

Supplier Assurance Audit - Distribution

Company Information	Audit Information
<p>Facility: C0218687 - Wrist USA - New Orleans</p> <p>Address: 300 Plaunche St Jefferson Parish, Louisiana United States, 70123</p> <p>Contact: Andrew Licht</p> <p>Title:</p> <p>Phone:</p> <p>Fax:</p> <p>Email: anli@wrist.com</p>	<p>Audit# - Visit#: 2398258 - 1912417</p> <p>Audit Type: SADCPR - Supplier Assurance Audit - Distribution</p> <p>Template Version: 1</p> <p>Audit Category: REGULAR</p> <p>Auditor: Terlisha Faison</p> <p>Audit Start Time: 18-SEP-2019 08:15:00 AM</p> <p>Audit End Time: 18-SEP-2019 03:15:00 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	0	0	0	100.00%
Section D - Sanitation, Housekeeping and Hygiene	1	0	0	95.00%
Section E - Rodent and Pest Control Management	3	0	0	85.00%
Section F - Approved Suppliers, Receiving and Inventory Control	0	0	0	100.00%
Section G - Process and Product Evaluation	0	0	0	100.00%
Section I - Storage and Shipping	0	0	0	100.00%
Section J - Training Requirements	0	0	0	100.00%
Section K - Food Defense	1	0	0	95.00%

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	93.00%

Present at Audit					
Name	Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
James Powers	Operations Manager (New Jersey Location)	Yes	Yes	Yes	Yes
Andrew Licht	VP & QA Regional Manager	Yes	Yes	Yes	Yes
Mike Liantonio	CEO/ Acting Branch Manager	Yes	Yes	Yes	No
Justin Fabre	Inventory Analyst	Yes	Yes	Yes	Yes
Demetrius Carter	Warehouse Manager/ HACCP Manager	Yes	Yes	Yes	Yes

GENERAL INFORMATION	
No	Question/Notes
1.1	<p>Facility and Operations Description.</p> <p>Auditor's Notes: Wrist USA- New Orleans is a subsidiary of Wrist North America, a member of the Wrist Group A/S headquartered in Aalborg, Denmark. This 55,000 sq. ft. warehouse located in an industrial park in Jefferson Parrish, Louisiana just East of New Orleans includes 42,875sq. ft. of dry storage, 5,225 sq. ft. of refrigerated storage and 6,900 sq. ft. of freezer storage. Wrist supplies the maritime industry with a wide variety of food products and ingredients as well as industrial supplies specific to the needs of commercial vessels and cruise lines with this facility servicing customers along the Gulf Coast from Lake Charles, LA. to Jacksonville, Florida. Goods are transported utilizing Wrist's fleet of temperature controlled vehicles and drivers</p>
1.2	<p>Regulatory Inspection Type and Establishment #:</p> <p>FDA Regulatory registration number xxxxxx6128. Exp 12/31/2020.</p>
1.3	<p>Products warehoused/produced at this facility.</p> <p>Shelf stable, refrigerated and frozen products such as peanut butter; canned nuts; soda; frozen pre-packaged crustacea; frozen fish; frozen meat; frozen poultry; eggs; fluid milk; wheat flour and legumes are held for further distribution. This is a pass-through warehouse only, no products are re-packaged at this facility.</p>
1.4	<p>The following departments and individuals participated in the audit process:</p> <p>Andrew Licht- QA Manager/ Vice President; Mike Liantonio- CEO; Justin Fabre- Inventory Specialist; Demetrius Carter- Warehouse Manager</p>
1.5	<p>Notes from Auditor</p> <p>The facility was observed to be in great, clean condition. The facility was well prepared with policies, procedures and supporting documentation readily available to show to the auditor. Their hospitality was awesome! Any nonconformances that could be addressed immediately were done so. The facility had a contractor to come and access the nonconformances in reference to the NCs identified in E.2 and E.4. A plan is already in place to have these areas fixed/corrected.</p>

Non-Compliance Summary		
No	Question/Notes	Result
Section A/A.6	<p>Document and Records Management <i>The facility has a Documentation & Record Keeping Procedure. All policies are reviewed annually.</i> <i>The QA Regional Manager stated that the obsolete documents are saved into an archive folder that is restricted and controlled by the Regional QA Manager.</i></p> <p><i>NC- The policy does not clearly identify obsolete documents being retained or to avoid the use of invalid obsolete documents per the NSF standard.</i></p>	Non-Conformance*
Section A/A.9	<p>Crisis and Natural Disaster Management <i>Auditor reviewed the Wrist North America (New Orleans) Crisis Management Plan. A contact list for both team members and emergency contact, including regulatory agencies are in place. The last review was completed on 2/21/2019. The plan is in current review as of 8/29/2019. A fire drill was conducted on 9/10/2019 and documented.</i></p> <p><i>NC- There was no evidence within the Crisis Management Plan that describes, in the event of prolonged interruptions, what plans are in place for alternate product supply to customers per the NSF standard.</i></p>	Non-Conformance*
Section D/D.7	<p>Personal Hygiene and Good Manufacturing Practices <i>Auditor observed 2 employees, in the warehouse, chewing gum.</i></p>	Non-Conformance*

Section E/E.2	<p>Outside Premises Management (Grounds, Waste Disposal Areas) <i>NC- There was pooling water on the side of the building, near bait station #11, that was coming from the drain that leads to the freezer.</i> <i>NC- Cigarette butts were observed scattered throughout the grounds areas near the shipping/receiving dock area.</i></p>	Non-Conformance*
Section E/E.3	<p>Inside Premises Management <i>Interior conditions were observed to be clean and orderly.</i> <i>NC- There was only one trap on the side of the interior side of the doorway that leads to the outside.</i></p>	Non-Conformance*
Section E/E.4	<p>Pest Tight Doors and Entrance Closures <i>NC- The Shipping/Receiving exit door, that leads to the outside, weather stripping was completely missing. There was visible light observed.</i> <i>NC- Aisle 11 in the warehouse has a vent, that leads to the outside, that was observed open and unscreened.</i></p>	Non-Conformance*
Section K/K.2	<p>Human Element <i>Background checks and drug screens are completed on all employees prior to hire.</i> <i>The Visitors Entry Procedure is under section 6.3.6 in the QA Manual. Visitors are required to sign in on the Visitor's Log at the Receptionist's desk. Food defense training is completed for all new hires and annually as a refresher training.</i> <i>NC- Auditor's ID was not verified nor did auditor receive a copy of the facility's Visitor's Entry Procedure prior to signing the Visitor's Log for acknowledgment.</i></p>	Non-Conformance*

Section A. Administration and Regulatory Compliance		
No	Question/Notes	Result
A.1	Organization and Responsibilities <i>Org Chart is current, dated (8/19/2019) and approved by the QA Department. The Regional QA Manager report to the CEO/ Interim Branch Manager. The Regional QA Manager is responsible for the control and release of recalls and products.</i>	Acceptable
A.2	Policies and Procedures Manual <i>The facility has a QA Manual (Wrist North America New Orleans Quality Assurance Food Safety and HACCP Plan) The policy is dated 8/29/2019 and approved by the QA department.</i>	Acceptable
A.3	Management Awareness and Commitment <i>The Regional Quality Manager and the Warehouse Manager participated throughout the entire audit process.</i>	Acceptable
A.4	Product Identification, Traceability and Recall Plans and Procedures <i>Auditor reviewed the Product Recall/ Traceability policy. The recall team consist of both local and corporate associates. Roles and responsibilities are identified. 24/7 contact information is listed. The Quality Manager is the recall coordinator and the purchasing Manager is the spokes person. The policy mentions that mock recalls are conducted twice per year. FDA contact information is listed. Auditor reviewed the completed mock recall form QAF B10 Recall Worksheet. The mock recall was completed on 6/28/2019. The mock recall was completed in under 4 hours with 100% recovery.</i>	Acceptable
A.5	Regulatory Compliance <i>The facility is regulated by the FDA. The most recent visit (routine)was conducted on 9/6/2019. Auditor was shown the visitor's log with the FDA representative signature on it. The facility has not received the report as of yet. The previous FDA visit was on 9/18/18- 9/19/2019. There were no FDA-483's issued. The facility was inspected by the State of Louisiana Department of Health and Hospitals Office of Public Health Food And Drug Unit on 1/22/2019. There were 3 violations in which one of the violations were documented as completed during the audit. The other 2 were documented and sent via email to the auditor on 2/01/2019.</i>	Acceptable
A.6	Document and Records Management <i>The facility has a Documentation & Record Keeping Procedure. All policies are reviewed annually. The QA Regional Manager stated that the obsolete documents are saved into an archive folder that is restricted and controlled by the Regional QA Manager.</i> <i>NC- The policy does not clearly identify obsolete documents being retained or to avoid the use of invalid obsolete documents per the NSF standard.</i>	Non-Conformance*
A.7	Change Management <i>Management of Change Policy was reviewed.</i>	Acceptable
A.8	Documentation to Track Effectiveness of Policies	Acceptable
A.9	Crisis and Natural Disaster Management <i>Auditor reviewed the Wrist North America (New Orleans) Crisis Management Plan. A contact list for both team members and emergency contact, including regulatory agencies are in place. The last review was completed on 2/21/2019. The plan is in current review as of 8/29/2019. A fire drill was conducted on 9/10/2019 and documented.</i> <i>NC- There was no evidence within the Crisis Management Plan that describes, in the event of prolonged interruptions, what plans are in place for alternate product supply to customers per the NSF standard.</i>	Non-Conformance*
A.10	Customer/Consumer Complaints (Policies, Follow Up and Response) <i>The facility has a Customer Complaint policy in place.</i>	Acceptable

Section B. HACCP Management		
No	Question/Notes	Result
B.1	Preliminary HACCP Tasks <i>Auditor reviewed the The HACCP plan. Team members roles and responsibilities identified. The last team meeting was held on 8/27/2019. Auditor reviewed the QAF H03 Minutes- HACCP Team Meeting form with signatures from the team members. The HACCP Coordinator and HACCP Administrator completed a 2 day HACCP training on 3/05/2019-3/06/2019, with certificates reviewed. The Regional QA Manager completed PCQI training on 8/03/2018, with certificate reviewed.</i>	Acceptable
B.2	Hazard Analysis (HACCP Principle 1)	Acceptable

Section B. HACCP Management		
No	Question/Notes	Result
	<i>Auditor reviewed the Hazard Analysis Worksheet.</i>	
B.3	Critical Control Points (HACCP Principle 2) <i>The Hazard Analysis determined there are no CCPs at this facility.</i>	N/A
B.4	Critical Limits (HACCP Principle 3) <i>There are no CCPs at this facility.</i>	N/A
B.5	CCP Monitoring (HACCP Principle 4) <i>There are no CCPs at this facility.</i>	N/A
B.6	Corrective Actions (HACCP Principle 5) <i>There are no CCPs at this facility.</i>	N/A
B.7	Verification and Validation (HACCP Principle 6) <i>HACCP plan was last reviewed on 8/29/2019.</i>	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>Auditor reviewed the 2018 Jefferson Parish Water Quality Report. Auditor reviewed passing backflow prevention test dated 3/29/2019.</i>	Acceptable
C.2	Facility Construction and Design <i>The facility is constructed of insulated metal panels with sealed concrete floors.</i> <i>Refer to the NC in E.2 in reference to the standing water.</i>	Acceptable
C.3	Facility Condition (Walls, Ceilings, Floors, etc.) <i>The facility was observed to be in clean condition.</i>	Acceptable
C.4	Employee Facilities <i>The break room and restrooms were observed to be in clean condition.</i>	Acceptable
C.5	Handwashing Facilities <i>Hand washing facilities are located in the restrooms. Water tempered quickly. There were hand washing signs with technique posted on the walls.</i>	Acceptable
C.6	Equipment Layout, Design and Conditions <i>All food items are stored on racks that were observed to be in good, sanitary condition. is adequate with racking observed to be in good condition. There was no condensation observed on the refrigeration drip pans.</i>	Acceptable
C.7	Plant Lighting and Protection <i>Auditor read the facility's Glass Policy. Glass audits are completed during the monthly internal audits. The facility was well illuminated.</i>	Acceptable
C.8	Maintenance Standard (Support of GMPs, Housekeeping, Lubricants) <i>Auditor reviewed the Maintenance Schedule. Frequency of maintenance ranges from daily to annually or as needed.</i>	Acceptable

Section D. Sanitation, Housekeeping and Hygiene		
No	Question/Notes	Result
D.1	Master Sanitation Schedule and Monitoring <i>Auditor reviewed the MSS. Frequency of cleanings range from daily through quarterly or as needed.</i>	Acceptable
D.2	Standard Sanitation Operating Procedures and Monitoring <i>The MSS documents the cleaning methods in place. All sanitation duties are completed, documented and initialed by the responsible party. All sanitation duties are signed off by the Supervisor.</i>	Acceptable
D.3	Cleaning Chemical and Sanitizer Control <i>Cleaning chemicals are stored in a locked, mezzanine area.. All chemicals were labeled. Auditor reviewed the SDS.</i>	Acceptable
D.4	Pre Operational Monitoring and Corrective Action <i>This is a distribution center only. There is no manufacturing completed at this facility.</i>	N/A
D.5	Verification of Cleaning Effectiveness	Acceptable
D.6	Operational Housekeeping and Monitoring <i>The facility was observed to be in clean condition.</i>	Acceptable
D.7	Personal Hygiene and Good Manufacturing Practices <i>Auditor observed 2 employees, in the warehouse, chewing gum.</i>	Non-Conformance*
D.8	Internal Audits and Corrective Actions	Acceptable

Section D. Sanitation, Housekeeping and Hygiene		
No	Question/Notes	Result
	<i>Monthly internal audits are documented on the QAF B09 Internal Audit form. Auditor reviewed completed audits for the months of July and August of this year.</i>	

Section E. Rodent and Pest Control Management		
No	Question/Notes	Result
E.1	Documented and Specific Pest Control Program <i>PCO is Ecolab. PCO services the facility once per month for the external bait stations and bimonthly for for internal traps. The facility conducts inspections on the internal traps on the off week that the PCO does not inspect them. All information for Ecolab was reviewed online in the Ecolab portal. The PCO applicator's license expires on 12/31/2022. The liability insurance expires on 12/31/2019. The Map is current and dated 12/17/2018. Trend reports were available that showed low pest activity. The Pesticide Usage Log documents pesticide chemicals used, where, why, how much, target pests, method of application and EPA registration number. Service logs for August and September of this year were reviewed.</i>	Acceptable
E.2	Outside Premises Management (Grounds, Waste Disposal Areas) <i>NC- There was pooling water on the side of the building, near bait station #11, that was coming from the drain that leads to the freezer.</i> <i>NC- Cigarette butts were observed scattered throughout the grounds areas near the shipping/receiving dock area.</i>	Non-Conformance*
E.3	Inside Premises Management <i>Interior conditions were observed to be clean and orderly.</i> <i>NC- There was only one trap on the side of the interior side of the doorway that leads to the outside.</i>	Non-Conformance*
E.4	Pest Tight Doors and Entrance Closures <i>NC- The Shipping/Receiving exit door, that leads to the outside, weather stripping was completely missing. There was visible light observed.</i> <i>NC- Aisle 11 in the warehouse has a vent, that leads to the outside, that was observed open and unscreened.</i>	Non-Conformance*
E.5	Secure Storage and Documentation of Pest Related Chemicals <i>Pest Related Chemicals are stored off site with the PCO.</i>	N/A
E.6	Detailed Activity Reports with Corrective Actions <i>Service reports were available for review and signed by the PCO applicator.</i>	Acceptable

Section F. Approved Suppliers, Receiving and Inventory Control		
No	Question/Notes	Result
F.1	Supplier Approval Policies and Procedures <i>Auditor reviewed the Approved & Beverage Suppliers policy. Approved Suppliers are handled by the Purchasing Manager in corporate. An example of acceptable criteria is conducting an on-site audit of the potential supplier prior to approval.</i>	Acceptable
F.2	Incoming Vehicle Inspection and Documentation <i>Auditor reviewed the Procedure for Loading and Unloading of Food (Chilled, Dry and Frozen). All items received in are documented on the QAF BO2: Receiving Temperature Log. Temperatures as well as the condition of the trailers are documented on this log. There is a corrective action section on this form.</i>	Acceptable
F.3	Release Criteria for Ingredients <i>All items are ready to ship upon approval during receiving.</i>	Acceptable
F.4	Storage and Handling Policies and Practices	Acceptable
F.5	Bulk Receiving Systems Sanitation and Monitoring <i>There is no bulk receiving at this facility.</i>	N/A
F.6	Restricted and/or Sensitive Ingredient Control, Including Chemical Compounds	Acceptable

Section G. Process and Product Evaluation		
No	Question/Notes	Result
G.1	Process Control and Documentation Procedures <i>This is a distribution center only. There is no processing a this facility.</i>	N/A
G.2	Specification and Formulation Control and Accuracy <i>This is a distribution center only. There is no processing a this facility.</i>	N/A
G.3	Routine Calibration of Operational Equipment and Measuring Devices <i>Thermometer calibration is documented monthly on the QAF H06: Thermometer Calibration form. Acceptable Variance range is +/- 1.8 degrees F or +/- 1 degree Celsius. The facility uses a NIST certified thermometer to complete the monthly calibration using an ice water bath. The thermometer is replaced annually.</i>	N/A
G.4	Foreign Material Control <i>This is a distribution center only. There is no processing a this facility.</i>	N/A
G.5	Application of Statistical Control <i>This is a distribution center only. There is no processing a this facility.</i>	N/A
G.6	Allergen and Sensitive Ingredient Controls <i>Auditor reviewed the Food Allergen Control Policy. Allergens are stored separately to prevent cross contamination. Allergens are not stored above non allergens. The Aisle have Allergen placards that are specific to the type of allergen stored. Allergen training is completed for new hires and as an annual refresher training with all employees.</i>	Acceptable
G.7	Specification Compliance Documentation <i>This is a distribution center only. There is no processing a this facility.</i>	N/A
G.8	Rework and Carryover Products <i>This is a distribution center only. There is no processing a this facility.</i>	N/A
G.9	Analytical Records Management <i>This is a distribution center only. There is no processing a this facility.</i>	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 <i>Auditor reviewed the Procedure For Receiving Returned Goods- Stock And Non Stock Items- Dry/ Chilled/ Frozen Forms completed for all returns are Return From Vessel, Return To Vendor and Goods Return Record. The facility has designated areas for cooler returns and freezer returns.</i>	Acceptable
I.3	Storage Facility and Dock Maintenance	Acceptable
I.4	Transport Condition <i>Auditor reviewed the Procedure for Loading and Unloading of Food (Chilled, Dry and Frozen). All items shipped out in are documented on the QAF B03: Transportation & Delivery Temperature Log. Temperatures as well as the condition of the trailers are also documented on this log. There is a corrective action section on this form.</i>	Acceptable
I.5	Release Authorization to Ship Product <i>This is a distribution warehouse only. There is no manufacturing conducted at this facility.</i>	N/A

Section J. Training Requirements		
No	Question/Notes	Result
J.1	New Hire Training <i>New Hire complete trainings on Food Defense, HACCP, Allergens, Personal Hygiene and GMPs. There are also job specific training conducted for all new hires.</i>	Acceptable
J.2	Training Language <i>Training is completed in English and can be translated in Spanish if needed.</i>	Acceptable
J.3	Prerequisite Program Training	Acceptable
J.4	Refresher Training <i>Refresher trainings are completed on Food Defense, HACCP, Allergens, Personal Hygiene and GMPs</i>	Acceptable
J.5	Proof of Knowledge	Acceptable

Section J. Training Requirements		
No	Question/Notes	Result
J.6	Training Records	Acceptable
J.7	Training Program Review	Acceptable

Section K. Food Defense		
No	Question/Notes	Result
K.1	Management <i>Auditor reviewed the facility's Food Defense Plan that is also inclusive of the risk assessment. Team member are established. The last noted review is dated 12/02/2018. The Food Defense Plan is in current review. Computer access is granted to users who are given their own, individual access and passwords that are updated regularly. Access is removed upon termination.</i>	Acceptable
K.2	Human Element <i>Background checks and drug screens are completed on all employees prior to hire. The Visitors Entry Procedure is under section 6.3.6 in the QA Manual. Visitors are required to sign in on the Visitor's Log at the Receptionist's desk. Food defense training is completed for all new hires and annually as a refresher training.</i> <i>NC- Auditor's ID was not verified nor did auditor receive a copy of the facility's Visitor's Entry Procedure prior to signing the Visitor's Log for acknowledgment.</i>	Non-Conformance*
K.3	Facility <i>CCTV monitoring system is in place. The facility has a finger print scanner to enter the facility for all employees. Management has alarm codes that can be used to enter the facility as well. The front office entry to the facility is locked and access is granted upon buzzing in and stating the nature of your business. All doors were observed to be locked from the outside.</i>	Acceptable
K.4	Operations	Acceptable

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