Consultare Inc. Group
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I. SERVICE PROPOSAL

FSVPQI/US Agent Representation Services and Compliance Management System Software via interlinkIQ

Prepared for:

Marcatus QED

Quinnie Jiang

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Proposal Ref. No.: MQED-25-01
Date Issued: Mar 12, 2025
Valid Until: Apr 12, 2025

Need Statement

The client expressed interest in the following:

- Third-party consultant or someone to serve as the FSVP Importer/US Agent residing in the USA to be responsible for their products, preferably with FSVP documentation management platform within the same service/company.
- A digitized FSVP management system software to automate notifications of any FDA import alerts or FSVP violations on implicated suppliers.

Proposed Solution

A. U.S. Agent Representation Services
B. Compliance Management System Software via interlinkIQ

II. SUBSCRIPTION/ SERVICE AGREEMENT ACCEPTANCE

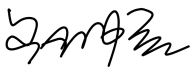
Subscription Description	Subscription Fee (per facility)	Payment Terms	Payment Link	Please select or mark your preferred subscription plan
U.S. Agent Designation Services and Compliance Management System Software) - Monthly Fee	US $745.00	monthly	https://consultareincgroup.com/chargebee-monthly-745/	☑
U.S. Agent Designation Services and Compliance Management System Software) - Annual Fee	US $7,740.00 *$745.00 - $100.00* ***Discount*** *= $645.00/mo * 12 months*	yearly	https://consultareincgroup.com/chargebee-yearly-7740/	☐

Other Payment Options

By Bank Deposit		***By Check***	
Bank Name:	Bank of America	Payable To:	Consultare Inc. Group
Payable To:	Consultare Inc. Group	Address:	1331 Pine Trail Tomball, TX 77375, USA
Routing No.:	111000025		
Account No.:	488115531688		

Service Fees as of Mar 12, 2025
Note: Subscription fee(s) is only valid for one month from the date of the proposal's issuance.
Prices are subject to change without prior notice.

Service Start Date:
Company Name: Marcatus QED
Company Address: 43 Hanna Ave, Unit C-424 Toronto, ON, M6K1X1 Canada
Contact Person: Quinnie Jiang
Email: Quinnie.Jiang@marcatusqed.com
Phone: +1 (905) 337 1105

Signature: 

Date Signed: March 20, 2025

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IV. STATEMENT OF CONFIDENTIALITY

This proposal and supporting materials contain confidential and proprietary business information of Consultare Inc. Group. These materials may be printed or photocopied for use in evaluating the proposed project, but are not to be shared with other parties.

V. COPYRIGHT NOTICE

VI. SUBSCRIPTION/ SERVICE AGREEMENT BREAKDOWN

6.1 FSVPQI/US Agent Representation Services

6.1.1 Scope of Services

Appointment of Agent	1. The Foreign Entity hereby appoints the Agent as its exclusive agent for the provision of services related to representing the Foreign Entity in the United States ("Agent Services"). 2. The Agent accepts the appointment as described in the Scope of Services and agrees to perform the Agent Services diligently and to follow the terms of this Agreement.
Scope of Services	1. Acts as a liaison or communication link between the Foreign Entity and regulatory authorities in the United States, including the U.S. Food and Drug Administration (FDA): a. Serving as the primary point of contact between the foreign food facility and the FDA to ensure coordination; b. Receiving communications from the FDA on the designated U.S. agent's United States address and/or email, including regulatory notifications such as inspection notices or compliance inquiries, and ensuring prompt delivery of these communications and changes to the Foreign Entity; c. Transmitting information from the regulatory body(ies) to the Foreign Entity, ensuring that the information is promptly and accurately relayed; d. Facilitating response to the FDA's requests for information (e.g., third-party certifications, food safety plans, supply-chain records) or actions to correct non-compliance issues (e.g., response letters, CAPA reports); and e. Keeping the FDA up-to-date with the U.S. agent's contact information (e.g., U.S. address, email address, phone number) and the foreign facility's information. 2. Assists in regulatory enforcement actions and emergencies that may arise in relation to food safety issues including, but not limited to, FDA-initiated inspections, product recalls, detentions, and food safety-related issues, with the U.S. agent ensuring prompt execution of the following: a. Ensuring that the foreign facility is notified about the inspection, and helping the Foreign Entity ensure that the necessary logistical arrangements are set and scheduled for the authorities to access the facility; b. Initiating timely and proper communication with its customers, partners, stakeholders, and regulatory and certification bodies in the United States in any event of a recall, detention, and complaints facilitated by the FDA; and c. Serving as the point of contact to provide timely communication and to ensure swift responses to address potential public health risks associated with the food product. 3. Monitors anticipated compliance activities, regulatory changes, and/or alerts, and performs the following: a. Promptly notify the Foreign Entity of any FDA or USDA warning letters, import alerts, or enforcement actions

	related to their industry. b. Communicating with the Foreign Entity to notify or remind of periodic compliance activities, including but not limited to: i. Supplier evaluations and reevaluations ii. Mock recall exercises iii. Internal audits iv. Food fraud vulnerability assessments for ingredients and suppliers (FFVA) and key activity types (KATVA) v. Documentation reviews and updates vi. Updating substantiations for product claims (e.g., certification, accreditation, health claims) to reduce the risk of mislabeling or false claims vii. Corrective action implementations for non-conformances viii. FDA annual food facility registration updates or renewals c. Providing insights into current regulatory enforcement trends across both FDA and USDA regulations. 4. Monitors corrective and preventive action records as part of the verification of addressing non-conformances observed during the conduct of monitoring and verification activities. 5. Verifies compliance with product labels to ensure they meet FSMA, FDA, and USDA labeling standards, including ingredient lists, nutritional information, and allergen declarations. 6. Regularly monitors FDA and USDA regulatory updates with notifications on changes affecting the Foreign Entity's operations, and ensures compliance by the conduct of the following: a. Providing regular advisory(ies) to the Foreign Entity in case of amendments in the relevant regulatory and statutory requirements. b. Assistance with any required changes to product labels, ensuring alignment with updated FDA and USDA labeling standards, including ingredients, allergen, and nutritional information declarations as mandated. c. Monitoring for any new facility registration requirements under FSMA or FDA regulations. d. Providing advice regarding any additional operational or documentation changes for the following compliance agenda: i. Adhering to the latest FSMA and 21 CFR guidelines; and ii. Develop and implement corrective and preventive actions following any non-conformance observations during monitoring and verification activities. 7. Provides guidance to address identified gaps or areas for improvement in the Foreign Entity's compliance practices.
Additional Services	1. Provides any additional services mutually agreed upon by the parties in writing.
Deliverables	1. Liaison between Foreign Entity and U.S. Regulatory Authorities 2. Regulatory Enforcement & Emergency Notifications 3. Monitoring Compliance with U.S. Laws & Regulations 4. Regulatory Changes Monitoring and Notifications

	5. Corrective and Preventive Action Support 6. Product Label Compliance Monitoring 7. Regulatory Updates Monitoring and Guidance 8. Guidance for Identified Compliance Gaps

6.2 Compliance Management System Software via interlinkIQ (without customizable Templates)

6.2.1 Scope of Services

Compliance Dashboard - 21 CFR 1 Subpart L - Foreign Supplier Verification Programs for Food Importers	1. Manages compliance requirements for certification, accreditation, and regulatory requirements. 2. Includes: a. Management of document control requirements programs, policies, procedures, forms for records, and lessons for training materials and comprehension quizzes. b. Management of reports, document expiration tracking, and notification. c. Management of assigned collaborators for performance, tracking of assessments, reviews, verifications, and approvals. d. Compliance with internal audit and annual review management audits with the percentage of completion tracking. e. Collaborative management of paper-based uploaded documents compliance verification, reviews, and approvals with comments and history tracking compliant with 21 CFR Part 11 for digitized document control compliance. f. Itemized compliance and annual review action items were performed, as well as performance and review tracking frequency. g. Management of references, videos, and tasks collaborations.
Risk Assessment	1. Assess risks and liabilities associated in the areas of agreements, contracts, allergen management, audits, calibration, CAPA, change controls, computerized systems, crisis management, customer complaints, distribution, document control, environmental monitoring, facility and food defense, food safety, GMPs, HACCP, FSP management, hiring practices, investigations, labeling, loss information, preventive maintenance, packaging, quality assurance, QMS, receiving, regulatory compliance, recall and traceability, safety, shipping, SSOPs, SOPs, storage, warehouse management, supplier requirements, testing, training, and vehicles. 2. Includes: a. Insurance Claims Qualification Survey. b. Risk assessment questionnaires provided by insurance companies that incorporate best practices based on food safety management systems and preventive controls.
Enterprise Management	1. Manages organization's information legal name, country of origin, and key emergency contacts for recall and food safety events. 2. Includes: a. Management of activities related to employees, import/export, product and service offerings, processes, and categories. b. Manages the organization's information encompassing its business structure, trademarks, parent company details, as well as regulatory, certification, and accreditation records.
Facility Management	1. Manages additional facility(ies) information, registration/organization, crisis management/ customer service team, functions(operations), certification and

	accreditation records, allergens/ quality systems used, and size of physical plant/facilities.
HR and Training Management	1. Manages organizational structure (primary and alternate), departments, job descriptions, employee rosters, training, comprehension quizzes, and training requirements. 2. Includes: a. Management of the onboarding process for employees, including the activation and deactivation of accounts for access control, as well as assigning user roles such as collaborator, reviewer, and/or approver. b. Management of employee and worker training requirements and documentation at hire, refresher training at prescribed frequencies (at least annually), and retraining when deficiencies are identified, and as required by prevailing regulation.
Product Management	1. Manages product details (images, labeling instructions, product codes, names, vendor codes, categories, packaging details, intended use and consumers, and temperature requirements). 2. Includes: a. Management of product characteristics (organoleptic, sensory, physico-chemical, and microbiological). b. Management of allergens, packaging dimensions, storage, distribution, manufacturing, mock and trace exercises, documents, and testing lab details. c. Management of approved specifications (label, ingredient, packaging, process, coding, finished product, equipment, shipping, storage, and handling).
Supplier Management	1. Manage supply chain compliance (details, contacts, status, notification, frequency, and regulatory compliance number tracking). 2. Includes: a. Customized management of requirements such as statements, agreements, contracts, monitoring, registrations, importing, exporting, FSVPs, guarantees, warranties, COA, COC, COO, COI, supplier approvals, and audits. b. Management of products and services, audit review submission. c. Co-Manufacturing and/or Co-Packing compliance functions.
Customer Management	1. Manages customer's details, contacts, status, notification, and frequency. 2. Includes: a. Customized management of requirements such as statements, agreements, contracts, monitoring, registrations, importing, exporting, FSVPs, guarantees, warranties, COA, COC, COO, COI, supplier approvals, and audits. b. Management of products and services, audit review submission.
Corrective and Preventive Action Management (CAPAM) Module	1. Manages requirements under 21 CFR Part 117.150 Corrective actions and corrections.
Foreign Supplier Verification Program Module	1. Manages requirements under 21 CFR Part 1 Subpart L Foreign Supplier Verification Programs for Food Importers.
Food Fraud Vulnerability Assessment Module	1. Manages requirements under 21 CFR 121: Mitigation Strategies to Protect Food Against Intentional Adulteration.

May Include 10 E-Forms	1. Monitoring Forms Tracks and manages form submissions, ensuring accuracy, compliance, and streamlined data collection and analysis processes within your organization. 2. May Include: a. Checklists: Organizes tasks, ensuring completeness and accuracy, improving efficiency, and minimizing errors in various processes, from project management to daily routines. b. Inspection Forms: Facilitates thorough evaluations, ensuring compliance, safety, and quality standards are met while streamlining data collection and reporting processes. c. Verification Forms: Validates information, confirming accuracy and authenticity, essential for compliance, authentication, and documentation in various processes and transactions. d. Validation Forms Ensure the accuracy and completeness of data by verifying information against set criteria. This is crucial for quality assurance and compliance in various processes.

VI. TERMS AND CONDITIONS

6.1 FSVPQI/US Agent Representation Services

6.1.1 General Statement:

a. The Agreement shall commence upon the payment date of the monthly subscription and shall continue in full force and effect until terminated by either party upon 30 days prior written notice to the other party.

6.1.2 Subscription Term:

a. Month-to-Month or Annual

6.1.3 Payment Terms:

a. Service fees are billed monthly or annually, and are prepaid.
b. Subscription payments referred to herein are not refundable under any circumstances, including but not limited to the termination of this Agreement for any conceivable cause.
c. The parties may agree to additional compensation for any additional services provided by the Agent beyond the scope of this Agreement.

6.1.4 Confidentiality

a. The Agent shall maintain the confidentiality of all information disclosed to it by the Foreign Entity during the term of this Agreement.
b. The Agent shall not disclose any confidential information about the Foreign Entity to any third party without the prior written consent of the Foreign Entity.

6.1.4 Non-Payment Notice:

a. In the event of non-payment, all service engagement will cease.

6.1.5 Termination of Services:

a. Either party may terminate this Agreement upon written notice to the other party if the other party commits a material breach of any provision of this Agreement and fails to cure such breach within 30 days after receiving written notice thereof.
b. If the Client decides to terminate this agreement, a termination fee equivalent to 10% of the remaining balance will be applied and due. The termination fee is payable within 30 days of the effective termination date.
c. The Client may terminate this agreement by providing written notice to Consultare Inc. Group (CIG) at least one month before the start of the next billing cycle.
d. Upon termination of this Agreement, the Agent shall promptly return to the Foreign Entity any documents, records, or other materials belonging to the Foreign Entity.

6.1.6 Governing Law and Dispute Resolution:

a. This Agreement shall be governed by and construed under the laws of the State of Texas, without regard to its conflict of laws principles.

6.1.7 Entire Agreement:

a. This Agreement constitutes the entire agreement between the parties for the subject matter hereof. It supersedes all prior and contemporaneous agreements and understandings, whether written or oral, relating to such subject matter.

6.2 Compliance Management System Software via interlinkIQ (without customizable Templates)

6.2.1 General Statement:

b. Server storage assessment of five (5) dollars per gigabyte will be assessed annually on the anniversary of this subscription agreement.

c. The server storage fee will be incorporated into the monthly subscription.

6.2.2 Subscription Term:

b. Month-to-Month or Annual

6.2.3 Payment Term:

a. InterlinkIQ Management System Software subscription fees are invoiced monthly or annually, and are prepaid.

b. InterlinkIQ Management System Software Set-up is charged on a one-time payment basis and prepaid. (if applicable)

c. InterlinkIQ E-Form Subscription fees are invoiced monthly and prepaid. (if applicable)

d. Subscription payments referred to herein are not refundable under any circumstances, including but not limited to the termination of this Agreement for any conceivable cause.

6.2.4 Non-Payment Notice:

a. In the event of non-payment, an interruption in access to the InterlinkIQ Connectivity System may occur.

b. Access may be reinstated upon settlement of outstanding dues.

6.2.5 Termination of Services:

a. The Client may terminate this agreement by providing written notice to CIG at least one month before the start of the next billing cycle.

b. In the event the Client terminates this agreement, a termination fee equal to 20% of the subscription amount is applicable.

c. The termination fee is due within 30 days of the effective termination date.

d. Client's InterlinkIQ Connectivity System which includes the InterlinkIQ Management System Dashboard and client's uploaded documents will be archived for 30 days prior to deletion.

e. For retrieval of archived Systems and documents, a retrieval fee of $750.00 will be applied and must be prepaid prior to the retrieval process.

f. If the Client wishes to discontinue and terminate all services, the Client's documents will be transferred to the Client via email once the retrieval fee is paid.

6.2.6 InterlinkIQ Software Set-Up Non-Responsiveness Statement:

a. The client is required to submit for uploading all necessary documents into the system within 20 days of the service commencement. If the documents are not submitted within this timeframe, the service will be considered complete after the 20th day. (if applicable)