

Supplier Assurance Audit - Distribution

Company Information	Audit Information
<p>Facility: C0173407 - Wrist USA - Houston</p> <p>Address: 1485 E Sam Houston Pkwy SSuite 100 Pasadena, Texas United States, 77503</p> <p>Contact: Andrew Licht</p> <p>Title: Corporate Quality Assurance Manager</p> <p>Phone: 510-385-3715</p> <p>Fax:</p> <p>Email: anli@wrist.com</p>	<p>Audit# - Visit#: 2414415 - 1924026</p> <p>Audit Type: SADCPR - Supplier Assurance Audit - Distribution</p> <p>Template Version: 1</p> <p>Audit Category: REGULAR</p> <p>Auditor: Nate Brown</p> <p>Audit Start Time: 21-AUG-2019 07:55:00 AM</p> <p>Audit End Time: 21-AUG-2019 04:55:00 PM</p>

Explanation of Section Scorings (below)

Section scorings in the below table are provided as a reference and are calculated on the following formula:

Non-Conformance	Deduction of 5% per finding
Major Non-Conformance	Deduction of 25% per finding
Critical	0%

Summary By Section

Section Name	Non-Conformance	Major Non-Conformance	Critical	Score
Section A - Administration and Regulatory Compliance	2	0	0	90.00%
Section B - HACCP Management	0	0	0	100.00%
Section C - Facilities and Equipment	3	0	0	85.00%
Section D - Sanitation, Housekeeping and Hygiene	0	0	0	100.00%
Section E - Rodent and Pest Control Management	1	0	0	95.00%
Section F - Approved Suppliers, Receiving and Inventory Control	0	0	0	100.00%
Section I - Storage and Shipping	2	0	0	90.00%
Section J - Training Requirements	0	0	0	100.00%
Section K - Food Defense	0	0	0	100.00%

Explanation of Overall Audit Result (below)

The overall score result is based on the total number and level of non-conformances. The audit is allocated 100% and deductions made as follows:

- Non-Conformance = 1% deduction per finding off the total score
- Major Non-conformance = 10% deduction per finding off the total score
- Critical Non-conformance = 25% deduction per finding off the total score

Scoring Guide	
Final Audit Rating	Based on Score
Meets Expectations	100-95%
Needs Improvement	94.99-85%
Significant Improvement Needed	84.99-76%
Fail	≤ 75.99%

Overall Audit Result	
Grade Rule Result	% Score
Needs Improvement	92.00%

Present at Audit					
Name	Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Martin Deal Rolando Garza Danielle Kotlajich Prithvi Govind Andrew Licht Justin Fabre Demetrius Carter	Warehouse Manager Provisional Stock Purchaser Branch Manager HACCP Coordinator QA Manager/VP Visitor Visitor	Yes	Yes	Yes	Yes

GENERAL INFORMATION	
No	Question/Notes
1.1	<p>Facility and Operations Description.</p> <p>Auditor's Notes: Wrist USA Inc. –Houston distribution branch has occupied its current location since 2005 in a light industrial area of Pasadena, TX. The facility is 72,000 square feet including office space. The freezer is 6,600 square feet, the cooler is 5,400 square feet and the dry storage warehouse is 48,000 square feet. The building is constructed of concrete walls and floors; with a metal roof. The facility has 125 employees and operates on the following schedule: Warehouse: 8am-5pm Mon-Fri; Skeleton crew on Sat and Sun. Office: 8am-5pm Mon-Fri; Skeleton crew on Sat and Sun (8am-Noon).The facility is NOT closed on company holidays. The facility performs box in, box out shipping functions with partial cases used for piece sales. The warehouse facilities include a palletizing system, dry storage, frozen and refrigerated storage that is routinely monitored. NO food handling/processing operations are present. Deliveries are made utilizing the Wrist fleet of delivery vehicles including temperature controlled, refrigerated trucks. The facility has One(1) HACCP plan that covers Chilled Storage, Freezer Storage and Dry Storage.</p>
1.2	<p>Regulatory Inspection Type and Establishment #:</p> <p>The facility is inspected by the City of Pasadena Department of Health. License: 10076, Expiration date: 2/15/2020. The facility is licensed as a Prepackaged Food Establishment. The facility is inspected by the Texas Department of State Health Services Regulatory Licensing Unit. There are two(2) licenses as follows: WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS-License #: 1001189, Expires March 19, 2021, and FOOD WHOLESALE & NON PRESCRIPTION DRUG DISTRIBUTOR & DEVICE DISTRIBUTOR-License #: 0067497, Expires: August 22, 2020. The facility is registered with the FDA under the Bioterrorism Act of 2002. Their registration number is xxxxxxx9216.</p>
1.3	<p>Products warehoused/produced at this facility.</p> <p>The company is a broad line distributor of frozen foods, refrigerated foods, produce, dry groceries, beverages, and nonfood merchandise. The facility has expertise in supplying the cruise ship industry.</p>
1.4	<p>The following departments and individuals participated in the audit process:</p> <p>Martin Deal- Warehouse Manager Rolando Garza- Provisional Stock Purchaser Danielle Kotlajich- Branch Manager Prithvi Govind- HACCP Coordinator Andrew Licht- QA Manager/VP Justin Fabre- Visitor Demetrius Carter- Visitor</p>
1.5	<p>Notes from Auditor</p> <p>The facility is well managed and maintained. The operation allows for the safe handling of the products that are handled on a Box-In/Box-Out basis.</p>

Non-Compliance Summary		
No	Question/Notes	Result
Section A/A.6	<p>Document and Records Management</p> <p><i>Site has a Document and Record Keeping Procedure with a revision date of 08/06/2019. the site policy indicates 2-year retention of all documentation.</i></p> <p><i>Minor: Non-conformance: During record review auditor observed documentation for receiving products with corrections (line through) without initialing. (2) Site is using "ditto" marking in product description column. (3) During document review of sanitation procedure, auditor observed correction to paperwork with whiteout.</i></p>	Non-Conformance*

Section A/A.9	Crisis and Natural Disaster Management <i>Minor: The site has a Crisis Management Plan Entitled Wrist North America (Houston) Crisis Management Plan. The site' plan has a revision date of 02/21/2019. The plan has identified most likely to occur crisis and lists a crisis management team with 24 hrs. contact numbers. Minor Non-conformance: The site has not documented specific training for the Crisis Management Team.</i>	Non-Conformance*
Section C/C.2	Facility Construction and Design <i>Minor: During facility tour, auditor observed a leak from blower unit falling on to outer surface of boxed product. Product was moved to prevent product contamination.</i>	Non-Conformance*
Section C/C.3	Facility Condition (Walls, Ceilings, Floors, etc.) <i>Minor: Auditor observed a hole in wall with insulation showing in reefer above forklift door.</i>	Non-Conformance*
Section C/C.8	Maintenance Standard (Support of GMPs, Housekeeping, Lubricants) <i>Minor: During facility tour auditor observed an unmanned scissor lift with chemicals on platform. One chemical was leaking onto platform, creating an opportunity for contamination of products.</i>	Non-Conformance*
Section E/E.4	Pest Tight Doors and Entrance Closures <i>Roll-up door near rodent trap #4 has a 1 1/2 inch gap at top of door creating a pest entry.</i>	Non-Conformance*
Section I/I.3	Storage Facility and Dock Maintenance <i>Minor: Racks in reefer storage adjacent to pharmaceutical wall has dust build up.</i>	Non-Conformance*
Section I/I.4	Transport Condition <i>Minor: A company owned truck waiting to be loaded was observed with three large holes in panel walls with insulation showing. There was no documented evidence that the damage had been noted.</i>	Non-Conformance*

Section A. Administration and Regulatory Compliance		
No	Question/Notes	Result
A.1	Organization and Responsibilities <i>A.L., Operations Quality Assurance Manager is responsible for supporting facility quality decisions. He has a dotted line reporting structure to the facility General Manager. The Organization Chart was last reviewed on 08/06/2019.</i>	Acceptable
A.2	Policies and Procedures Manual	Acceptable
A.3	Management Awareness and Commitment <i>M.D., Warehouse Mgr., R.G, Provision Stock Purchaser, D.K, Branch Mgr., P.G Business Process Mgr./HACCP Mgr., A.L, QA Mgr./Vice President, J.F, Visitor, D.C, Visitors were from New Orleans plant and were present during all stages of audit.</i>	Acceptable
A.4	Product Identification, Traceability and Recall Plans and Procedures <i>Product Identification, Traceability and Recall Plans and Procedures The facility has a documented, current and implemented Recall program (7.6). The program was last reviewed on 08/06/2019.</i> <i>Production date: N/A</i> <i>Best Before/Expiry Date: 08/11/2019</i> <i>Amount received: 788 units</i> <i>Amount on hand: 503 units</i> <i>Amount removed from use: 285 units</i> <i>Amount to customer sales: 285 units</i> <i>100% recovery in 40 mins</i> <i>TE Date: 07/15/2019</i> <i>Product description: Gravy Brown Powder Mix 32 oz</i> <i>Brand Name: HACO</i> <i>Supplier: Swiss Chalet Foods</i> <i>Batch Code: 000887404</i> <i>Production date: 05/15/2019</i> <i>Best Before/Expiry Date: 01/11/2021</i> <i>Amount in hand before trace: 4 units</i> <i>Amount received: 48 units</i> <i>Amount on hand: 26 units</i> <i>Amount removed from use: 26 units</i> <i>Amount to customer sales: 26 units</i> <i>100% recovery in 45 mins</i>	Acceptable
A.5	Regulatory Compliance <i>The site had an audit performed by the FDA on 07/11/2019. No finding was observed during that audit. The site has documentation of that audit on file.</i>	Acceptable
A.6	Document and Records Management <i>Site has a Document and Record Keeping Procedure with a revision date of 08/06/2019. the site policy indicates 2-year retention of all documentation.</i> <i>Minor: Non-conformance: During record review auditor observed documentation for receiving products with corrections (line through) without initialing. (2) Site is using "ditto" marking in product description column. (3) During document review of sanitation procedure, auditor observed correction to paperwork with whiteout.</i>	Non-Conformance*
A.7	Change Management	Acceptable
A.8	Documentation to Track Effectiveness of Policies	Acceptable
A.9	Crisis and Natural Disaster Management <i>Minor: The site has a Crisis Management Plan Entitled Wrist North America (Houston) Crisis Management Plan. The site' plan has a revision date of 02/21/2019. The plan has identified most likely to occur crisis and lists a crisis management team with 24 hrs. contact numbers.</i> <i>Minor Non-conformance: The site has not documented specific training for the Crisis Management Team.</i>	Non-Conformance*
A.10	Customer/Consumer Complaints (Policies, Follow Up and Response) <i>The Customer Complaints (7.5) program was last reviewed on 08/06/2019. NO customer complaints were received over the last year.</i>	Acceptable

Section B. HACCP Management		
No	Question/Notes	Result
B.1	Preliminary HACCP Tasks <i>The following employees are members of the HACCP team: General Manager, Business Process Manager/ HACCP Administrator; Inventory Supervisor, BTS/Provision Purchaser, Order Fulfillment Supervisor, Logistic Supervisor, Warehouse Manager, HACCP Regional Quality Manager. The training for the Warehouse Manager/HACCP Coordinator/Team Leader, P.G, is as follows: "HACCP Training for Processors"; May 12, 2019. The HACCP team has a documented monthly review meeting.</i>	Acceptable
B.2	Hazard Analysis (HACCP Principle 1) <i>The site has conducted a risk analysis and found that the most likely risk to product is pathogen growth. Site has a flow diagram.</i>	Acceptable
B.3	Critical Control Points (HACCP Principle 2) <i>The facility has identified the following Critical Control Points: CCP-1: Receiving & Inspection of Food and Beverages and CCP-2: Cooler Storage.</i>	Acceptable
B.4	Critical Limits (HACCP Principle 3) <i>The facility has identified the following Critical Limits: CL-1: Chilled Food above 40 F (5 C) Eggs at 45 F or Below, Acceptable at or between (33 F to 40 F) (0 C to 5 C) and CL-2: Chilled food at 40 F (5 C) Acceptable at or between (33 F to 40 F) (0 C to 5 C).</i>	Acceptable
B.5	CCP Monitoring (HACCP Principle 4)	Acceptable
B.6	Corrective Actions (HACCP Principle 5) <i>Product received above CL are rejected. Product returned above CL are segregated stored and destroyed.</i>	Acceptable
B.7	Verification and Validation (HACCP Principle 6)	Acceptable
B.8	Documentation and Record Keeping (HACCP Principle 7)	Acceptable

Section C. Facilities and Equipment		
No	Question/Notes	Result
C.1	Potable Water, Ice, Backflow Prevention, Steam and Waste Water Management <i>Water is provided to the facility by the City of Pasadena, TX. The site uses a Houston annual water report as a way to show portability. The site does not use water or ice that comes in contact with food or food contact surfaces. The facility backflow prevention was tested and passed on 2/15/2019. Observed the waste disposal process handled to promote a safe food environment. This is a box in/box out operation.</i>	Acceptable
C.2	Facility Construction and Design <i>Minor: During facility tour, auditor observed a leak from blower unit falling on to outer surface of boxed product. Product was moved to prevent product contamination.</i>	Non-Conformance*
C.3	Facility Condition (Walls, Ceilings, Floors, etc.) <i>Minor: Auditor observed a hole in wall with insulation showing in reefer above forklift door.</i>	Non-Conformance*
C.4	Employee Facilities	Acceptable
C.5	Handwashing Facilities <i>There is adequate tempered water, soap and single service towels available at the handwashing stations. The facility uses the toilet areas at the employee entrance to the warehouse for handwashing. There is an additional handwash station in the shipping area. There is adequate signage requiring hand wash available.</i>	Acceptable
C.6	Equipment Layout, Design and Conditions <i>This is a box in and box out facility. No production or processing is performed at this facility.</i>	Acceptable
C.7	Plant Lighting and Protection	Acceptable
C.8	Maintenance Standard (Support of GMPs, Housekeeping, Lubricants) <i>Minor: During facility tour auditor observed an unmanned scissor lift with chemicals on platform. One chemical was leaking onto platform, creating an opportunity for contamination of products.</i>	Non-Conformance*

Section D. Sanitation, Housekeeping and Hygiene		
No	Question/Notes	Result
D.1	Master Sanitation Schedule and Monitoring <i>The facility has a documented Master Sanitation Schedule that includes the Break Room area; the Cooler/Freezer areas; the restrooms; the Warehouse and the Yard area. The Master Sanitation Schedule (14.3) was last reviewed on 8/6/2019.</i>	Acceptable
D.2	Standard Sanitation Operating Procedures and Monitoring <i>The Standard Sanitation Operating Procedures consist of sweeping, dusting and janitorial work.</i>	Acceptable
D.3	Cleaning Chemical and Sanitizer Control	Acceptable
D.4	Pre Operational Monitoring and Corrective Action	Acceptable
D.5	Verification of Cleaning Effectiveness	Acceptable
D.6	Operational Housekeeping and Monitoring	Acceptable
D.7	Personal Hygiene and Good Manufacturing Practices	Acceptable
D.8	Internal Audits and Corrective Actions	Acceptable

Section E. Rodent and Pest Control Management		
No	Question/Notes	Result
E.1	Documented and Specific Pest Control Program	Acceptable
E.2	Outside Premises Management (Grounds, Waste Disposal Areas)	Acceptable
E.3	Inside Premises Management	Acceptable
E.4	Pest Tight Doors and Entrance Closures <i>Roll-up door near rodent trap #4 has a 1 1/2 inch gap at top of door creating a pest entry.</i>	Non-Conformance*
E.5	Secure Storage and Documentation of Pest Related Chemicals	Acceptable
E.6	Detailed Activity Reports with Corrective Actions	Acceptable

Section F. Approved Suppliers, Receiving and Inventory Control		
No	Question/Notes	Result
F.1	Supplier Approval Policies and Procedures <i>The Supplier Approval Policy (11.2) was last reviewed on 8/6/2019. The program uses a questionnaire for approval that asks for information about company information, commercial information (including 3rd party audits), factory and product standards, environment/health & safety & personnel and materials (compliance with the correct regulatory requirements). Documented second party audits are in use by the facility for companies that do not have 3rd party audits.</i>	Acceptable
F.2	Incoming Vehicle Inspection and Documentation	Acceptable
F.3	Release Criteria for Ingredients	Acceptable
F.4	Storage and Handling Policies and Practices	Acceptable
F.5	Bulk Receiving Systems Sanitation and Monitoring <i>This site does not receive bulk items. This is a box in box out facility.</i>	N/A
F.6	Restricted and/or Sensitive Ingredient Control, Including Chemical Compounds <i>The chemicals for the ship's orders are stored in an isolated area of the warehouse. SDS sheets are available for all the chemicals stored on site.</i>	Acceptable

Section G. Process and Product Evaluation			
No		Question/Notes	Result
		N/A	

Section H. Packaging and Labeling		
No	Question/Notes	Result
N/A		

Section I. Storage and Shipping		
No	Question/Notes	Result
I.1	Warehouse and Finished Product Management	Acceptable
I.2	Retained and Returned Products	Acceptable
I.3	Storage Facility and Dock Maintenance <i>Minor: Racks in reefer storage adjacent to pharmaceutical wall has dust build up.</i>	Non-Conformance*
I.4	Transport Condition <i>Minor: A company owned truck waiting to be loaded was observed with three large holes in panel walls with insulation showing. There was no documented evidence that the damage had been noted.</i>	Non-Conformance*
I.5	Release Authorization to Ship Product <i>This is a box in/Box out facility.</i>	N/A

Section J. Training Requirements		
No	Question/Notes	Result
J.1	New Hire Training	Acceptable
J.2	Training Language	Acceptable
J.3	Prerequisite Program Training	Acceptable
J.4	Refresher Training	Acceptable
J.5	Proof of Knowledge	Acceptable
J.6	Training Records	Acceptable
J.7	Training Program Review	Acceptable

Section K. Food Defense		
No	Question/Notes	Result
K.1	Management <i>There is a documented food defense team that is the same as the crisis management team. Responsibilities are noted for each member. The plan addresses employees, visitors and unauthorized personnel. The plant is registered with the FDA bio terrorism preparedness act. FDA Registration expires 12/31/19 xxxxxxx6246.</i>	Acceptable
K.2	Human Element	Acceptable
K.3	Facility	Acceptable
K.4	Operations	Acceptable

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