GMP Boot Camps

Certificate of Training

Presented to:

Paul Edward

In Recognition of Attending the 8-Hour Webinar Boot Camp Conference

cGMP QMS 8-Hour Boot Camp Webinar

'GMPs From the Auditor's Perspective'

Presented with Congratulations on;

May 14th 2024

John Cuspilich, Sr. Instructor, Sr. Auditor
GMP Boot Camps, The Auditing Group
and GMP Publications

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February 8th 2023

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GMP AUDIT

Vendor Name	Chef Rubber			**Date:**	01/16/24
Vendor Street Address	6627Schuster St.				
Vendor City	Las Vegas		**State:** NV	**Zip:**	89193
Contact:	Paul Edward				

Nature of Audit	**Initial**			
	Routine	X		
	Problem Investigation		**Description:**	

Summarize Complaints/ Holds/ Rejections since last audit:

MATERIALS SUPPLIED

Materials	**Receiving Locations**

Comments

Audit Score: 100%

Rating: EXCELLENT

Next Scheduled Audit Date: _____

Audited By: SB _____ **Date:** **01**/16/2024

_____

ACTION PLAN:

Category	Score		By	When
A. Receiving	100%			
B. Manufacturing	100%			
C. Packaging	100%			
D. QC/ QA	100%			
E. SPC	100%			
F. Records	100%			
G. Facility/GMP	100%			
H. Security	100%			
I. Micro	100%			
J. Organic	100%			
Document	100%			
Pest Control	100%			
Cleaning+Sanit.	100%			
Steam/water/air	100%			

General:

Overall Score	**100%**	**Previous Audit Score**	
Rating:	**EXCELLENT**		

Chef Rubber

VENDOR ASSURANCE GMP AUDIT

A.	RECEIPT OF RAW MATERIALS	2	1	0	n/a
1	Are receiving areas clean, uncluttered, compartmentalized and protected?	x			
2	Are raw materials properly handled, stored and segregated to prevent damage, contamination or loss?	x			
3	Are there documented procedures for receiving/using/rejecting raw materials? Are they being followed?	x			
4	Does the vendor track freshness/time vs. temp. of raw materials and does this information determine acceptability for use?	x			
5	Are raw materials analyzed with the proper instruments/equipment?	x			
6	Are the instruments/equipment calibrated and documented on a regular basis?	x			
7	Are the receiving procedures and records adequate to keep track of date of receipt, incoming materials quality and supplier source?	x			
8	Are there approved areas and procedures for sampling?	x			
9	Are there receiving practices in place to assure that shipping containers, transporting vehicles and storage areas do not transfer allergenic food substances to all incoming ingredients, and are raw material receiving procedures linked to the HACCP program to protect against any food safety problems ?	x			

COMMENTS ON RECEIPT OF RAW MATERIALS:

A6 Weigh scales calibrated yearly

A9 See A7 Comment

B.	MANUFACTURING	2	1	0	n/a
1	Are all instruments/equipment necessary for manufacturing product, present and functioning properly? (i.e., detectors, sensors, meters, ovens, thermometers, scales, timers etc.)	x			
2	Are the instruments/machinery calibrated and documented on a regular basis?	x			
3	Do manuals/references exist that clearly state operating parameters for all machinery? (i.e. temps, vents, timers, rates, tensions, gap settings etc.)	x			
4	Are specification and procedure manuals available to all associates?	x			

5	Is there a method to inform relevant associates of changes in the process or specifications?	x			
6	Does the process for change management/change control give consideration to risks of allergen contamination?				
7	Are there quality procedures that provide evidence of conformance of the finished product to all specifications?	x			
8	Are records of production steps maintained that include quantities, lot numbers and supplier source of materials used?	x			
9	Are records maintained to provide evidence that the product has passed inspection/tests with defined acceptance criteria?	x			
10	Are other operations appropriately separated to prevent odor, microbiological, foreign material and other types of contamination?	x			
11	Are raw and processed materials and processes controlled to prevent cross contamination? Is traffic in the process areas adequately controlled to protect the process and process environment from contamination?	x			
12	Are waste materials clearly identified in proper containers and disposed of to minimize odors and prevent the attraction of insects, birds and other animals?	x			
13	Are areas that are dusty or subject to microbial contamination properly controlled and appropriately decontaminated?	x			
14	Is there an adequate program to reject or reprocess off standard in-process or finished materials?	x			

COMMENTS ON MANUFACTURING:

B7

Color control established by use of recipe control and by use of color standard comparison.

C. PACKAGING/SHIPPING

		2	1	0	n/a
1	Are packaging materials stored to prevent contamination and deterioration?	x			
2	Is a code dating system used?	x			
3	Are appropriate shipping containers used?	x			
4	Are all shipping containers properly marked to identify contents?	x			

5	Does the vendor practice FIFO stock rotation?	x			
6	Do guidelines exist to properly inspect shipping containers prior to use?	x			
7	Do guidelines exist to properly inspect and clean new and/or recycled containers, tank cars, trucks, railcars and storage tanks prior to use? Is this documented?				x
8	Are tank cars and trailers properly sealed and temperature controlled during shipment?				x
9	Are products shipped only after all laboratory tests are completed?				x

COMMENTS ON PACKAGING/SHIPPING:

D. QUALITY CONTROL/ASSURANCE

		2	1	0	n/a
1	Are on-line critical control point audits performed on a regular basis and is the data generated, used to adjust the process?	x			
2	Are adequate steps taken to prevent foreign materials from entering the process, by use of detectors, magnets, screens, light shields, etc?	x			
3	Are all instruments necessary for QC evaluation present, calibrated and functioning properly? Are they included and documented in their preventive maintenance program?	x			
4	Are laboratory standards checked on a regular schedule?	x			
5	Does a reference guide exist that clearly lists all possible non-conforming products and is it available for associate referral?	x			
6	Are hold procedures documented and in place? Are they available for associate references?	x			
7	Does the hold system ensure that product which does not conform to specific requirements is prevented from inadvertent use?	x			
8	Are acceptance-rejection limits enforced and documented?	x			
9	Are sampling procedures documented, in place and available for associate reference?	x			
10	Does the sampling system appear effective for determining frequencies of non-conforming/defective material?	x			

11	Are the causes of non-conforming product identified, and the corrective action needed to prevent recurrence, investigated and implemented?	x			
12	Is there a HACCP (Hazard Analysis and Critical Control Point program) or other Quality System in place and available for inspection? Is it kept up to date?	x			
13	Is the program to perform finished product testing adequate to meet the specification?	x			
14	Is there an experienced manager who is responsible for quality?	x			
15	Are laboratory samples for analysis appropriately identified and controlled?	x			
16	Are there adequate programs to test for extraneous materials or contaminants (i.e., pesticides, antibiotics, metals, etc.)?	x			
17	Is there a functioning sensory program to evaluate incoming materials and finished products?	x			
18	Does the laboratory appear to have good safety and chemical hygiene procedures?	x			
19	Is there an allergen control and awareness program?	x			
20	Is there allergen policy adequate to prevent cross contamination.	x			
21	Is Allergen Awareness training performed?	x			
22	List all allergenic products processed in the plant (in Comments) peanut, tree nuts, soy, wheat (gluten), egg, milk/dairy, fish, shellfish NONE				
23	List all allergenic products processed on lines or in equipment used to manufacture products. NONE				

COMMENTS ON QUALITY CONTROL/ASSURANCE:

C19-1 No allergens are present in the facility and no eating is allowed. However, allergen policies and awareness are still recommended for any food ingredient company or food manufacturer.

E.	**STATISTICAL PROCESS CONTROL**	2	1	0	n/a
1	Do the vendor's processes demonstrate control?	x			
2	Are the vendor's processes capable of meeting specification?	x			

3	Are the vendor's processes meeting specification?	x			
4	Have adequate statistical techniques, required for verifying the acceptability of process capability and product specifications, been established where appropriate?	x			

COMMENTS ON STATISTICAL PROCESS CONTROL:

F. QUALITY RECORDS/DOCUMENTATION CONTROL

		2	1	0	n/a
1	Are quality records collected, filed, maintained and available for reference upon request?	x			
2	Are the quality records legible/identifiable to the relevant process/product?	x			
3	Are records monitored for completeness and accuracy?	x			
4	Do the quality records state all relevant control limits?	x			
5	Do the quality records state all relevant sample specifications?	x			
6	Do the quality records state all relevant sample frequencies?	x			
7	Do the quality records state appropriate corrective actions?	x			
8	Do the quality records include sign-off areas for all appointed associates? (i.e. line op, superv., mgr.)	x			
9	Are the quality records dated?	x			
10	Does the facility have an adequate written policy to control specifications, test methods and other documents?	x			
11	Are sanitation procedures, records of cleaning frequencies, and reports of environmental/safety conditions maintained and available for inspection?	x			
12	Are pest management documents appropriately maintained?	x			
13	Are acceptance/rejection limits documented and enforced?	x			
14	Do you have tracking procedures in place to ensure adequate product lot traceability? (describe in comments section)	x			
	a) material from your supplier to you	x			
	b) material from receipt to shipping	x			
	c) from your facility to ours	x			
15	Do you perform mock recalls? (Write in comments frequency)	x			

COMMENTS ON QUALITY RECORDS/DOCUMENTATION CONTROL:

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G.	FACILITY CONDITION/SANITATION/SAFETY/TRAINING	2	1	0	n/a
1	Does the plant location promote product quality and regulatory compliance?	x			
2	Are the grounds, drives and roofs well cared for? Are roofs inaccessible to pests and free of excess debris and attractants?	x			
3	Are smoking and eating prohibited where necessary?	x			
4	Are special apparel requirements such as hats, uniform, jewelry removal, etc., conformed to?	x			
5	Do employees appear to be neat, knowledgeable and quality conscious?	x			
6	Are adequate bathroom facilities available and are signs posted to direct employees to wash hands before working?	x			
7	Are break areas and lunch rooms enclosed, with self-closing doors? Are the areas sanitary and free of pest attractants and harborages?	x			
8	Are buildings and equipment adequate for the processes, well maintained and used appropriately? (i.e. clean floors, ceilings, pipes, insulation, fixtures, etc.) Are valves and associated pipes (steam, water, etc.) free of leaks?	x			
9	Are buildings and equipment designed for effective cleaning?	x			
10	Are drains adequate and are ceilings, floors and walls in good condition to prevent contamination from paint chips or dust?	x			
11	Are the product lines, equipment and utensils cleaned and sanitized either manually or with a satisfactory CIP system on a regular basis?	x			
12	Are product and any critical room air handling systems adequate and fitted with proper filters?	x			
13	Are doors, windows and other openings in good repair and do they effectively exclude insects, birds and other pests? (i.e. functional aircurtains?)	x			
14	Is temperature and relative humidity control adequate for the operations performed?	x			
15	Is lighting adequate for the needs of the operation? Light intensity? Shielded lights where necessary?	x			

16	Are cleaning compounds, pesticides and sanitizers properly stored, labeled and handled to prevent contamination of product and packaging materials?	x			
17	Are hazard material classification signs posted where necessary?	x			
18	Are raw materials and finished product warehouses well organized and of sufficient size to provide an 18" perimeter for inspection and cleaning?	x			
19	Are there safety, GMP, quality, etc. training programs in place?	x			
20	Are certified/approved persons or outside agencies employed to administer the pest control program? (List under comments)	x			
21	Are insect electrocuters, bait stations and other pest control devices located and maintained for maximum effectiveness?	x			
22	Are exterior pest control traps locked and mounted?	x			

COMMENTS ON FACILITY CONDITION/SANITATION/SAFETY/TRAINING

G19 **One man operation does not require a training program, however the addtion of employees will require training programs for GMPs, allergens, etc.**

H. SECURITY

		2	1	0	n/a
1	Do your vendors ship material to you in sealed/tamperproof containers? Do you record and document their receipt? If not are they verified safe for use?	x			
2	Do you use tamper proof security measures (seals) for outbound loads? Are the seal numbers recorded on the Bill of Lading?	x			
3	Do LTL have seals applied, are they replaced if removed?				x
4	Do you require seals to be replaced if they are removed at inspection points? (example: inspections in state borders)				x
5	Do all materials shipped have a CofA with the load on delivery? Are they either faxed or electronically transferred?	x			
6	Does the vendor use an approved trucking company?	x			
7	Is the building able to restrict unknown personnel access to the building? Is the site alarmed, patrolled and/or CCTV after hours?	x			
8	Is the finished goods warehouse locked, closed automatically during normal working hours?	x			

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9	Does the security at the facility include personnel restrictions to high-risk areas, badges? Do you have logs for signing in and out of these areas?	x				
10	Are all the external inlet points for raw materials capped and secured? (example: sealed and/or locked)	x				
11	Do you record visitors and contractors visits and issue permits/badges?				x	visitors not allowed
12	Are temporary personnel/contractors distinguished from permanent employees?				x	not allowed
13	Are toxic and potentially hazardous materials adequately and effectively contained (in tamper proof containers), identified and documented? Are MSDS sheets maintained?	x				
14	Are all chemical/hazardous materials stored in a locked/secure location away from food processing areas?	x				
15	Is the usage of all chemical/hazardous materials tracked and responsible associates listed on usage records	x				
16	Is printed but unsaleable packaging rendered unuseable. (I.,e. shredding, compacting, defacing, etc.)	x				

COMMENTS ON SECURITY

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I.	MICROBIOLOGICALLY SENSITIVE INGREDIENTS	2	1	0	n/a
1	Does this supplier location produce ingredients sensitive to microbial contamination? If "No", mark (NA) for all questions in this section.				x
2	Does the facility have an active current HACCP program for each product supplied? Include the HACCP flow diagrams or summaries for each product. Summarize sampling, testing and lot definitions for each product on the Product Testing Summary Forms.	x			
3	Does the facility test finished product to assure compliance to the specification?	x			
4	Are test method detection limits for microbiology equivalent to or more sensitive than those specified? Complete a finished product testing summary for each ingredient supplied.	x			
5	Is an autosampler used to sample finished goods?	x			
6	Does the facility monitor in-process samples for microbiology ?	x			
7	Is there an active monitoring program for Salmonella and Listeria in the process environment? How often?	x			
8	Are critical process areas (bagging rooms, dryer rooms, etc.) adequately protected to prevent microbial contamination?	x			
9	Does the supplier send monthly summary reports to? Who receives these reports?				x
10	Is the supplier's laboratory (on-site or contracted) approved to perform microbiological testing? List the name of the lab used to perform microbiological testing.	x			
11	Did the auditor perform swabs? Mark [2] for YES and [n/a] for NO	x			
12	Were results of the swabs acceptable?	x			

COMMENTS ON MICROBIOLOGICALLY SENSITIVE INGREDIENTS

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J. ORGANIC INGREDIENTS

1	**Documentation**	2	1	0	n/a
1.1	Is the vendors organic certificate current and in date?	x			
1.2	Is the vendors certification authority, accredited by the USDA?	x			
1.3	Are all certified finished ingredients listed on the certificate?	x			
1.4	Does the vendor have on file, copies of current organic certificates for all raw materials processed at the facility?	x			
1.5	Does the Bill of Lading clearly describe the raw materials supplied for processing as "Organic"?	x			
1.6	If processing aids are used, are they acceptable under the National Organic Program? (RECORD TYPE USED UNDER COMMENTS)	x			
1.7	Does the vendors documentation clearly demonstrate that only organic raw materials where used to produce the finished ingredient?	x			
1.8	Are organic record kept for 5 years? (Required by USDA)	x			
2	**Pest Control**				
2.1	If the vendor uses an outside pest control company, have they been formally informed that organic ingredients are processed and stored at the facility?	x			
2.2	Has the vendor, required that their pest control company, sign an affidavit confirming that they understand the new organic standards and will abide by them?	x			
2.3	If an automatic fogging system is install in the facility, is it locked of and use formally recorded?				x
2.4	Do pest control records clearly indicate that no pest control treatment has been carry out (inside or outside) at the time of organic production, or the production of organic before 48 hours has elapsed following the completion of fogging or fumigation?	x			
2.5	Does the vendor have a formal record of all organic ingredients and packaging being removed from the building before fogged or fumigated commenced?				x
2.6	Are all pest control chemicals stored outside of the production/storage facility in a locked container and use formally documented?	x			
3	**Cleaning and Sanitation**				
3.1	Are formal procedures written that clearly explain how the process should be cleaned, sanitized and rinsed prior to organic processing?	x			
3.2	Are cleaning schedule formally monitor and signed off?	x			
3.3	Are all surfaces that come in contact with product double rinsed?	x			

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3.4	Are all sanitized surfaces test for chemical residue? (<10 ppm)	x			
3.5	Are all chemicals locked a cage and use formally monitored?	x			
4	**Process Steam, Water and Air Supply**				
4.1	If direct steam is used that may/will come in contact with the product are boiler additives approved for use on organic products?				x
4.2	If an unapproved boiler additive is used, is the dosing system to the boiler locked off during organic production and a formal record kept?				x
4.3	Does the vendor have a current copy of the City Water Analysis Report or other documentation that shows the water supply is being monitored for trace metal/chemicals?	x			
4.4	Is the air supply to the process filtered and are air inlets from the outside appropriately positioned and protected to prevent contamination from localized industry?	x			

COMMENTS ON ORGANIC INGREDIENTS

VENDOR ASSURANCE GMP AUDIT

SCORE SUMMARY

CATEGORY	POTENTIAL SCORE # of obs. X2	No. of obs satisf. x2	No. of obs provis. X1	obs unsatisf. (scores 0)	TOTAL SCORE	% SCORE	PASS MARK
A. Receipt Raw Mat.	18	18	0	(0)	18	100%	75
B. Manufacturing	26	26	0	(0)	26	100%	75
C. Packaging/ Shipping	12	12	0	(0)	12	100%	75
D. QC/ QA	42	42	0	(0)	42	100%	75
E. Statistical Process Control	8	8	0	(0)	8	100%	75
F. Quality Records	36	36	0	(0)	36	100%	75
G. Fac. San. Safe. Train.	44	44	0	(0)	44	100%	75
H. Security	24	24	0	(0)	24	100%	75
I. Micro Sensitive Ingredients	18	18	0	(0)	18	100%	75
J. Organic Ingredients	38	38	0	(0)	38	100%	75
J.1.Documentation	16	16	0	(0)	16	100%	75
J.2.Pest Control	8	8	0	(0)	8	100%	75
J.3.Cleaning and Sanitation	10	10	0	(0)	10	100%	75
J.4.Process Steam, Water, Air	4	4	0	(0)	4	100%	75
OVERALL SCORE	**266**	**266**	**0**	**0**	**266**	**100%**	**75**

100 - 95% EXCELLENT
94 - 85% GOOD

RATING = EXCELLENT

84 - 75% SATISFACTORY
74 - 0% NEEDS IMPROVEMENT

IF ANY CATEGORY FAILS TO RECEIVE A 75% SCORE, THE AUDIT MAY BE RATED AS "NEEDS IMPROVEMENT"