

Requirements/Specifications:**Description:**

Service of a Certifying Body to the Project: "Surveillance Audit for ISO 9001:2015 Quality Management System (QMS)" of the Food and Drug Administration.

Scope of Certification:

FDA's Core Processes: Licensing of Health Establishments and Radiation Facilities, Registration of Health Products and Post-Marketing Surveillance of the Food and Drug Administration.

Sites/Location and Complete Addresses:

Site 1:	Main Office - Food and Drug Administration <i>Civic Drive, Filinvest City, Alabang, Muntinlupa City, 1781</i>
Site 2:	Regional Field Office I <i>G World Real Estate, Quezon Avenue, Brgy. III, La Union, 2500</i>
Site 3:	Regional Field Office II <i>DOH-RO II Compound, Brgy. Carig, Tuguegarao City, Cagayan, 3500</i>
Site 4:	Regional Field Office III <i>Primus Medicus Bldg., San Isidro, San Fernando, Pampanga, 2000</i>
Site 5:	Regional Field Office - CAR <i>BSP Bldg., 146 Kisad Road, Baguui City, Benguet, 2600</i>
Site 6:	Regional Field Office IV-A <i>Milan Prestige Bldg., National Highway, Brgy. Halang, Calamba City, Laguna, 4027</i>
Site 7:	Regional Field Office IV-B <i>Halcon Heights Bldg., Roxas Drive cor. Dama de Noche, Brgy. Lumangbaya, Calapan, Oriental, Mindoro, 5200</i>
Site 8:	Regional Field Office – NCR <i>G/F Annex Bldg., Civic Drive, Filinvest City, Alabang, Muntinlupa City, 1781</i>
Site 9:	Regional Field Office V <i>DOH-RO V Compound, Legazpi City, Albay, 4500</i>
Site 10:	Regional Field Office VI <i>DOH-RO VI Compound, Q. Abeto St., Mandurriao, Iloilo City, 5000</i>
Site 11:	Regional Field Office VII <i>North Road, Jagobiao, Mandaue City, Cebu City, 6014</i>
Site 12:	Regional Field Office VIII <i>Perpetual Help Credit Cooperative Inc. Bldg, cor Real Sagkahan, Calanipawan Road, Tacloban City, Leyte 6500</i>
Site 13:	Regional Field Office X <i>Almie Rose Chan Yu Bldg., Zone 7, Bulua, Cagayan De Oro City, 9000</i>
Site 14:	Regional Field Office XI <i>Lotrim Construction Inc. Bldg., Quimpo Blvd., Ecoland, Davao City, 8100</i>
Site 15:	Regional Field Office XII <i>Nimfa Tiu Bldg., Acosta Subd., Libertad, Butuan City, 8600</i>
Site 16:	Regional Field Office IX <i>PAFCPIC Bldg., Azucena Suterville, San Jose Gusu, Zamboanga City, 7000</i>
Site 17:	Regional Field Office XII & ARMM <i>UGA Bldg., Gen. San Drive, Koronadal City, South Cotabato, 9506</i>
Site 18:	Food and Drug Administration – Cebu Testing and Quality Assurance Laboratory <i>North Road, Jagobiao, Mandaue City, Cebu City, 6014</i>
Site 19:	Food and Drug Administration – Davao Testing and Quality Assurance Laboratory <i>Energy Park, Apokon, Tagum, Davao City, 8100</i>

Total No. of Employees:	1046
<p><u>Specification:</u></p> <p>a.) Will only conduct 2nd Surveillance Audit for QMS – Year 2.</p> <p>b.) Must be accredited by International Accreditation Forum (IAF), or similar standards relating to Total Quality Management (TQM)</p> <p>c.) Must be accredited by DTI-Philippine Accreditation Bureau (PAB)</p> <p>d.) Must use the relevant Committee on Conformity Assessment (CASCO) standard.</p> <p>e.) Have previously certified/accredited a Philippine health regulatory agency to ISO 9001:2015.</p> <p>f.) Mode of Payment – 15% upon delivery of Audit Plan, remaining after the conduct of Stage 2 (On-site) Audit.</p>	
<p><u>Deliverables:</u></p> <p>1. Audit Plan with detailed activities and timelines. <i>(1 week before the on-site audit)</i></p> <p>2. Provide initial and final audit results, report and recommendations.</p> <p>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 <i>(off-site and on-site audit)</i>.</p> <p>4. Free of charge ISO certificates per site in A4 size <i>(hard and soft copies)</i>, complimentary all-weather tarpaulins/banners, ISO stickers and test-mark logos.</p>	

DTN: 20210209154915