# Independent Assessment of FDA Device Review Process Management

# Statement of Work (SOW)

## 1. Background

Pursuant to the Performance Goals and Procedures adopted under the 2012 Medical Device User Fee Amendments (MDUFA III), the Food and Drug Administration (FDA) agreed to participate with the medical device industry in a comprehensive assessment of the process for the review of medical device submissions. The parties, FDA and the medical device industry, agreed to a two-phase assessment to be conducted under an FDA contract by a private, independent consulting firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to objectively assess FDA's premarket review processes.

In the first phase, FDA and the medical device industry will participate in the comprehensive assessment of the process for the review of medical device submissions. FDA will analyze the recommendations of the assessment and implement selected actions as appropriate. FDA also will incorporate the selected outcomes of the assessment into a Good Review Management Practices (GRMP) guidance document. FDA's implementation of the GRMP guidance will include initial and ongoing training of FDA staff and periodic audits of compliance with the guidance. In the second phase, the contractor will evaluate the implementation of recommendations adopted under phase one and publish a written assessment.

The scope and requirements are further described within the sections of this statement of work (SOW).

## 2. Objectives

This requirement is to conduct a comprehensive assessment of FDA premarket review processes for medical devices and to identify opportunities for improvement that will significantly impact the review of device premarket submissions. Primary objectives include:

- Identification of best practices and prioritization of process improvements for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards
- In-depth analyses of the elements of the review process in order to identify best practices and opportunities for improvement, including root cause analyses of selected significant factors
- Assessment of resource allocation to premarket medical device reviews across FDA
- Development of metrics to ensure successful implementation of recommendations and demonstrate achievement of expected results
- Evaluation of the implementation of selected recommendations

## 3. Scope

In conducting the assessment:

- The focus of the study is FDA's management of the medical device review process, i.e., the "business process."
- The contractor's recommendations must draw on sources of information at FDA or external sources of information that are currently available for use. Otherwise, the contractor may make recommendations about specific new information to collect.

- Baseline analysis of MDUFA II submissions, review activities, management processes, and performance shall be conducted to the extent that the analysis will establish a valid, comparable basis for assessing changes under MDUFA III.
- Prospective and real-time analysis of submissions currently under review shall be conducted to the extent that the analysis provides insight into the review management processes and outcomes. This assessment is not intended to duplicate the annual performance assessment that FDA submits to Congress.

Certain actions are beyond the scope of this contract:

- The medical and scientific bases of review decisions are beyond the scope of this study.
- Examination of FDA's methodology for measuring standard costs and FDA's system for time reporting are beyond the scope of this study.
- This study is not intended to serve as a report on FDA's progress toward meeting MDUFA performance goals per se, nor should it duplicate information found in the annual MDUFA performance report to Congress unless there is a specific analytical purpose supported by citing performance information.

## 4. Specific Tasks

The contractor shall assess FDA's premarket review process using an assessment framework that draws from appropriate quality system standards, including management responsibility, document controls and records management, corrective and preventive action, and process control and process validation. Interviews with review staff and industry representatives, as well as observation of meetings between FDA and industry will be part of the data and information gathering process. All data collection tools and methods shall be reviewed by FDA before use.

The assessment will be undertaken in two phases, the first phase of which will consist of several stages, outlined below.

(4.0) The contractor shall develop a project workplan in conjunction with the FDA.

(4.1) The contractor shall conduct a series of assessments and analyses of various aspects of the medical device premarket review process.

(4.2) From these initial assessments and analyses, the contractor shall identify opportunities for improvement, best practices, and areas that require additional assessment.

(4.3) The contractor shall develop findings and recommendations for the improvement of the medical device premarket review process and present these to FDA in two parts: high-priority recommendations shall be presented first, within six months of contract award; this shall be followed by a full report on findings and recommendations within 1 year of contract award.

(4.4) At the time of the final presentation of results to FDA, the contractor shall present an evaluation plan including metrics to assess the implementation and impact of the recommendations adopted.

(4.5) Phase 2 of the contract is contingent upon the contractor's performance during Phase 1 (4.0 – 4.4, outlined above) and will consist of an evaluation of the implementation of the recommendations provided during Phase 1 of the assessment.

Further details for each stage of the assessment are included on the following pages.

**4.0 Workplan**

4.0.1 Develop a project workplan in conjunction with the FDA to accomplish the requirements of this statement of work. The workplan will identify the sources, methods, and metrics to be included in the analysis; specify the schedule of deliverables, including FDA review time of draft materials; detail the sources, methods, and metrics to be used; identify the project personnel and organizational structure; and explain the procedures to be followed to ensure proper communications, reporting, and project management controls.

**4.1 Initial Assessments and Analyses**

4.1.1 Conduct a baseline analysis of MDUFA II submissions, review activities, management systems, and performance. The objective of this analysis is to establish a baseline description of data and prior review management processes that are comparable to MDUFA III data and processes so that a valid assessment of changes from MDUFA II to MDUFA III can be done in Phase 2.

4.1.2 Analyze elements of the current MDUFA III review process (i.e., Q submissions including the Pre-Submission process; clinical laboratory improvement amendments (CLIA) process; and IDE, HDE, 510(k), device BLA, and PMA reviews) that consume or save time to facilitate a more efficient process. This includes:

- Characteristics of the product, submission, submitter, and review team;
- Quality and effectiveness of FDA-applicant interactions, including use of interactive review by various means, i.e., by telephone, by facsimile, by e-mail, and formal requests for additional information by letter;
- Completeness and thoroughness of FDA and applicant documents;
- Analysis of root causes for inefficiencies that may affect review performance and total time to decision; and
- Recommended actions to correct any failures to meet MDUFA goals.

4.1.3 Analysis of the review process shall include considerations specific to the review of combination products, companion diagnostics, and laboratory developed tests, including but not limited to the impact of inter-Center consults and collaborative review on the effectiveness of the review process.

4.1.4 Assess the efficiency and effectiveness of the current IT infrastructure to support and document the performance of complete, high-quality MDUFA submission reviews.

4.1.5 Analyze a variety of review processes, ensuring analyses include trends across divisions, product types, and submission types. Benchmark the review processes at the Center, Office and division level, identifying challenges to and characteristics of an effective and efficient review. Identify and describe the root causes of variation in review practices at all levels. This will be accomplished through random direct observations of the Medical Device Reviewer to uncover non-routine events (NRE); events that deviate from the ideal review process.

4.1.6 Assess FDA methods and controls for collecting and reporting information on premarket review process resource use and performance and, if applicable, make recommendations about specific new information to collect.

4.1.7 Assess the current models and tools used for workload management and recommend improvements to the system if needed.

4.1.8 Assess the effectiveness of FDA's Reviewer Training Program implementation. Include any recommendations for training materials or Standard Operating Procedures.

Provide recommended methodologies to assess the quality and effectiveness of the training program.

4.1.9 Assess best practices used by similar agencies, industry, and organizations, including but not limited to the Patent and Trademark Office, that can enhance FDA's retention of review staff and management of the medical device review process.

**4.2 Opportunities for Improvement, Best Practices, and Additional Assessment Needs**

4.2.1 Identify process improvements and best practices for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards.

4.2.2 Provide recommendations that can be used to:

- Increase the quality of FDA-submitter interactions;
- Increase the quality of submissions;
- Enhance early notification of submission deficiencies;
- Promote the timely resolution of deficiencies;
- Improve the consistency of review performance across the program;
- Reduce the total time to decisions; and
- Develop Good Review Management Practices (GRMP) guidance.

4.2.3 Improvements should increase the quality and efficiency of reviews, and eliminate unnecessary multiple reviews without compromising patient safety and product efficacy standards.

4.2.4 Develop recommendations for ongoing periodic assessments and any additional, more detailed or focused assessments that FDA may determine are required.

**4.3 Findings and Recommendations**

4.3.1 Create reports of findings and recommendations generated from among the best practices and areas for improvement. Findings and recommendations shall include summary statistics (such as mean, median, and standard deviation), descriptive graphs (such as scatter plots and histograms), and a comprehensive analysis providing important observations and be presented to FDA in multiple stages:

- Identify the recommendations that are likely to have the most significant effect on review times. Present these priority recommendations to FDA within six months of the contract award.
- Present to FDA the remaining findings and recommendations from the assessments and analyses within six months following presentation of priority recommendations.

**4.4 Controls and Validation**

4.4.1 Develop metrics to assess the implementation and impact of the selected recommendations provided under this contract.

4.4.2 Prior to implementation of any portion of the contract, a baseline shall be established by the contractor, in consultation with FDA, so that the outcome can be adequately measured.

4.4.3 The technical proposal shall include an outline for how metrics will be developed, validated, and used to evaluate the implementation and impact of the recommendations.

### 4.5 Evaluation of Implementation

4.5.1 Evaluate the implementation of the selected recommendations and publish a written assessment.

## 5. Place of Performance

Work may be performed at FDA locations (10903 New Hampshire Ave, Silver Spring, MD; 5515 Security Ln, Rockville, MD; 1401 Rockville Pike, Rockville, MD; 5516 Nicholson Ln, Rockville, MD; and/or 9000 Rockville Pike, Bethesda, MD) and the Contractor's site depending on the nature of the task. Refer to 32 CFR 154.16 Subpart C for information pertaining to personnel security clearance requirements.

## 6. Period of Performance

The contract will have a three year performance period from March 31, 2013 through February 1, 2016. The performance period of this contract shall have two phases as follows:

Phase 1: March 31, 2013 – September 30, 2014

Phase 2: October 1, 2014 – February 29, 2016

The period of performance will begin on the date of the award of the contract and run through February 29, 2016. The second phase of the assessment is contingent upon the contractor meeting the requirements of the contract during the first phase. Upon completion and review of the results of Phase 1, FDA will have the option of deciding whether Phase 2 will be completed by the same contractor. Funding for Phase 1 will be provided at the time of award. Funding for Phase 2 will be provided at the time FDA exercises its option for the second phase.

## 7. Reporting Requirements/Schedule of Deliverables

Deliverables and schedule will be coordinated by the FDA Contracting Officer's Representative (COR). All reports will include data collected and sources of the data.

**Schedule of Deliverables**

**Phase 1**

| Deliverable | Specific Task | Due By |
|---|---|---|
| Contract kickoff meeting between FDA and contractor. | | Within 10 calendar days of the task order award. Will be scheduled by the FDA COR. |
| A draft workplan that identifies the specific task order deliverables; the sources, methods, and metrics to be used; and the delivery schedule. | 4.0 | Within 15 calendar days of the kickoff meeting. FDA will provide comments within 10 calendar days of receipt. |
| Final workplan. | 4.0 | Within one week of receipt of FDA comments. |

| Deliverable | Specific Task | Due By |
|---|---|---|
| Written progress and financial reports to the FDA COR. | 4.1 | Will commence within 30 calendar days of the task order award and continue monthly subject to change at the discretion of the FDA COR. |
| Oral presentations. | 4.1 | Oral presentations to the Program Advisory Group (PAG) will be made on each major report or plan deliverable prior to delivery. The FDA COR will schedule presentations with the contractor, and the contractor is responsible for drafting minutes for each meeting. |
| Email progress reports. | 4.1 | Weekly/bi-weekly progress reports via email at the discretion of the FDA COR. |
| Draft report on preliminary findings and high-priority recommendations including data collected and sources. | 4.1, 4.2, 4.3 | August 16, 2013 |
| Meeting with FDA to discuss high-priority recommendations. | 4.3 | Within 30 days of FDA receipt of draft report on high-priority recommendations. |
| Final written report on preliminary findings and high-priority recommendations including data collected and sources. | 4.1, 4.2, 4.3 | September 30, 2013 |
| Draft report on final findings and recommendations including data collected and sources. | 4.1, 4.2, 4.3 | February 10, 2014 |
| Meeting with FDA to discuss final recommendations. | 4.3 | Within 30 days of FDA receipt of draft report on final recommendations. |
| Final written report on findings and recommendations including data collected and sources. | 4.1, 4.2, 4.3 | March 31, 2014 |
| The contractor shall provide draft final reports and the Section 508 narratives and tables for FDA review and comment. | 4.3 | 45 calendar days before due date of the final report or plan. FDA shall provide feedback within 15 calendar days of receipt or as determined by the FDA COR. |
| The contractor shall provide all final reports for FDA redaction to remove confidential commercial information or other information exempt from disclosure. | 4.3 | Within 10 calendar days of receipt of FDA feedback. FDA will redact the final report within 15 calendar days or as determined by the FDA COR. |

| Deliverable | Specific Task | Due By |
|---|---|---|
| The contractor shall provide two versions of all final FDA redacted reports for publication: A Microsoft Word version and a pdf version compliant with Section 508 of the Rehabilitation Act ready to be posted on FDA's website. | 4.3 | Within 5 calendar days of FDA redaction. |
| The contractor shall provide electronic versions of all presentations, reports, databases, methodologies, and models in formats compatible with FDA-authorized platforms in a Microsoft environment. | 4.3 | As the time of final report presentation to FDA (no later than September 30, 2014). |

**Phase 2**

| Deliverable | Specific Task | Due By |
|---|---|---|
| Phase 2 kickoff meeting between FDA and contractor. | | Within 10 calendar days of the award (contingent on Phase 1 performance). |
| A draft workplan that identifies the specific task order deliverables; the sources, methods, and metrics to be used; and the delivery schedule. | 4.5 | Within 15 calendar days of the kickoff meeting. FDA will provide comments within 10 calendar days of receipt. |
| Final workplan. | 4.5 | Within one week of receipt of FDA comments. |
| Written progress and financial reports to the FDA COR. | 4.5 | Will commence within 30 calendar days of the task order award and continue monthly subject to change at the discretion of the FDA COR. |
| Oral progress reports. | 4.5 | Oral presentations to the Program Advisory Group (PAG) will be made on each major deliverable prior to delivery. The FDA COR will schedule presentations with the contractor.<br><br>Regular weekly reports or at the discretion of the FDA COR. |
| Draft report on results of evaluation of implementation of recommendations provided in Phase 1 including data collected and sources. | 4.5 | December 15, 2015 |

| Deliverable | Specific Task | Due By |
|---|---|---|
| Final written report of results of evaluation of implementation of recommendations provided in Phase 1 including data collected and sources. | 4.5 | February 1, 2016 |
| The contractor shall provide draft final reports and the Section 508 narratives and tables for FDA review and comment. | 4.3 | 45 calendar days before due date of the final report. FDA shall provide feedback within 15 calendar days of receipt or as determined by the FDA COR. |
| The contractor shall provide all final reports for FDA redaction to remove confidential commercial information or other information exempt from disclosure. | 4.3 | Within 10 calendar days of receipt of FDA feedback. FDA will redact the final report within 15 calendar days or as determined by the FDA COR. |
| The contractor shall provide two versions of all final FDA redacted reports for publication: A Microsoft Word version and a pdf version compliant with Section 508 of the Rehabilitation Act ready to be posted on FDA's website. | 4.3 | Within 5 calendar days of FDA redaction. |
| The contractor shall provide electronic versions of all presentations, reports, databases, methodologies, and models in formats compatible with FDA-authorized platforms in a Microsoft environment. | 4.3 | As the time of final report presentation to FDA (no later than February 29, 2016). |

## 8. Security

All personnel performing on this contract must have a minimum-security clearance level as required by the FDA. While the actual software, data, and reports generated by the contractor are not classified, they are restricted and are subject to NOFORN (not releasable to foreign nationals) and general non-disclosure limitations. Contractors must validate in writing that staff supporting this contract comply with this requirement. Also during the performance of this contract, Contractor staff may be required to use or come in contact with proprietary government information. Contractor will process the paperwork for a National Agency Check on all assigned employees. Contractor must have a complete knowledge of, and comply with, all standard HHS security procedures, including the process of information release through the Freedom of Information Act (FOI).

## 9. Government Furnished Equipment (GFE)/Government Furnished Information (GFI)

FDA will provide laptops, scanners, tokens, and badges as necessary for access to relevant FDA data systems. Otherwise, the contractor will be responsible for providing their own equipment. FDA badges and Government furnished equipment will be provided to the contractor within one month following the date of award. For activities

requiring on-site participation, FDA will provide the contractor with work space as necessary on the White Oak campus. The Contractor shall sign for issuance of Government furnished equipment. The Contractor shall return all furnished equipment prior to the period of performance end date or immediately upon request of the FDA COR.

## 10. Government-Furnished Information/Reference Material

The Government will furnish information as needed for the Contractor to fulfill the obligations of the contract.

The contractor shall not release any information concerning the contract or any information gained due to such work without the advance, written consent of the contracting officer. Much of the work performed shall be considered management confidential and may at times be subject to the Privacy Act. All contractor work product produced by the contractor while under contract with the FDA shall be considered the property of the Federal Government.

## 11. Conflict of Interest

As a regulatory agency charged with protection of public health, FDA must maintain public confidence in the integrity of its decisions. The FDA has policies and procedures that safeguard against actual and apparent conflict of interest on the part of its employees. In contracting for review and evaluation of scientific data and information submitted to the agency, it is critical that the FDA be assured that there is no actual or apparent conflict of interest on the part of the individual contractor. Offerors performing work under this contract must assure the protection of information and data they receive under this contract from unauthorized use or disclosure, and must avoid actions that would cause a reasonable person to question the impartiality of the contractor.

**Definition of Conflict of Interest**

Conflict of interest means that because of other activities or relationships with other persons or organizations, a person is unable or potentially unable to render impartial assistance or advice to the Government, that the person's objectivity in performing the contract is or might be otherwise impaired, or that the person has or might acquire an unfair competitive advantage (see FAR 9.501).

**Contractor's Conflict of Interest Responsibilities**

The individual contractor must be free of conflict of interest prior to performing under this contract.

Any time prior to or during the performance of the contract the individual contractor believes that a potential or actual conflict exists, the individual should notify the FDA COR. The FDA COR shall determine whether or not a conflict of interest exists and how to resolve or mitigate it. The contractor should not commence or continue working on the contract until directed by the FDA COR.

**Conflict of Interest Screening**

An individual offeror /contractor submitting a proposal in response to this solicitation must submit the following information (if no relevant information exists, please provide a statement to that effect).

1. A list of any stock holdings and investments for you, your spouse and minor children.

2. Any positions, either compensated or not, that you currently hold (or have under negotiation).
3. Any contracts, grants, or cooperative research and development assignments that you are working on or have under negotiation;
4. Any other sources of income (not mentioned above)
5. Any other relevant information concerning any past, present, or planned interests that may have a bearing on the responsibilities described in the Statement of Work.

The FDA COR shall conduct a review of the information submitted and determine if a conflict of interest exists prior to forwarding any documents to the contractor. Prior to submitting new work assignments, the FDA COR shall follow-up with the contractor to determine if any changes to his/her financial interest have occurred.

**Conflict of Interest Agreement**

In executing this contract, the individual contractor agrees:

1. To report to the proper authority within the FDA (the COR), any situation or event that may constitute a conflict of interest, whether actual or potential.
2. To act impartially and not give preferential treatment to any individual or organization which has submitted applications, information, and or data.
3. Not to solicit any gift or other item, nor accept any gift or other item, of monetary value exceeding $20.00 from any person or entity seeking official action from, doing business with or conducting activities related to the evaluations and work performed under this contract. Aggregate market value of individual gifts should not exceed $50.00 in a calendar year.
4. Not to disclose any information and/or data within his or her purview, or to which he/she has access as a result of performing work under this contract.
5. Not to participate in any matter involving specific parties who are likely to or can directly affect the financial interest of a member of his household or a relative with whom they have a close personal relationship; and
6. To disqualify himself from participating in particular matters involving former employees or their representatives, with whom they have worked within the past one (1) year and who might represent a conflict of interest.

## 12. Access to Non-Public Information

All contractor and subcontractor employees are required to sign the Contractor's Commitment to Protect Non-Public Information (NPI) Agreement (Form FDA 3398) provided. If a person who has signed this agreement resigns, is dismissed, or is otherwise no longer working on this contract, the Contractor shall notify the FDA COR and the Contracting Officer. Any new contractor or subcontractor employee assigned to this contract shall sign the form, and the Contractor shall hand-deliver it to the Contracting Officer ten (10) days prior to said new employee's commencement of work on this contract.

The prime contractor, subcontractors, and consultants shall not be provided nor possess non-public information in any form unless written approval has been granted, nor shall they have unaccompanied access to an FDA facility unless a facility clearance has been granted. Non-public information shall include any intellectual property or confidential information provided by FDA or non-FDA parties during the assessment.

## 13. Performance Criteria

**Technical Proposal Ratings**

FDA will evaluate all technical factors as exceptional, acceptable, marginal, or unacceptable.

**"Tradeoff" Evaluation Rating Standards**

| Rating | Standard |
|---|---|
| Exceptional | An exceptional Proposal contains significant strengths and no weaknesses. The Proposal exceeds the performance and technical capability requirements defined in the SOW. The Proposal offers value-added methodologies for improving service that benefits the Government. The evaluator has no doubt that the offeror can successfully achieve the requirements in the SOW if the technical approach proposed is followed. The offeror acknowledges risks and develops an approach that proactively identifies and mitigates risks, and looks to reduce or eliminate future risks. |
| Acceptable | An acceptable Proposal contains strengths that outweigh any existing weaknesses. The offeror's Proposal meets the performance and technical capability requirements defined in the SOW. The evaluator is confident that the offeror can successfully achieve the requirements in the SOW if the technical approach is followed. The Proposal addresses risks and the proposed risk mitigation approach is sufficient to manage the task. |
| Marginal | The Proposal meets the bare minimum performance and technical capability requirements defined in the SOW, and the Proposal also has significant weaknesses. The evaluator is not confident that the offeror can successfully complete the required tasking without significant Government oversight or participation. The Proposal either fails to address risks or the proposed risk mitigation approach is not deemed to be sufficient to manage the task. |
| Unacceptable | An unacceptable Proposal contains one or more significant weaknesses and deficiencies. The Proposal fails to meet specified minimum performance and technical capability requirements defined in the SOW. The evaluator is confident that the offeror will be unable to successfully complete the required tasking. The Proposal does not adequately acknowledge or address risk or mitigate risk, and may actually introduce risk. |

**Technical Evaluation Factors**

**1. Technical Approach and Understanding**

Offeror shall submit a technical proposal demonstrating the offeror's understanding of and approach to meeting and accomplishing the objectives and requirements listed in the statement of work (SOW). The technical proposal shall not exceed 25 pages exclusive of resumes and information about previous projects.

Offeror shall indicate how it would staff and execute the contract. The offeror shall demonstrate the ability to apply relevant elements of evaluation and statistical techniques. It also shall demonstrate expertise and methodology for developing and using best practices benchmarking to evaluate current performance and improve future outcomes.

Ratings for this factor will be based on a judgment of the degree to which the offeror demonstrates the ability to successfully meet and accomplish the objectives and requirements listed in the SOW.

**2. Key Personnel**

Offeror shall demonstrate that it employs the personnel requisite to perform high caliber qualitative and quantitative analyses. The offeror shall name the participating personnel, identify their qualifications and experience, and for each person, indicate the percentage of time that would be devoted to this contract. It is expected that at least one evaluator who has extensive training and experience and a minimum of a master's degree in a relevant discipline will oversee the project. This evaluator will be considered the key contact person for the task.

Offeror shall demonstrate that available personnel possess evaluation and analytical capabilities of various types and the research capabilities needed to perform the study.

Offeror shall demonstrate that personnel have direct evaluation and analysis experience with FDA's medical product review programs and business processes as they currently operate, especially medical device processes, including the electronic submission and review environment. Ideally, personnel should possess evaluation and analysis experience with FDA's medical product review programs, especially medical device programs, within an FDA-regulated industry as they currently operate, especially in the areas of new product development and the submission process for FDA premarket review.

Ratings for this factor will be based on a judgment of the degree to which the offeror describes an effective and efficient staffing approach, as well as personnel qualifications as determined by identified deficiencies, weaknesses, and/or strengths.

**3. Past Performance**

Offeror shall demonstrate:

a) Past experience in conducting high caliber qualitative and quantitative analyses for program operations and performance. Offeror shall provide FDA with a table containing the title of each previous project, contracting organization, organization contact, dollar amount, and type of analysis (evaluation, cost and benefit, etc.). Offeror shall demonstrate that available personnel possess direct experience and knowledge of conducting program evaluations and studies.

b) Direct evaluation and analysis experience with FDA's medical product review programs and business processes as they currently operate, especially medical device processes, including the electronic submission and review environment. Evaluation and analysis experience with FDA's medical product review programs, especially medical device programs, within an FDA-regulated industry as they currently operate, especially in the areas of new product development and the submission process for FDA premarket review.

FDA will evaluate the information provided to determine the extent to which the contractor has demonstrated experience that is relevant to the objectives and requirements in the SOW, increasing the potential to successfully fulfill the objectives and requirements of the SOW.

In the case of an offeror that is without a record of relevant past performance or for whom information or past performance is not available the offeror may not be evaluated

favorably or unfavorably with respect to past performance. The rating shall be characterized as "Neutral" in such circumstances.

**4. Project Management**

Offeror shall provide information on the administration of the project tasks. This should include management plans; methods for implementing, reviewing, and effecting interim adjustments and corrections; and quality control and cost control procedures.

**5. Price Quote**

Price is not the most important evaluation factor, but its degree of importance will increase commensurably with the degree of equality among different offerors' technical proposals. Prospective offerors are forewarned that a proposal meeting the SOW requirements with the lowest price may not be selected if award to a higher priced proposal is determined to be most advantageous to the Government.

The offeror shall submit a price quote that includes loaded ceiling hourly rates for all labor categories. Offerors' price quotes will be evaluated to determine reasonableness. The government will be evaluating all quotations to determine best value.

**Basis of Award**

FDA anticipates awarding a task order to a responsible offeror whose offer conforms to the objectives and requirements of the SOW and is evaluated as being appropriate for the task. Technical merit is more important than price. The award will not be automatically determined by numerical calculation or formula relationship between price and technical merit. The contracting officer will determine what trade-off between technical merit and price promises the greatest value to FDA. For evaluation purposes, the technical factors are listed in descending order of importance.

1) Technical Approach & Understanding
2) Key Personnel
3) Past Performance
4) Project Management
5) Price

**Technical Evaluation Panel**

The technical proposal will be reviewed and scored based on the above criteria by a Technical Evaluation Panel. All members of the panel shall be Federal employees.

## 14. Other Pertinent Information or Special Considerations

**Rehabilitation Act Compliance** - The Contractor should be familiar with Section 508 requirements as described at http://www.section508.gov/ in order to ensure that documents generated as part of the contract are fully Section 508-accessible using the available COTS tools. All reports submitted should be in a Section 508 compliant .pdf format ready for posting on the FDA website if FDA shall choose to do so.

**Travel** – The contractor shall make an effort to conduct all meetings in the local Washington, D.C. area. On as-needed bases, the Contractor may be required to travel to various locations not specified under the Place of Performance and the Contractor shall travel as required to meet the contractual obligations. The Contractor shall obtain advanced written approval for travel from the FDA COR prior to incurring any such

costs. The contractor shall pay all travel expenses and other expenses necessary to meet contract requirements. Approval of travel expenses outside the local Washington, D.C. area will be reimbursed at the current per diem rates at the time of travel in accordance with the Federal Travel Regulations.

The Contractor must comply with the requirements of the Federal Travel Regulation (www.gsa.gov/ftr).

## 15. POC

The FDA COR is responsible for the acceptance of work. The FDA COR designated and approved by FDA's Office of Acquisitions and Grants is Amber Sligar, amber.sligar@fda.hhs.gov, 301-796-9384, 10903 New Hampshire Avenue, White Oak Building 32, Room 3291, Silver Spring, MD 20993.

## 16. Post-Award Administration

Completion of all deliverables, quality and timeliness of delivery, as well as incidents and types of defects, will be used to evaluate the Contractor's progress and suitability.