CENTRALIZED BIDS AND AWARDS COMMITTEE

REQUEST FOR PROPOSAL
(CENBAC Reference No. NP-RFP-2024-0064-IMS)

PROCUREMENT FOR THE ENGAGEMENT OF SERVICES OF A CERTIFICATION BODY TO CONDUCT 2nd SURVEILLANCE AUDIT OF THE ISO 9001:2015 STANDARD REQUIREMENTS

1. The Food and Drug Administration, through the Maintenance and Other and Operating Expense (MOOE) intends to apply the sum of **One Hundred Eighty Two Thousand Pesos Only (Php182,000.00)** being the Approved Budget for the Contract (ABC) to payments under the contract for the **Procurement for the Engagement of Services of a Certification Body to Conduct 2nd Surveillance Audit of the ISO 9001:2015 Standard Requirements**. Bids received in excess of the ABC shall be automatically rejected at the opening of the financial proposals.

2. The Food and Drug Administration now calls for the submission of eligibility documents for the **Procurement for the Engagement of Services of a Certification Body to Conduct 2nd Surveillance Audit of the ISO 9001:2015 Standard Requirements**

3. **Eligibility documents of interested certifying body must be duly received by the BAC Secretariat on or before April 11, 2023, 9:00am only (*Late submission shall not be accepted*)**, at BAC Secretariat Room, 2nd Floor, FDA Annex Bldg., Civic Drive, Filinvest City, Alabang, Muntinlupa City or you may email us at bacsec@fda.gov.ph. Applications for eligibility will be evaluated based on a non-discretionary "pass/fail" criterion. **Only Short listed consultants shall be invited to participate in the bidding for this project through a Notice of Eligibility and Short Listing issued by the FDA-BAC.**

4. Interested bidders may obtain further information from BAC Secretariat Room, 2nd Floor, FDA Annex Bldg., Food and Drug Administration, Civic Drive, Filinvest City, Alabang, Muntinlupa City and inspect the Bidding Documents from 8:00am to 5:00pm Monday to Friday or call at 857-1900 local 8307. Likewise, visit the FDA website at *www.fda,gov.ph* or email at *bacsec@fda.gov.ph*.

5. A complete set of Bidding Documents may be acquired by interested Bidders on 06 April 2024 from the BAC Secretariat

   It may also be downloaded free of charge from the website of the Philippine Government Electronic Procurement System (PhilGEPS) and the website of the Procuring Entity, provided that Bidders shall pay the applicable fee for the Bidding Documents not later than the submission of their bids.

6. The BAC shall draw up the short list of consultants/certifying body from those who have submitted Expression of Interest, including the eligibility documents, and have been determined as eligible in accordance with the provisions of Republic Act 9184 (RA 9184), otherwise known as the "Government Procurement Reform Act", and its Implementing Rules and Regulations (IRR). The criteria and rating system for short listing are:

Criteria	Weight
Technical Proposal a. Applicable Experience and Capability of the Participating Consultant - No. of years of auditing experience (10%) - Similar engagements completed within five (5) years (10%) - Similar projects conducted in government institutions within the last five (5) years (10%) - Satisfactory Performance (5%)	35%
b. Qualification and Competence of Auditors to be assigned to the team - Audit team members with actual hands-on experience on QMS who are qualified to conduct audits in the name of the CB (10%) - Audit team members with background or knowledge on the QMS Process Scope (10%) - Audit team members with minimum of two (2) years ISO 9001:2015 auditing experience (10%) - Educational attainment/applicable accreditation of Audit Team members (5%)	35%
Financial Proposal	30%
Total	**100%**

7. Bidding will be conducted through open competitive bidding procedures using non-discretionary "pass/fail" criterion as specified in the IRR of RA 9184.

   Bidding is restricted to Filipino citizens'/sole proprietorships, cooperatives, and partnerships or organization with at least sixty percent (60%) interest of outstanding capital stock belonging to citizens of the Philippines.
8. The Procuring Entity shall evaluate bids using the **Quality-Cost Based Evaluation/Selection (QCBE/QCBS)**, procedure. The Procuring Entity shall indicate the weights to be allocated for the Technical and Financial Proposals/. The criteria and rating system for the evaluation of bids shall be provided in the Instructions to Bidders.

9. The contract shall commence upon receipt of Notice to Proceed (NTP) and ends with the post evaluation and submission of technical and financial documentation and evaluation reports and its supporting documents.

10. The FDA reserves the right to reject any and all bids, declare a failure of bidding, or not award the contract at any time prior to contract award in accordance with Section 41 of RA 9184 and its IRR, without thereby incurring any liability to the affected bidder or bidders.

ENGR. ANA TRINIDAD F. RIVERA, MSc
FDA, CenBAC Chairperson

FOOD AND DRUG ADMINISTRATION

TERMS OF REFERENCE

FOR THE ENGAGEMENT OF SERVICES OF A CERTIFICATION BODY TO CONDUCT 2nd SURVEILLANCE AUDIT OF THE ISO 9001:2015 STANDARD REQUIREMENTS

1. OBJECTIVE

The Food and Drug Administration (FDA), as the National Regulation Agency of the Philippines, intends to engage the services of a third-party certification body that will conduct the 2nd surveillance audit of FDA QMS ISO 9001:2015 standard requirements.

2. DEFINITIONS OF TERMS

The following terms used under the TOR shall be understood as follows:

2.1 ISO – Stands for *International Organization for Standardization*. It is a worldwide federation of national standards bodies, with representatives from each of the approximately 175 countries.

2.2 ISO 9001:2015 – It is the international standard specifying requirements for quality management systems and is the most prominent approach to quality management systems. It aims to help the FDA meet the standards of our customers and other stakeholders more effectively.

2.3 Quality Management System - It is a formalized system that documents FDA regulatory processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct the FDA's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on continuous basis

3. SCOPE OF WORK

3.1 The Certification Body (CB) hereby undertakes to perform the Project entitled: "**For the Engagement of Services of a Certification Body to Conduct 2nd Surveillance Audit of the FDA IMS 9001:2015 Standard Requirements**" in accordance with the existing ISO 9001:2015 auditing standards and Auditor Code of Conduct and Ethics.

3.2 The CB shall submit an audit plan to the FDA upon receipt of the Notice to Proceed (NTP).

3.3 The CB shall perform the 2nd Surveillance Audit services:

3.3.1 Prepare and submit an audit report detailing observations, opportunities for improvement and any non-conformity to ISO 9001:2015 standard and suggestions on how to address them

3.3.2 Issuance of ISO 9001:2015 Certification valid for one (1) year.

3.4 Qualifications and Requirements for the Certification Body

3.4.1 In compliance with Executive Order No. 80, s. 2012, the CB shall be accredited by the International Accreditation Forum for ISO 9001 certification activities. Preferably, the CB is accredited by the Philippine Accreditation Bureau (PAB) of the Department of Trade and Industry (DTI) with the scope of accreditation covering the process being applied for ISO 9001 certification.

3.4.2 The CB must have at least five (5) years of ISO 9001:2015 auditing experience.

3.4.3 The CB must have conducted at least five (5) similar engagements within the last five (5) years for a government institution and at least two (2) years for a Regulatory Authority.

3.5 The CB shall submit the following eligibility and technical requirements:

CHECKLIST AND TABBING OF ELIGIBILITY AND TECHNICAL REQUIREMENTS

TAB NUMBER	DESCRIPTION
1	Valid and current Accreditation from the PAB of the DTI
2	Mayor's/ Business Permit
3	PhilGEPS Registration Number
4	Omnibus Sworn Statement "with Secretary's Certificate for partnership or corporation"
5	Company Profile highlighting the related projects, scope of work and implementation methodology
6	Professional License/Curriculum Vitae
7	FINANCIAL PROPOSAL SUBMISSION FORM

4. RESPONSIBILITIES OF THE CERTIFICATION BODY

4.1 In order to avoid conflict of interest, certification bodies that have provided quality management system consulting services or site-specific auditor training within the prior two (2) years to a particular group/unit within the FDA, shall not be contracted as CB for the agency.

Note: Consulting refers to the provision of training documentation development, or assistance with implementation of quality management systems to a specific organization. Training that is open to the public, not organization specific, and held at a public forum is not considered as consulting.

4.2 *The* CB shall include in their audit activities, a procedure for client appeals. If resolutions on good terms for disputes between the FDA and the CB cannot be made, the FDA shall be afforded the right to lodge appeals about the decisions of the audit team to an independent arbitrator. Independently from this, the legal path is open to both parties.

4.3 All information reviewed and recorded by the CB audit team would be treated in the strictest confidence at all times.

4.4 The CB shall adhere to the agreed scope of work/ deliverables which were prior approved by the FDA's selection committee.

4.5 The CB audit team shall provide a full report on the operations audited consistent with the content of the approved scope of work/ deliverables to the FDA within five (5) calendar days of 2nd surveillance audit unless otherwise agreed by the FDA.

4.6 The CB shall ensure that, during the 2nd surveillance audit, the audit teams, shall satisfy the following:

a. Consist of five (5) certified auditors with at least two (2) years of experience to conduct audits in the name of CB;
b. Have team members with background or knowledge on the QMS Process Scope and government procurement process;
c. No member of the audit team should have provided consultancy for the FDA within two (2) years prior to the audit;
d. Replacement of any team or team member shall require prior written approval from the FDA.

5. CRITERIA

5.1. The proposals shall be evaluated based on Quality-Cost Based Evaluation. The criteria

and rating system for the selection of the winning certifying body are as follows:

Criteria	Weight
Technical Proposal a. Applicable Experience and Capability of the Participating Consultant - No. of years of auditing experience (10%) - Similar engagements completed within five (5) years (10%) - Similar projects conducted in government institutions within the last five (5) years (10%) - Satisfactory Performance (5%)	35%
b. Qualification and Competence of Auditors to be assigned to the team - Audit team members with actual hands-on experience on QMS who are qualified to conduct audits in the name of the CB (10%) - Audit team members with background or knowledge on the QMS Process Scope (10%) - Audit team members with minimum of two (2) years ISO 9001:2015 auditing experience (10%) - Educational attainment/applicable accreditation of Audit Team members (5%)	35%
Financial Proposal	30%
Total	**100%**

6. ENGAGEMENT FEE

The cost of engagement of the CB shall be based on an agreed contract between the two parties. Payments shall be based on the completion of the following activities as evidenced by the submission and acceptance by the FDA of the required deliverables for the identified business processes.

7. DURATION OF SERVICES

The services subject of the procurement shall be for a period of one (1) year starting upon receipt of the Notice to Proceed (NTP).

8. CONFIDENTIALITY AGREEMENT

8.1. Each Party undertakes not to divulge at any time to any third person any confidential information relating to the other, except upon prior written consent of the other or where required under the law or regulation or by a valid order of a court or other governmental authority with competent jurisdiction.

8.2. The CB and its audit team members shall execute and sign a *Confidentiality and Non-Disclosure Undertaking* upon the CB's receipt of the *NTP*.

9. APPROVED BUDGET FOR THE CONTRACT (ABC)

The Approved Budget for the Contract (ABC) shall be **ONE HUNDRED EIGHTY-TWO THOUSAND PESOS (Php 182,000.00)** which is inclusive of Remuneration cost, Reimbursable costs and the Twelve Percent (12%) VAT.