describe the following factors as noted in PART 11.

12.1. FAR Provisions Incorporated by Reference

- 12.1.1. This contract incorporates one or more 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. Also, the full text of a clause may be accessed electronically at: www.acquisition.gov/far/index.html:

52.217-5, Evaluation of Options (July 1990)

The FDA will evaluate technical proposals adjectivally as Exceeds the Requirement, Fully Successful or Fails to Meet the Requirement. Technical approach is significantly more important than price in determining the successful Offeror. However, among equally rated technical proposals, price will be the determining factor.

12.2. Evaluation: Technical Approach

- 12.2.1. The offeror meets or exceeds the requirement to document relevant elements of evaluation and statistical techniques. The approach shall also document the offeror's expertise and methodology for developing and using best practices in benchmarking to evaluate current performance and improve future outcomes. In addition, the offeror has the ability to possess their proposed staffing mix to implement the proposed approach.
- 12.2.2. Offeror meets or exceeds the requirement to document primary data source identification and data access capability and the ability to work with databases of varying sizes and formats.
- 12.2.3. The offeror meets or exceeds the requirement to document both quantitative and qualitative data.
- 12.2.4. Offeror meets or exceeds the requirement to document information on the administration of the project tasks. This shall include management plans, methods for implementing, reviewing and effecting interim adjustments and corrections, and quality control and cost control procedures.
- 12.2.5. The offeror meets or exceeds the requirement to possess computer services that are compatible with IBM PC Systems in a Microsoft Windows XP environment using Microsoft desktop tools.
- 12.2.6. Evaluation – The FDA will evaluate the extent to which the Offeror's proposal demonstrates that it understands the requirement, the risks associated with the requirement, and has proposed a technical solution that is technically sound, logical, likely to be effective, and is proactive in mitigating risks.

12.3. Evaluation: Staffing Plan

- 12.3.1. Actual resumes of personnel proposed in PART 3.5. If actual personnel have not yet been identified, include representative resumes.
- 12.3.2. A listing of the labor categories proposed for and in addition to PART 3.5.
- 12.3.3. The Offeror meets or exceeds the minimum qualifications, education and experience for each labor category proposed.
- 12.3.4. The Offeror meets or exceeds the requirement that it employs the personnel requisite to perform high caliber innovative, exploratory qualitative and quantitative analyses over the range of studies and evaluations presented in Part 3, Scope of Work. The offeror meets the requirement to document key personnel's resumes indicating their names, identify their

qualifications, education and experience, and for each person, indicate the number of hours that would be devoted to this contract.

12.3.5. Offeror meets or exceeds the requirement to possess personnel with direct and relevant experience within the following areas:

12.3.5.1. Process improvement/quality systems design and implementation.

12.3.5.2. The application of advanced approaches including, but are not limited to, advanced statistics (Classical and Bayesian), statistical process control, operations research, risk analysis, sensor systems and signal processing, artificial intelligence, modeling and simulation, and other mathematical, statistical or engineering methods.

12.3.6. Evaluation – The Government will evaluate the Offeror’s proposal to the extent that the personnel proposed have the skills necessary to provide all of the services required. In addition, Offerors will be evaluated on sufficiency of their overall Staffing Plan and the degree to which it reflects a realistic awareness of the level of effort and workload balancing that is required to support the systems described in the sample task order. A highly rated proposal will provide a mix of labor categories that is likely to be both effective and efficient. The FDA will also evaluate the extent to which the Offeror demonstrates that it can staff up quickly and ensure that personnel with the necessary skill sets are available on short notice when work is funded under task order placement.

12.4. Evaluation: Relevant Experience

12.4.1. Offeror meet or exceeds the requirement that it possess experience in conducting innovative, cutting-edge and exploratory studies using sophisticated mathematical and statistical modeling and analysis, developing new methods and models and applying the principles and methods from the identified disciplines (see 3.5.1.2).

12.4.2. The offeror meets or exceeds the requirement to document on time deliverables and within budget and, when applicable, using specified formats.

12.4.3. The Offeror meets or exceeds the requirement to document experience with conducting exploratory studies of the technical merit or feasibility of developing or adapting advanced methods used in other industry sectors or by other government agencies.

12.4.4. The offeror’s ability to meet or exceed the requirement so that their expertise in method innovation and be grounded in experience conducting studies and analysis to optimize performance of time-critical organizational functions or large-scale operations with potential for high impact on public health or safety; experience with analysis of geographically-distributed operations and information monitoring and analysis, that may involve multiple sources with widely varying formats, quality and consistency; and experience with operations pertaining to the pharmaceutical and biotechnology industries, and to health care delivery systems.

12.4.5. Evaluation: The Government will evaluate the extent to which the Offeror’s relevant demonstrates the success of efforts on current and previous contracts, which are relevant to this contract and sample task order in terms of type, scope, complexity, and size. Offerors will also be evaluated on their experience that demonstrates the ability to overcome difficulties encountered during performance with minimum impact to the program.

12.5. Evaluation: Sample Task Order

12.5.1. The purpose of the Sample Task Order Proposal is for Offeror’s to demonstrate their technical capabilities, and “sample” pricing for evaluation purposes only. All offeror’s shall propose against the Sample Task Order Request proposed.

12.5.2. The Sample Task Order Proposal shall contain all the required information to evaluate the Offeror’s capability for performing the required services. The Sample Task Order Technical Proposal shall consist of a summary description of the Offeror’s technical and management approach of meeting the requirements stated in the Sample Task Order

Statement of Work. Exclusive of cover, table of contents, Key Personnel Resumes, and required data item deliverables, the Sample Task Order Technical Volume shall be limited to 15 pages, and limited to 3 pages for pricing. **Please submit the technical volume and price volume attachments separately.** This volume shall describe the Offeror's understanding of the work requirements and provide a summary of its ability to manage this effort. The Offeror shall describe their management approach for oversight of this task order and provide an approach that will be used under this task. The Offeror shall describe the processes and tools that will be applied to the assigned tasks and describe the impact of their application to the project. The Sample Task Order Proposal shall describe the unique Offeror's qualifications, processes, insights, and experiences that will be applied to the tasked efforts.

12.5.3. The Offeror shall include a detailed cost estimate and basis of estimate. All Offeror's labor rates shall be consistent with the Price Proposal as detailed in PART 2.

12.5.4. FDA reserves the right to award the sample task order.

12.5.5. Evaluation - The Government will evaluate the clarity and effectiveness of the Offeror's comprehensive approach to knowledge management systems all aspects of benchmarking and administration and whether the proposal describes a governance structure that meets the project requirements, (including tracking, reporting, and collaboration with FDA and other contractors).

12.6. Evaluation: Contract Sub-contracting Plan, if applicable

12.6.1. Evaluation - The Government will evaluate the subcontracting data and the effectiveness of the Offeror's approach to meeting the small business goals and a partnership that meets the project requirements (see 12.4.5).

12.7. Evaluation: Past Performance

12.7.1.1. The Government will evaluate the extent to which the Offeror's past performance demonstrates overall client satisfaction on current and previous contracts. Ratings for this section are Pass, Fail or Neutral (no past performance history).

12.8. Price Evaluation

12.8.1.1. The Offeror's pricing data meets the requirement set in PART 11.5.3.1 for the base contract and sample Task Order.

12.9. Fair and Reasonable Price

12.9.1.1. The Government will evaluate the Contractor's ability to deliver efficient, risk-free performance at a fair and reasonable price. As part of this evaluation, the Government will evaluate:

12.9.1.1.1. Overall five (5)-year pricing.

12.10. Cost/Price Realism

12.10.1.1. The Government will evaluate the realism of the Contractor's cost/price proposal. "Cost realism" may be determined, in part, by reference to the costs which, under FAR 15.404-1, the Contractor can reasonably be expected to incur in the performance of this effort. Proposed costs may be adjusted for purposes of an evaluation based on cost realism. Cost realism may also be considered in the evaluation of the technical proposal. When technical quality and/or accepted performance appear to be sacrificed within the proposed costs, a cost realism analysis may be performed and subsequently evaluated prior to award. When all other factors are equal, price becomes the determining factor.