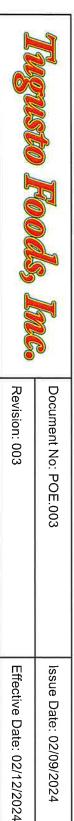


		Documen	Document No: POE.003		Issue Date: 02/09/2024	
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	Title: Supply-Cha	ain Prograr	Title: Supply-Chain Program (Supply Verification and	n and Approval)	val)	
		App	Appendix D			
	Supp	olier Eval	Supplier Evaluation Questionnaire	naire		
Company Name:						
Company Information:	☐ Corporate ☐	□ Public		□ Private	☐ Partnership	
Phone / Fax:			Website:			
Company Address:						
City:			State / Zip Code:		Country:	
Years in business:			Facility Size (Square foot):	e foot):		
Supplier Type:	☐ Raw Material	☐ Packagin	☐ Packaging Component ☐	Other Materials	erials	
Supplier Contact Information:	mation:					
Management:			Title:			
Phone:			Email:			
Quality:			Title:			
Phone:			Email:	-		



Title: Supply-Chain Program (Supply Verification and Approval)

Supplier Evaluation Questionnaire

not applicable to supplier services. Questionnaire: Please provide thorough and detailed responses to all applicable sections. Enter an N/A or line through a section if the section is

Question	Comments
Regulatory History:	
Has the facility been inspected by the FDA?	
If so, indicate dates for the last two inspections and submit copies of FDA Establishment Inspection Reports, Form 483's and/or	
Warning Letters received.	
Has the facility been inspected by the Department of Health	
or any other regulatory body?	
If so, what was the compliance rating? Submit copies of the	
What type of facility registration do you have with the FDA. DFA.	
or USDA? Provide registration numbers.	
What standard(s) do you employ for your manufacturing operations? (Food GMPs - 21 CFR 117; ISO, GFSI, other)	
Does the facility have any certifications? If so, list the Certifications	
and renewal dates.	
Has the facility been inspected by a third-party?	
If so, indicate the name of the third party, date for the last	
inspection and submit copies of the report issued.	



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Question	Comments
Personnel:	
Who is responsible for the Quality System at the facility? Provide their name, title, and document (biography, resume, or CV) that summarizes their education, experience, and training.	
Who is responsible for material manufacturing at the facility? Provide their name, title, and document (biography, resume, or CV)	
that summarizes their education, experience, and training.	
titles of key personnel, and reporting structure.	
What is the total number of personnel working at the facility?	-
Are Job Descriptions available to indicate the qualification requirements and job functions for all personnel?	
Describe the on-the-job training program employed and submit the corresponding SOP that governs the process. Submit copies of two associates training records along with the training matrix	
What are the requirements for personnel hygienic practices at the facility?	
Facility:	
What are the normal hours of operation of the facility?	
What is the square footage of the facility, including all buildings?	



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Ouestion	Comments
Facility:	
List all of the operations performed at the facility (farming, harvesting,	
manufacturing, packaging, labeling, testing, holding, and/or	
distribution).	
Are multiple facilities used to conduct any of the farming,	
harvesting,manufacturing, packaging, labeling, testing, holding, or distribution charations?	
Does the facility contract out any operations? If so, indicate what type	
of operations are performed by third parties, and by whom.	
List the major equipment available at the facility.	
ls all equipment qualified prior to use?	
Is all equipment calibrated prior to use and on a routine basis consistent with the manufacturers recommendations?	
What type of preventative maintenance program is in place?	
Are refrigerated and freezer storage available at the facility? How are these controlled temperature units verified to be suitable for use?	



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Question	Comments
Facility:	
Is the facility continually monitored for temperature and humidity?	
Has the facility where materials are held been mapped for temperature and humidity?	
Explain the Environmental Monitoring program used at the facility to	
limit material, product, and contact surface contamination. Attach a	
copy of the SOP that details this program.	
Summarize the pest control program employed at the facility. Provide a	
Are written procedures for cleaning of equipment and production areas developed?	
If so, are records for cleaning maintained? Submit copies of cleaning logs.	
How is cleaning of equipment and production rooms verified?	
Does the facility have a dedicated Sanitation Supervisor?	
Is line clearance performed on production rooms/equipment prior to production?	



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Question	Comments
Facility:	
Is there positive air pressure in the production rooms?	
What are the protective clothing requirements in the GMP areas? (ex: hairnets, lab coats, shoe covers etc.)	
Quality Systems:	
Provide a document(s) that gives an overview of the quality system such as an SOP Index or Quality Manual.	
Explain the document control system that is utilized at the facility.	
Is an electronic document control system in use? If so, indicate the software type.	
Are electronic software packages validated to be suitable for use?	
Submit a copy of your change control procedure to indicate how revisions to controlled processes and documents are managed at the site.	
How are customers notified of changes to processes, records, specifications, test methods, or contract terms that may impact their product?	



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Question	Comments
Quality Systems:	
Summarize the quality incident system and provide a copy of the	
SOP on Material Reviews.	
Are there procedures in place for managing and investigation Out of	
Specification (OOS), Out of Trend (OOT), and aberrant or unusual test	
results?	
Briefly explain the process of conducting an OOS investigation. Submit	
a copy of the Out of Specification (OOS) procedure.	
ls a specific format used to document an OOS investigation? Submit a	
copy of the form used.	
What is the procedure for handling deviations to test	
methods, manufacturing records, or controlled processes?	
Is there an established process for salvaging and re-distributing	
returned materials?	
Summarize the procedure used to handle complaints. Does the SOP	
include a description of what defines and Adverse Event (AE)?	
Is there a separate procedure on the classification and reporting of	
Serious Adverse Events (SAEs)?	



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Question	Comments
Quality Systems:	
How is a customer notified of an AEs and SAEs complaint received by the supplier in regards to their material?	
Is a procedure available for corrective and preventative action	
Food Safety, HACCP and Food Defense	
Is there a HACCP program in place?	
If so, list all the CCPs and CPs for the program.	
Were the CCPs and CPs equipment validated? If Yes, what	
qualifications were performed? (IQ, OQ, PQ)	
What is the revision frequency of the HACCP program? Is the HACCP	
program revised when changes to ingredients, equipment or procedures are made?	
Are control limits established using scientific data and or/regulatory	
guidelines? provide control limits for all CCPs and CPs.	
Are non-conformities at critical control point documented and corrective actions reviewed?	
Is there a written Foreign Supplier Verification Program (FSVP) in	



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	Is there CCTV video monitoring present at the facility?
	racility and the production rooms?
	ls there limited access control for employees and visitors to the
	ls there a Food Defense program in place? If so, Provide a copy.
	chemicals? If so, submit SOP.
	Are there written procedures for storage and approval of cleaning
	place? Submit copies of the SOP/Program.
	is there a written supplier qualification and management program in
	Do you have a written supply chain programs it so, submit copies.
	Do son basso a susitton Cumply Chain program J If no cultural coninc
	List all the hazards that require preventive control?
	how do you intend to be in compliance with above requirements?
	monitoring records for each control.If you answered "NO", when and
	ill so, submit copies of the Food Safety Flair/ Funt and examples of
	if the submit position of the Food Safety Diam / DOUE and examples of
	place? (PCHF or Food Safety plan)
	Is there a written Hazard Analysis and preventive controls program in
	Food Safety, HACCP and Food Defense
	Account.
Comments	Ougstion



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Question	Comments
Materials	
Are all incoming materials and components received into a	
Quarantine status? Provide a copy of the SOP that governs this	
process.	
Who is responsible for the release of incoming materials and	
components from Quarantine and what are the criteria used to make	
this decision?	
Is there a physically segregated Quarantine area? If so, what	
personnel have access to this area?	
What status indications such as Quarantine, Released, Hold, and	
Reject are utilized at the facility? Define each.	
Is an electronic system used to control the status of materials and	
products? If, so has this system been validated to comply with 21 CFR	
11, Electronic Records, Electronic Signatures?	
Are all materials clearly identified with a description, item number, lot	
number, quantity, and expiration date at all times?	
Are all materials and products identified with the assigned status	
indications at all times?	
Are all materials and products determined to be OOS, assigned a	
Reject status?	
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Question	Comments
Materials	
Is there a physically segregated Reject area? If so, what personnel	
have	
access to this area?	
How is the destruction of rejected material performed and	
Are all Returned Dietary Supplement clearly identified?	
Is there an Allergen program in place at the facility? If so, please describe.	
How are material labels controlled at the facility?	
Is a physically segregated Label Room utilized to control access to	
What are the label reconciliation requirements at the facility? Attach a copy of the SOP that dictates these.	
Are the packaging components free of BPA?	



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Question	Comments
Master Manufacturing Record (MMR)	
Has an MMR been established for every material manufactured?	
Does each MF indicate the intentional overage that is utilized for each ingredient in the product?	
Do the intentional overages applied to the MF account for	
Has an MMR been established for every product formulation and at each batch size?	
Is the MF included as part of the MMR?	
Does the MMR include detailed instructions for each point, step, or stage of the manufacturing process? Submit an example MMR template.	
Is there a separate manufacturing and packaging MMR?	
What is the nomenclature used for the unique batch or lot number that is assigned to every manufactured batch? Attach a copyof the SOP that dictates this system.	



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Question	Comments
Master Manufacturing Record (MMR)	
ls a Batch Production Record (BPR) generated for each product lot	
that is manufactured?	
Is the executed BPR an exact copy of the MMR?	
Does the completed BPR reference equipment and facility (room)	
cleaning requirements and logs?	
What is the process of obtaining a representative and statistical	
product sample? Is this dictated in the MMR or SOP?	
Describe the procedure for determining whether a material may be reprocessed. Attach a copy of the Reprocessing SOP.	
ls the customer notified prior to any reprocessing of their	
material or product? How is this communicated?	
Where are reprocessing instructions documented?	
How are the actual steps dictated in the reprocessing instructions	
Who is responsible for the release of manufactured material	
for distribution and what are the criteria used to make this decision?	
How is the final release of a manufactured material documented?	



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Question	Comments
Specifications	
Are all incoming materials sampled and inspected using a statistical and	
representative number of samples? What criteria are used? Attach	
Inspection SOP.	
Where are incoming materials sampled? What are the environmental controls in the area?	
ls there an established Raw Material Specification for each incoming	
aw illaterial; Subilit a naw Material Specification template.	
Material Specification documented?	
ls every lot of Raw material and finished material tested for	
everything as specified on the Specification?	
Is a Raw Material Qualification Program in place? If so, please provide brief explanation of program and submit SOP.	
What typical tests are used for in-process material testing?	
Are In-process Material Specifications established for all materials?	
Where are tests in accordance to In-process Material Specifications documented?	



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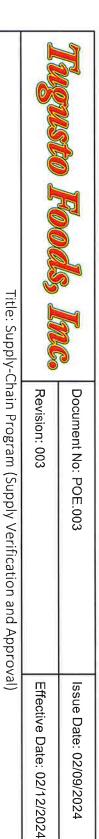
Question	Comments
Specifications	
Is there an established Finished Material Specification for each manufactured material?	
How is the documentation of the testing, in accordance to the Finished	
Material Specification documented?	
Is a Finished Product Qualification Program in place? If so, please	
provide brief explanation of program and submit SOP.	
Does each Raw Material, In-Process, and Finished Material	
Specification address the identity, purity, strength, composition, and	
lack of potential contaminants? Is there an SOP that dictates this? If	
so, attach SOP.	
Laboratory Operations:	
Does the facility have an in-house laboratory that performs raw material, in-process material, and finished material testing?	
Are third party Contract Laboratories used to perform testing of raw material, in-process material, and finished material testing? If so, what is the qualification process for the laboratory? Submit the SOP that governs this process.	



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Question	Comments
Stability:	
How many and what type of environmental / stability chambers are available at the facility?	
What is the current capacity of the chamber storage?	
Have all of the stability chambers been qualified and mapped for temperature and humidity?	
Are all of the temperature and humidity devices calibrated before use and at a frequency dictated by the manufacturer?	
How are stability protocols maintained, managed, and utilized?	
Who prepares stability summary reports and at what frequency?	
Distribution:	
How are distribution records documented and maintained?	
Is there traceability for all distributed product to the consumer?	
ls there a written recall procedure?	
Are Mock recalls performed by the facility? If so, how often?	
identify the system employed.	



Question	Comments
Distribution:	
If an electronic system is used, has it been validated to comply with	
Signatures?	
Are shipments received secured and sealed upon arrival? Is	
there inspection performed on the trailers delivering the	
materials. Submit copies of receiving and inspection procedures.	
Records	
How are records maintained at the facility?	
What are the storage duration requirements for records generated	
and used at the facility? Submit a copy of the SOP that governs	
records retention.	
Are customers informed prior to the destruction of any records	
pertaining directly to their product?	