



## FSVP/QI/US Agent Action Items

### 1. Compliance and Regulatory Preparation

#### Action Item 1.1: Review Foreign Entity's FSVP Program

- Deliverable: Detailed review report of the Foreign Entity's FSVP Program, including compliance status with FDA regulations.
- Responsibility: Consultare Inc. Group

#### Action Item 1.2: Supplier Compliance Assessment

- Deliverable: Supplier compliance report assessing adherence to FSVP requirements.
- Responsibility: Consultare Inc. Group

### 2. Communication and Liaison Services

#### Action Item 2.1: Establish Communication Channels

- Deliverable: Documented communication plan with U.S. customers, partners, and regulatory bodies.
- Responsibility: Consultare Inc. Group

#### Action Item 2.2: Liaison with Regulatory Authorities

- Deliverable: Records of interactions and correspondence with FDA, USDA, and FTC.
- Responsibility: Consultare Inc. Group

### 3. Documentation and Reporting

#### Action Item 3.1: Prepare Regulatory Reports

- Deliverable: Completed and submitted regulatory reports as required by U.S. authorities.
- Responsibility: Consultare Inc. Group

#### Action Item 3.2: Maintain Compliance Records

- Deliverable: Organized and accessible records of all compliance activities and regulatory interactions.
- Responsibility: Consultare Inc. Group

### 4. Additional Services and Custom Requests

#### Action Item 4.1: Identify Additional Service Needs

- Deliverable: List of additional services requested by the Foreign Entity beyond the standard agreement.
- Responsibility: Consultare Inc. Group and Foreign Entity



**Action Item 4.2:** Provide Custom Solutions

- Deliverable: Implementation of agreed-upon custom services, with progress reports.
- Responsibility: Consultare Inc. Group

**5. Monitoring and Review**

**Action Item 5.1:** Conduct Regular Review Meetings

- Deliverable: Meeting minutes and action item lists from regular review meetings to assess service performance and address any issues.
- Responsibility: Consultare Inc. Group and Foreign Entity

To avail of our professional services kindly contact [hello@consultareinc.com](mailto:hello@consultareinc.com) or call 1-202-982-3002.