Consultare Inc. Group
www.interlinkIQ.com
hello@consultareinc.com
1-202-982-3002

Foreign Supplier Verification Program/Qualified Individual (FSVP/QI) - Facility Exporting to US		
Requirements	**Scope**	**Action Items**
FDA Facility Registration	US Agent Designee	Designate a US Agent
	FDA Registration Number	Register the Facility with FDA
		Verify
		Validate
§ 1.500 What definitions apply to this subpart?	Facility/Product Identification	Assess the definition in accordance with requirement
§ 1.501 To what foods do the requirements in this subpart apply?	Importer's Qualification	Assess for exemption
		Assess the inapplicability
§ 1.502 What foreign supplier verification program (FSVP) must I have?	FSVP Requirement Program	Develop
		Maintain
		Follow
		Implement
		Implement preventive controls
		Implement a risk-based supply-chain program
		Verify
		Validate
	Labelling Requirements per Regulations (if applicable)	Implement
	Food Defense Plan	Assess the facility
		Draft the Food Defense Plan
		Key Activity Type Vulnerability Assessment
		Draft Food Defense Challenge
		Implement Food Defense Challenge
		Verify
		Validate
	Management of Suppliers of Raw Materials and Packaging	Provide Supplier Register
		Collect Supplier Register
		Provide Material Register
		Collect Raw Material Register
		Provide Packaging Material Register
		Collect Packaging Material Register
		Review Supplier Register
		Review Raw Material Register
		Review Packaging Material Register
	Temporary FSVP Policy for Emergency Suppliers	Identify
		Assess
		Draft the Program, Policy, Procedure
		Review
		Approve
		Implement
		Provide Records
		Collect Records
		Verify
		Validate
	Ingredients, Raw Materials, Products Foreign Supplier Importer Evaluation	Identify
		Assess
		Draft the Program, Policy, Procedure
		Review
		Approve
		Implement
		Provide Records
		Collect Records
		Verify
		Validate
1.503 - Who must develop my FSVP and perform FSVP activities?	FSVP Personnel Qualification Program	Assess
		Draft the Program, Policy, Procedure

Consultare Inc. Group
www.interlinkIQ.com
hello@consultareinc.com
1-202-982-3002

Foreign Supplier Verification Program/Qualified Individual (FSVP/QI) - Facility Exporting to US		
Requirements	**Scope**	**Action Items**
		Review
		Approve
		Implement
		Provide Records
		Collect Records
		Verify
		Validate
	FSVP Qualified Individual Checklist	Assess
		Draft the Form
		Review
		Approve
		Implement
		Provide Records
		Collect Records
		Verify
		Validate
	Job Description	Assess
		Draft the Form
		Review
		Approve
		Implement
		Provide Records
		Collect Records
		Verify
		Validate
	FSVP Audit Program	Assess
		Draft the Program, Policy, Procedure
		Review
		Approve
		Implement
		Provide Records
		Collect Records
		Verify
		Validate
	FSVP Qualified Auditor Registry	Assess
		Draft the Form
		Review
		Approve
		Implement
		Provide Records
		Collect Records
		Verify
		Validate
	FSVP Audit Schedule	Assess
		Draft the Form
		Review
		Approve
		Implement
		Provide Records
		Collect Records
		Verify
		Validate
	FSVP Audit Plan	Assess
		Draft the Form
		Review

Consultare Inc. Group
www.interlinkIQ.com
hello@consultareinc.com
1-202-982-3002

Foreign Supplier Verification Program/Qualified Individual (FSVP/QI) - Facility Exporting to US		
Requirements	**Scope**	**Action Items**
		Approve
		Implement
		Provide Records
		Collect Records
		Verify
		Validate
	FSVP Audit Checklist	Assess
		Draft the Form
		Review
		Approve
		Implement
		Provide Records
		Collect Records
		Verify
		Validate
1.504 - What hazard analysis must be conducted?	Hazard Analysis	Identify
		Evaluate
		Conduct Analysis
		Assess
		Draft
		Review
		Approve
	HACCP Plan	Provide Record
		Collect Record
		Assess
		Review
		Implement
		Verify
		Validate
	Transportation Agreement	Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
1.505 - What evaluation and approval of Foreign suppliers must be conducted	Foreign Supplier Evaluation	Evaluate Performance
		Evaluate Risk
		Determine the appropriate supplier verification activities
		Assess
		Draft
		Review
		Approve
		Verify
		Validate
	FDA Food Safety Regulations	Assess
		Review
		Implement
		Verify
		Validate
	FSVP Products Description	Provide Product Description
		Collect Product Description
		Assess
		Draft

Consultare Inc. Group
www.interlinkIQ.com
hello@consultareinc.com
1-202-982-3002

Foreign Supplier Verification Program/Qualified Individual (FSVP/QI) - Facility Exporting to US		
Requirements	**Scope**	**Action Items**
		Review
		Approve
		Implement
		Verify
		Validate
	Product/Service Specifications	Provide Product Specifications
		Collect Product Specifications
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	FSVP Team Roster	Provide Team Roster
		Collect Team Roster
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Foreign Supplier Verification Activity(ies) Worksheet	Provide Verification records
		Collect Verification records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Supplier Requirements Letter	Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
1.506 - What Foreign Supplier Verification must be conducted?	Foreign Supplier Verification and related activities Program	Assess
		Draft
		Review
		Approve
		Verify
		Validate
	Finished Product COA	Provide Records
		Collect Records
		Assess
		Draft
		Review
		Approve
		Verify
		Validate
	Mock recall exercise	Conduct
		Review

Consultare Inc. Group
www.interlinkIQ.com
hello@consultareinc.com
1-202-982-3002

Foreign Supplier Verification Program/Qualified Individual (FSVP/QI) - Facility Exporting to US		
Requirements	**Scope**	**Action Items**
		Approve
		Provide records
		Collect records
		Verify
		Validate
	Allergen Policy Statement	Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	California Transparency in Supply Chain Act of 2010 Statement (if applicable)	Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	California Proposition 65 Warranty (if applicable)	Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Details of Coding, Traceability & Recall Systems	Provide Records
		Collect Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	FSMA Compliance Statement-Supplier	Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	FSVP Compliance Statement	Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Pallet Requirements	Assess
		Draft
		Review
		Approve
		Implement
		Verify

Consultare Inc. Group
www.interlinkIQ.com
hello@consultareinc.com
1-202-982-3002

Foreign Supplier Verification Program/Qualified Individual (FSVP/QI) - Facility Exporting to US		
Requirements	**Scope**	**Action Items**
		Validate
	Policy for Product Events	Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Non-GMO Statement	Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Certificate of Liability Insurance	Provide Records
		Collect Records
		Review
		Approve
		Verify
		Validate
	Product/Service Specifications	Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	FDA Bioterrorism Registration Affidavit/ FDA Food Facility Registration	Provide Records
		Collect Records
		Review
		Approve
		Verify
		Validate
	Country of Origin Certificate	Assess
		Draft
		Review
		Approve
		Implement
		Verify
	Bill of Lading	Provide Records
		Collect Records
		Review
		Approve
		Verify
		Validate
	SDS/MSDS (if applicable)	Provide Records
		Collect Records
		Review
		Approve
		Verify
		Validate
	Quality Agreement	Assess
		Draft
		Review

Consultare Inc. Group
www.interlinkIQ.com
hello@consultareinc.com
1-202-982-3002

Foreign Supplier Verification Program/Qualified Individual (FSVP/QI) - Facility Exporting to US		
Requirements	**Scope**	**Action Items**
		Approve
		Implement
		Verify
	Authenticity Validation test results	Provide Records
		Collect Records
		Review
		Approve
		Verify
		Validate
	Hold Harmless Agreement, Guaranty-Warranty of Product (Supplier)	Assess
		Draft
		Review
		Approve
		Implement
§ 1.507- What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation?	Exempted from § 1.505 and § 1.506	Assess
		Identify
	FSVP Import Foods Hazard Program	Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Hazard Analysis	Assess
		Determine
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Compliance Statement	State that the food is *"not processed to control [identified hazard]"*
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Customer Written Assurance	Provide Annually
		Collect Annually
		State that the food is *"not processed to control [identified hazard]"*
		Assess
		Draft
		Review in accordance to applicable food safety requirements
		Approve
		Implement
		Verify
		Validate
	FSVP Requirement Program	Establish
		Document
		Implement

Consultare Inc. Group
www.interlinkIQ.com
hello@consultareinc.com
1-202-982-3002

Foreign Supplier Verification Program/Qualified Individual (FSVP/QI) - Facility Exporting to US		
Requirements	**Scope**	**Action Items**
		Verify
		Validate
		Contains the following: (1) Effective date; (2) Printed names and signatures of authorized officials; and (3) The assurance specified in the applicable paragraph.
§ 1.508 - What corrective actions must I take under my FSVP?	FSVP Corrective Action Program	Provide Records
		Collect Records
		Assess
		Determine
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Corrective Action Report (CAPA Report)	Provide Records
		Collect Records
		Assess
		Determine
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
1.509 - How must the importer be identified at entry?	Qualified Individual Checklist	Assess
		Determine
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	FSVP CBP Filing Form	Assess
		Determine
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	FSVP Ingredient Product Register	Provide Records
		Collect Records
		Assess
		Determine
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Importer Information Form	Provide Records
		Collect Records

Consultare Inc. Group
www.interlinkIQ.com
hello@consultareinc.com
1-202-982-3002

Foreign Supplier Verification Program/Qualified Individual (FSVP/QI) - Facility Exporting to US		
Requirements	**Scope**	**Action Items**
		Assess
		Determine
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Data Universal Numbering System (DUNS) number - UFI	Provide Records
		Collect Records
		Assess
	FDA Bioterrorism Registration Affidavit/FDA Food Facility Registration	Provide Records
		Collect Records
		Assess
		Determine
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
1.510 - How must I maintain records of my FSVP?	Document Control Program	Provide Records
		Collect Records
		Assess
		Determine
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Change History Document Form	Provide Records
		Collect Records
		Assess
		Determine
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Master Document Register-Form	Provide Records
		Collect Records
		Assess
		Determine
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Document Destruction Record-Form	Provide Records
		Collect Records
		Assess
		Determine

Consultare Inc. Group
www.interlinkIQ.com
hello@consultareinc.com
1-202-982-3002

Foreign Supplier Verification Program/Qualified Individual (FSVP/QI) - Facility Exporting to US		
Requirements	**Scope**	**Action Items**
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Records Program	Provide Records
		Collect Records
		Assess
		Determine
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
§ 1.511 What FSVP must I have if I am importing a food subject to certain requirements in the dietary supplement current good manufacturing practice regulation?	21 CFR Part 111 - Current Good Manufacturing Practice In Manufacturing, Packaging, Labeling, Or Holding Operations For Dietary Supplements Requirements	Provide Records
		Collect Records
		Assess
		Review
	Imported Goods Subjected to Dietary Supplement Regulation Program	Draft
		Review
		Approve
		Implement
		Verify
		Validate
§ 1.512 What FSVP may I have if I am a very small importer or I am importing certain food from certain small foreign suppliers?	Very Small Importer/ Small Foreign Supplier	Assess
		Review
	FSVP Imported Goods from Small Foreign Supplier Program	Provide Records
		Collect Records
		Assess
		Determine
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
§ 1.513 What FSVP may I have if I am importing certain food from a country with an officially recognized or equivalent food safety system?	Countries with FDA Officially Recognized or Equivalent Food Safety System (if applicable)	Assess
		Determine
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
		Monitor whether the foreign supplier is in good compliance standing
		Review any information obtained
	Import Food from Equivalent Food Safety System Program (if applicable)	Provide Records
		Collect Records
		Assess
		Determine
		Draft

Consultare Inc. Group
www.interlinkIQ.com
hello@consultareinc.com
1-202-982-3002

Foreign Supplier Verification Program/Qualified Individual (FSVP/QI) - Facility Exporting to US		
Requirements	**Scope**	**Action Items**
		Review
		Approve
		Implement
		Verify
		Validate
	Exemptions	Identify if you meet the conditions and requirements of Countries with FDA Officially Recognized or Equivalent Food Safety System, *then you are not required to comply with the requirements in §§ 1.504 through 1.508. You would still be required to comply with the requirements in §§ 1.503, 1.509, and 1.510.*
§ 1.514 - What are some consequences of failing to comply with the requirements of this subpart?	U.S. Owner or Consignee	Identify
		Review
		Implement
		Verify
	Designated a U.S. Agent or Representative	Identify in accordance with § 1.500
		Review
		Implement
		Verify
	FSVP Requirements	Comply FSVP
	Consequences of Non-Compliance Program	Provide Records
		Collect Records
		Assess
		Determine
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
To avail of our professional services kindly contact hello@consultareinc.com or call 1-202-982-3002.		