FOOD AND DRUG ADMINISTRATION

TERMS OF REFERENCE

FOR THE ENGAGEMENT OF SERVICES OF A CERTIFICATION BODY TO CONDUCT RECERTIFICATION 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 a re-certification 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 Recertification 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 to the FDA within fifteen (15) working days a re-certification audit plan from the issuance of the Notice to Proceed (NTP).

3.3 The CB shall perform the Re-certification 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 three (3) years.

3.3.3 Submit proposed surveillance plan for the second and third year of the validity of the issued ISO Certification for the FDA's option to renew the service during the three year cycle duration of the certification, subject to the Market Study and satisfactory performance as maybe recommended by the IMS

3.4 Qualifications and Requirements for the Certification Body

3.4.1 In compliance with the 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 of which at least two (2) are for government institutions.

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 re-certification audit unless otherwise agreed by the FDA.

4.6 The CB shall ensure that, during the certification, 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 Recertification Contract (ABC) shall be **TWO HUNDRED SIXTY FOUR THOUSAND EIGHT HUNDRED EIGHTY PESOS ONLY (Php 264,880.00)** which is inclusive of Remuneration cost, Reimbursable costs and the Twelve Percent (12%) VAT.

Requirements / Specifications:	
Scope of Certification: FDA's Core Processes: Licensing of Health Establishments and Radiation Facilities, Registration of Health Products and Post-Marketing Surveillance.	
Sites/Location and Complete Addresses:	
Site 1:	Site 1: FDA Central Office *Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City, 1781
Site 2:	Site 2: FDA Regional Field Office (RFO) 1 *GNET Bldg., Quezon Avenue, Brgy. III, City of San Fernando 2500, La Union
Site 3:	Site 3: FDA Regional Field Office (RFO) 2 *3/F Diwa Building, College Avenue 3500, Tuguegarao City, Cagayan
Site 4:	Site 4: FDA Regional Field Office (RFO) 3 *3rd Floor Primus Medicus Bldg. Brgy. San Isidro, Mac Arthur Highway, City of San Fernando, Pampanga 2000
Site 5:	Site 5: FDA Regional Field Office (RFO) CAR *Jovelyn Quilacio Realty Services Bldg., Purok 1 Padre Zamora St. 2600, Baguio City
Site 6:	Site 6: FDA Regional Field Office (RFO) 4A *7F Kingston Excel Building, Centennial Drive, Filinvest Corporate City, Alabang, Muntinlupa City, 1781
Site 7:	Site 7: FDA Regional Field Office (RFO) 5 *DOH CHD Bicol Compound, Legazpi City, Albay 4500
Site 8:	Site 8: FDA Regional Field Office (RFO) NCR **7F Kingston Excel Building, Centennial Drive, Filinvest Corporate City, Alabang, Muntinlupa City, 1781
Site 9:	Site 9: FDA Regional Field Office (RFO) 6 *3/F Gaisano City Mall, Luna St., La Paz, 5000, Iloilo City
Site 10:	Site 10: FDA Regional Field Office (RFO) 7 *G/F One Central Hotel and Suites Corp. Leon Kilat St., cor. Sanciangko St.,Pahina Central 6000 Cebu City
Site 11:	Site 11: FDA Regional Field Office (RFO) 8 *Perpetual Help Credit Cooperative Bldg. cor Real Sagkahan, Calanipawan Road 6500, Tacloban City
Site 12:	Site 12: FDA Regional Field Office (RFO) 9 *2/F, PAFCPIC Bldg., Azucena Street, Suterville, San Jose Gusu, Zamboanga City, Zamboanga del Sur, 7000
Site 13:	Site 13: FDA Regional Field Office (RFO) 10 *2/F Chan Yu Bldg., St. John Caltex, Zone 7, Bulua, Cagayan de Oro City, 9000, Misamis Oriental
Site 14:	Site 14: FDA Regional Field Office (RFO) 11 *3rd Floor Biosite Medical Instruments Building, 553 Mangga St., Juna Subdivision, Matina, 8000 Davao City
Site 15:	Site 15: FDA Regional Field Office (RFO) 12 *2/F, UGA Bldg., General Santos Drive, Koronadal City, 9506, South Cotabato
Site 16:	Site 16: FDA Regional Field Office (RFO) 13 *Nimfa Tiu Bldg., Acosta Subdivision, Libertad, 8600, Butuan City
Site 17:	Site 17: CSL Cebu (Cebu Testing and Quality Assurance Laboratory) *FDA Bldg., North Road, Jagobiao, 6014, Mandaue City, Cebu
Site 18:	Site 18: CSL Davao (Davao Testing and Quality Assurance Laboratory) *Energy Park, Apokon, Tagum City, 8100, Davao Del Norte
Site 19:	Site 19: FDA Regional Field Office (RFO) 4B *Unit 13 Filifiniana Complex Brgy, Sto. Mino Calapan City, Oriental Mindoro 5200
Total No. of Employees:	1,116
Specification: a.) Shall conduct a Virtual/On-site/Hybrid Audit for the Re-Certification of ISO 9001:2015.	

b.) Must be accredited by International Accreditation Forum (IAF), or similar standards relating to Total Quality Management (TQM) c.) Must be accredited by DTI-Philippine Accreditation Bureau (PAB) d.) Have previously certified/accredited a number of government agencies to ISO 9001:2015. e.) **Mode of Payment:** Send-bill Arrangement after the completion of the actual audit and submission of the audit report.
Deliverables: 1. Audit Plan with detailed activities and timelines. *(At least 1 week before the actual audit)* 2. Provide initial and final audit results, report and recommendations. 3. Prepare and submit audit report detailing observations, opportunities for improvement and any non-conformity to ISO 9001:2015 standards or on documented procedures and suggestions on how to address them within five (5) working days after the conduct of the audit *(off-site and on-site audit)*. 4. Free of charge ISO certificates per site in A4 size *(soft copies)*, complimentary all-weather tarpaulins/banners and test-mark logos.

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