



RTE Validation Set-up Services			
Requirements	Scope	Action Items	
Initial Assessment of RTE Product 21 CFR 117.165 Verification of implementation and effectiveness	Identification of the RTE products	Provide Records	
		Collect Records	
		Assess	
		Review	
	Specifications of RTE products	Provide Records	
		Collect Records	
		Assess	
		Review	
	Microbiological Testing	Provide Microbiological Testing/Analysis records, if available	
		Collect Records	
		Assess	
		Review	
	Process Validation	Provide Process Validation records, if available	
		Collect Records	
		Assess	
		Review	
	Shelf-Life Testing	Provide Shelf-Life Testing records, if available	
		Collect Records	
		Assess	
		Review	
	Regulatory Compliance	Provide records, if available	
		Collect Records	
		Assess	
		Review	
HACCP Validation 21 CFR 120.11 Verification and validation.	Process Description	Provide the following information: Finished Product Type Process Category Product Name(s) Manufactured For Product Description, including Important Food Safety Characteristics Process Type Ingredients Allergens Packaging Type Packaging Material Packaging Size(s) Intended Use Intended Consumers Shelf Life Lot Code Specification Labeling Instructions Storage and Distribution	
		Collect Records	
		Assess	
		Initial Review	
		Revisions of the document based on initial review	
		Final Review	
		Revisions of the document based on Final Review	
		Client Approval/Acceptance	
		Implement	
		Verify	
		Validate	
		Label Reference	Provide Label Reference
			Collect Records
			Assess



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		Initial Review
		Revisions of the document based on initial review
		Final Review
		Revisions of the document based on Final Review
		Client Approval/Acceptance
		Implement
		Verify
	Process Flow Diagram	Provide Process Flow Diagram (From Receiving to Distribution/Shipping)
		Collect Records
		Assess
		Initial Review
		Revisions of the document based on initial review
		Final Review
		Revisions of the document based on Final Review
		Client Approval/Acceptance
		Implement
		Verify
	Process Narrative	Provide Process Narrative / Description (From Receiving to Distribution/Shipping)
		Collect Records
		Assess
		Initial Review
		Revisions of the document based on initial review
		Final Review
		Revisions of the document based on Final Review
		Client Approval/Acceptance
		Implement
		Verify
	Hazard Risk Assessment (Likelihood)	Provide Hazard Risk Assessment for the Likelihood of hazard, if available
		Collect Records
		Assess
		Initial Review
		Revisions of the document based on initial review
		Final Review
		Revisions of the document based on Final Review
		Client Approval/Acceptance
		Implement
		Verify
	Hazard Risk Assessment (Severity)	Provide Hazard Risk Assessment for the Severity of hazard, if available
		Collect Records
		Assess
		Initial Review
		Revisions of the document based on initial review
		Final Review
		Revisions of the document based on Final Review
		Client Approval/Acceptance
		Implement
		Verify
	Hazard Analysis	Provide Hazard Analysis Worksheet,if available
		Collect Records



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		Assess
		Initial Review
		Revisions of the document based on initial review
		Final Review
		Revisions of the document based on Final Review
		Client Approval/Acceptance
		Implement
		Verify
	Process Preventive Controls / CCP	Provide Process Preventive Controls / Critical Control Points
		Collect Records
		Assess
		Initial Review
		Revisions of the document based on initial review
		Final Review
		Revisions of the document based on Final Review
		Client Approval/Acceptance
		Implement
		Verify
	Food Allergen Preventive Controls/ Food Allergen Ingredient Analysis	Provide Food Allergen Preventive Controls/Food Allergen Ingredient Analysis
		1. Raw Material Name
		2. Supplier Name / Supplier Register
		3. Allergens in Label
		Collect Records
		Review
		Client Approval/Acceptance
		Implement
		Verify
	Production Line Allergen Assessment	Provide Finished Products List and Allergen present
		Provide Production Line Schedule
		Collect Records
		Review
		Client Approval/Acceptance
		Implement
		Verify
	Hygienic Zoning	Provide Hygiene Zone Program/Map
		Collect Records
		Review
		Client Approval/Acceptance
		Implement
		Verify
	Approved Suppliers for Ingredients Requiring a Supply-Chain-applied Control	Provide Approved Supplier List/Register
		Date of Approval
		Verification Records
		Collect Records
		Review
		Client Approval/Acceptance
		Implement
		Verify
	HACCP Plan Validation	Provide Food Safety Plan Validation records, if available
		Collect Records
		Review



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Requirements	Scope	Action Items
		Client Approval/Acceptance
		Implement
		Verify
		Validate
Validation of Food Safety Control Measures (CAC/GL 69 – 2008 GUIDELINES FOR THE VALIDATION OF FOOD SAFETY CONTROL MEASURES)	Identification of Hazards	Assess
		Research
		Verify
	Identification of the Food Safety Outcome	Assess
		Research
		Review
	Identification of the Measures that are to be Validated	Assess
		Research
		Review
Validation Process (CAC/GL 69 – 2008 GUIDELINES FOR THE VALIDATION OF FOOD SAFETY CONTROL MEASURES)	Pre-validation tasks	Assess
		Research
		Review
	Approaches for validating control measures	Assess
		Research
		Review
	Parameters and Decision Criteria	Assess
		Research
		Review
	Relevant validation information	Assess
		Research
		Review
	Studies needed	Assess
		Research
		Review
		Conduct
	Result of Analysis	Provide Records
		Collect Records
		Review
	Validation	Draft Report
		Review
Approval		
Client Approval/Acceptance		
Verify		
	Implement	
Related Programs and/or Forms		
Product Temperature 21 CFR 117.165 Verification of implementation and effectiveness	Temperature Monitoring SOP	Provide Records
		Collect Records
		Assess
		Develop
		Review
		Approve
		Implement
	Thermometer Calibration SOP	Provide Records
		Collect Records
		Assess
		Develop
		Review
		Approve



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Requirements	Scope	Action Items
Process 21 CFR 117.165 Verification of implementation and effectiveness	Preparation SOP - Prevent cross contamination between raw and ready -to-eat foods - Identify where the processing will occur - The processing should be separate from other operations.	Implement
		Provide Records
		Collect Records
		Assess
		Develop
		Review
		Approve
		Implement
Employee Hygiene and Health Policy 21 CFR 117.165 Verification of implementation and effectiveness	Handwashing protocols and procedures prohibiting bare hand contact with ready-to-eat foods.	Provide Records
		Collect Records
		Assess
		Develop
		Review
		Approve
		Implement
	Reporting requirements and exclusion or restriction for ill food employees.	Provide Records
		Collect Records
		Assess
		Develop
		Review
		Approve
		Implement
Food Safety Training Program 21 CFR 117.165 Verification of implementation and effectiveness	Provide a food safety training program that shows employees and supervisors know -How to perform the steps in this plan -How to use necessary equipment -How to implement corrective actions. -Employees need to sign off on the training plan.	Provide Records
		Collect Records
		Assess
		Develop
		Review
		Approve
		Implement
Sanitation 21 CFR 117.165 Verification of implementation and effectiveness	Equipment SSOP - Describe how equipment is cleaned and sanitized. - Include how often in the process equipment is cleaned (before beginning, between types of foods, etc.)	Provide Records
		Collect Records
		Assess
		Develop
		Review
		Approve
		Implement
Equipment and Materials 21 CFR 117.165 Verification of implementation and effectiveness	Equipment and Utensils Program - Equipment must meet ANSI standards. (These standards are in 4-1 and 4-2 of the FDA Model Food Code.)	Provide Records
		Collect Records
		Assess
		Develop
		Review
		Approve
		Implement
	Equipment and Utensils Register - Provide list of equipment and materials used in the process.	Provide Records
		Collect Records
		Assess
		Develop
		Review
		Approve
		Implement
Environmental Monitoring 21 CFR 117.165 Verification of implementation and effectiveness	Environmental Monitoring Program - Describe the procedure, location and frequency of EMP in the facility	Provide Records
		Collect Records



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RTE Validation Set-up Services		
Requirements	Scope	Action Items
	- Identify the test microorganism(s)	Assess
		Develop
		Review
		Approve
		Implement
To avail of our professional services kindly contact hello@consultareinc.com or call 1-202-982-3002.		

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