



FDA U.S Agent Services Action Items

Communication Facilitation

- Serve as the primary contact between the Foreign Entity and U.S. stakeholders during recalls or food safety events.
- Coordinate communication between the Foreign Entity and its U.S. customers, partners, and distributors in the event of a recall.
- Facilitate communication with U.S. regulatory bodies during food safety incidents, ensuring timely updates and responses.
- Ensure prompt and clear information exchange to manage and resolve food safety incidents effectively.

Liaison with Regulatory Authorities

- Act as the designated U.S. agent for direct communication with the relevant U.S. regulatory agencies (e.g., U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA)), serving as the point of contact in relation to regulatory standards and other inspection processes.
- Submit required documentation, applications, or forms to the relevant U.S. authorities in accordance with responsibilities of the designated U.S. Agent, on behalf of the Foreign Entity.
- Ensure that the Foreign Entity remains compliant with regulatory documentation requirements during inspections, audits, or reviews.

Regulatory Compliance Support

- Stay updated on U.S. regulatory updates and ensure that the Foreign Entity is aware of any changes impacting its products or operations.
- Provide guidance on documentation preparation for regulatory audits, inspections, or reviews by U.S. agencies.
- Offer assistance on navigating U.S. laws, including guidance on obtaining necessary certifications and permits for product importation and sales.
- Support the Foreign Entity in preparing responses to any inquiries, notices, or warnings issued by U.S. regulatory bodies.

To avail of our professional services kindly contact hello@consultareinc.com or call 1-202-982-3002