1 Qualified Supplier Self-Evaluation Questionnaire

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This form is provided for our customers

The audit covers all plant operations from receiving of raw products and packaging materials to finished goods and lot tracking. Plant sanitation and Standard Operating procedures are a focal point within the audit process.

Manufacturing/Partner's Name:Zhengzhou Harmoni
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Henan Provence, PR China
Contact Person:Mary AbiFadel Hasrouni
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Questions			Response
1.0	**Receiving Controls:**		
	1.1	Who checks incoming shipments against the requirements of the purchase order, specifications and applicable drawings?	Factory QA and QC Lab, sign by QA manager
	1.2	Are material weight checks made upon receipt?	Yes, according to relevant procedure,, depend on different material specification, have different weight scale accuracy
	1.3	How are inspected items segregated from material awaiting inspection?	Place in separated location marked “to be inspected” according to QA procedure
	1.4	How is inspected material identified as to acceptance or rejections?	Place in designated location marked “suitable to use” or “reject” according to QA procedure
	1.5	What happens to material that is rejected?	Return to the vendor or use for food grade processing
	1.6	Is there an SOP for sampling incoming material and for accepting components? Explain	Yes, use sampling plan: square root (n-1) to take samples and test; sample tested Must meet specification
	1.7	How is the receipt of material documented?	
		1.7.1 Do the records reflect acceptance or rejection of incoming material?	Yes
		1.7.2 If material is rejected, is the reason for the rejection documented on the inspection records?	Yes
		1.7.3 Do you determine the cause for the rejected material and follow-up?	Yes, we notify the supplier and demand corrective actions. We also audit our major suppliers.
	1.8	How is the documentation of receiving records maintained?	For 3 years in the raw material receiving records, (all records kept for three years), after that place in Archive.

	Questions	Response
2.0	**Material Storage and Handling:**	
2.1	Who has access to the stockrooms and material storage areas?	Plant managers and Warehouse employees, access is restricted according to Warehouse SOP
2.2	How are the materials, storage and handling procedures documented?	According to material handling procedure and warehouse SOP
2.3	How are supplies stored and labeled?	Labeled by product name, vendor name, lot #, receipt date and weight
2.4	Describe the accountability system for labels.	Warehouse manager is accountable for labels, and QA manager as well
2.5	What safeguards are in place to prevent damage, contamination, mix-ups, loss and mis-labeling of materials?	Following warehouse SOP and related records and checking material flow, the SOP specifically address the prevention damage, contamination, cross-contamination, mix-ups, mis-placing, loss and mis-labeling.
2.6	How are stocks re-inspected and tested at specific intervals?	Re-inspection and re-test after 3 months if not used, to re-qualify for 3 additionally months. Usually stocks will be used by six months. If not will place in separate area for food grade usage, & sent to our food facilities.
2.7	How are accountability records kept to permit traceability of usage?	All the records throughout the process have a lot #, which can be traced from finished product all the way back to the raw material. We have a Mock-recall at least once a year and demand the complete recall and traceability to be completed within 2 hours. The traceability also includes the packing materials and other ingredients (if any) and the plant manager is held accountable for traceability of usage.
2.8	Do you use FIFO inventory control? If not, explain the system that is in use.	Yes
3.0	**Production / In-Process Controls:**	
3.1	Are there SOP's for the following production issues?	

Questions			Response
	3.1.1	Employee dress code	Yes - All required uniforms and head nets, sanitation hands and beard-cover, and internal shoes- no jewelry wearing is allowed in all areas.
	3.1.2	Equipment maintenance	Yes, with Preventive Maintenance Program as well
	3.1.3	Equipment operations	Yes, SOP with each equipment's work instruction and illustration
	3.1.4	Equipment cleaning	Yes, SSOP(standard sanitation operation procedure) for each equipment and a Master Cleaning schedule
3.2	How is documentation and/or log books maintained for the following production issues?		
	3.2.1	Equipment use	Work instructions and record for each equipment
	3.2.2	Equipment repair	Equipment Repair SOP and records
	3.2.3	Equipment cleaning	According to the SSOP and the Master Cleaning Schedule, after done put in SSOP records
	3.2.4	Facility use	Records on Facility and building, we have a facility SOP to follow
	3.2.5	Facility cleaning	According to the SSOP and Master Cleaning Schedule, after done put in SSOP records
	3.2.6	Describe your system for designating the equipment or the facility as "clean" "in-process" or "dirty".	Each cleaning is inspected by area manager and held accountable, if not clean re-work is ordered. The cleaning work and its result are required and defined by the SSOP. The QA Team and plant manager perform internal audit every month and results are recorded
3.3	How is the facility and/or equipment designed in order to prevent cross-contamination between batches?		The processing facility and equipment are only used to process garlic and no other products at all. The nutraceutical garlic and food grade garlic are in separated process time. Thorough cleaning is required before and after changing products.

Questions			Response
	3.4	What safeguards are in place to insure that batches are manufactured according to specifications?	Processing SOP and records, and QA testing work-in-process samples in 3 places during the processing every 2 hours. The results are recorded and recorded according to SPC (statistic process control) and the trend is monitored.
4.0	**Batch Records:**		
	4.1	Who writes the Master Batch Records?	Field workers. QA manager is responsible to approve the production batch records and master manufacturing records and revisions.
	4.2	Who checks the master Batch Records?	Area manager. QA manager is responsible to approve the production batch records and master manufacturing records and revisions.
	4.3	Who maintains the Master Batch Records?	Each record is kept with its workshop by QC inspector
	4.4	Do the Master Batch Records contain:	
		4.4.1 The weights of all the ingredients?	Yes
		4.4.2 The strength and overages of all the actives?	Yes
		4.4.3 The Lot #'s and sources of all the ingredients?	Yes
		4.4.4 A detailed, stepwise manufacturing procedure?	Yes
		4.4.5 Signatures, counter –signatures and dates for each manufacturing step?	Yes
		4.4.6 Theoretical yield and actual yield for the batch?	Yes, with material balancing table and calculation
		4.4.7 Reconciliation of material?	Yes, with material balance

Questions		Response
4.4.8	Safety precautions?	Yes, there is a safety procedure
4.4.9	In-process laboratory control results?	Yes, work-in-process testing every 2 hours and SPC
4.5	How are modifications and changes to batch records handled? How is this documented and approved?	According to SOP any modification and changes to batch records have different level of QA management requirements, if raw material vendor changes location, equipment or raw material supply, customers will be notified of the changes. Other changes need to go through approval of plant manager and QA manager. All changes and modification changes are documented in QA records.
4. 6	How are batch labels prepared and what precautions are in place to insure proper product labeling?	Batch labels are reviewed & verified by QA department and production. The label is color coded and different seizes are used for different purposes, also there is a sequence # to make sure every bag of raw material and every tote of finished product is traceable.
4.7	Do the batch records include packaging components?	Yes
4.8	If the product is produced from a combination of intermediate components, manufacturing processes or packaging procedures are there separate batch records for each process or does one batch record contain the manufacturing directions for the entire process?	Yes, batch records are well separated including packaging components. But our process is relatively simple, just garlic, however; we use the most completed and detailed records for each process
4.9	If the product is produced by a multi-step manufacturing/packaging procedure how do lot #'s / batch #'s correlate?	The lot # is designed to include info relating to every step from beginning to end.
4.10	If there becomes a problem with a component, can you quickly identify which lots of intermediate and/or finished product it is in?	Yes, with the traceable lot # ,any problem is identified & located within 2 hours

	Questions	Response
	4.11 Do you have written procedures for reprocessing batches?	Yes
	4.12 What type of in-process testing is routinely performed on batches?	Major specification items are sampled & tested every 2 hours at 3 points of in-process and the results are keyed into the computer as a normal procedure for statistic process control (SPC)
	4.13 What type of training do the production employees receive?	We have a Master Training Schedule planned for all levels of employees from the plant manager to floor cleaners with different topics and focus points every year. We also invite outside experts to do the training for GMP, HACCP, and SSOP and SPC
	4.14 What is your policy on process validation?	Performance must strictly follow SOP, audited and verified by monthly internal auditing and external 3rd party audits.
5.0	**Packaging, Shipping and Distribution:**	
	5.1 Is a checklist used to verify shipping requirements and documentation enclosed in the shipment?	Yes, there is a packaging, shipping and distribution SOP which includes a checklist and record
	5.2 How are special handling/storage/shipping conditions identified on the shipping directions and on the package labels?	There is a procedure of special handling and shipping in the SOP to follow. The SOP highlights how to identify a special situation and how to handle it. In case of non-compliance, Shipment will be halted. No shipment is allowed unless it is released & checked by QA department
	5.3 Is the product configuration verified prior to shipment?	Yes
	5.4 Do packing and shipping records reflect the individuals performing and inspecting the shipping operations?	Yes, they do, name and signature are noted and required.

Questions		Response
6.0	**Quality Control/Quality Assurance, Final Inspection:**	
6.1	How are production records reviewed?	By internal audit team each month
6.2	Is there an SOP for sampling? Explain.	Yes, there are a sampling plan and a sampling procedure for different raw material, work-in-process material, incoming raw material, packaging material, ingredients, and finished products. The plan and procedure also include re-works and non-compliant materials
6.3	How long are retain samples kept? How are they maintained?	For 3 years in the QA Lab and maintained by the QA personnel
6.4	How are defects determined and classified?	According to specification and SPC lower and upper limits
6.5	What final documentation is required in order to release a batch?	COA with “pass” conclusion and signed by the Lab Manager. The production and QA manager are responsible to review and approve the completed production record to ensure that it is complete and accurate prior to the release of the product
6.6	Who is responsible for the final review and release of a batch?	QA Lab Manager who sign the COA
7.0	**Quality Control Laboratories:**	
7.1	Are all components, manufacturing materials, in-process materials, packaging and labeling tested prior to release for production?	Yes, all the records of each lot are kept in the computer and SPC analysis
7.2	Are all of your test procedures documented? Have they been validated?	Yes, and they have been validated by the outside International Labs like SGS and Sino-Analytica, and by quarterly comparison testing results, also by customer’s lab results.

Questions		Response
7.3	Do you use material which are compendial items and do you test them according to the compendium?	No
7.4	How are laboratory reagents, test solutions and equipment identified and tested?	According to QA Lab SOP and working instructions
7.5	How is the documentation of instrument calibrations and test solutions standardization's maintained?	According to QA Lab SOP and Calibration scheduling, calibrated by the government standards bureau agency and records are kept.
7.6	Do you routinely monitor for microbial contamination in non-sterile products?	Yes, we do environmental testing, water and air, food contact surfaces, wall and floor, and employee's hand swab testing every month

	Questions	Response
	7.7 How long do you maintain the documentation on raw material files?	3 years
8.0	**Quality Assurance:**	
	8.1 Is there a written directive of the responsibilities of QA?	Yes, and job descriptions
	8.2 How does QA document and control changes in the manufacturing process or in a change in any of the components?	According to SOP any modification and changes in the manufacturing process or a change in any of the components have different levels of QA requirement, if process change, raw material vendor change, location, equipment or raw material supply change must inform the customer, other changes need go through approval of plant manager and QA manager. All changes and modification changes are documented in QA records.
	8.3 Are records maintained which reflect a history of change incorporation?	yes
	8.4 Does QA have the authority to approve/reject plant equipment, process and procedural changes?	No. These changes must go through the plant manager and the president/CEO after being suggested by the quality team. Any changes will be reviewed periodically by the quality team to update the procedures.
	8.5 Does QA approve/reject product manufactured, processed, packaged or held under contract by another company? If not, who does?	Yes
	8.6 Is QA responsible for document control? If not, who is?	QA is responsible for document control of its related fields stipulated by the SOP, every area, e.g. warehouse, workshops, maintenance, sanitation, pest control, HACCP team, etc, keep their own document control. QC also periodically audit the documents related to GMP that are kept by other

Questions		Response
		departments to verify that they are complete, up to date and accurate.
8.7	How is your stability program set up? Who maintains and monitors it?	We use SPC to set up the control upper limits and lower limits, and continuously monitor and report the production process and material quality stabilization. We also use control points and critical control points to monitor and record the key control parameters
8.8	How often are batch record data reviewed in order to determine continual acceptability of quality standards, specifications, manufacturing and control procedures.	SPC data are input daily and monitored daily. They are reviewed weekly to make sure every parameters are correct
8.9	How are product complaint/product failure handled?	According to non-compliant material handling procedure in our SOP. , Corrective Action Procedure and Internal Audit Procedure

Questions			Response
9.0	**Facility Engineering and Metrology:**		
	9.1	Describe the following items: how they are maintained and documented;	
		9.1.1 Ventilation systems including control of air pressure, temperature, humidity, microorganisms and particulate matter	According to the Perimeter and facility SOP to make sure air pressure, temperature, humidity, micro-gens and particles are correctly maintained and documented.
		9.1.2 Drains and sewers	Keep clean by following SSOP and Master Cleaning Schedule
		9.1.3 Pest control	SOP for Pest control, and use outside experts (Eco-Labs) to maintain and training
		9.1.4 Lighting	According to the Perimeter and facility SOP to keep adequate lighting
		9.1.5 Wash rooms/toilets	We have designated people for the wash rooms and toilets cleaning and maintenance, according to the SSOP requirements.
		9.1.6 Waste collection and disposal system	We have designated people for the waste collection and disposal system maintenance, according to the SSOP requirements.
		9.1.7 Heating/cooling systems	According to Maintenance Procedure and records
		9.1.8 Support systems such as water, vacuum and compressed air	According to Maintenance Procedure and records
	9.2	Are there written procedures for calibration of instruments? How is this documented?	Yes. They are documented in calibration records with QA Lab and all places that have calibrated instruments. There are also tags on each instrument and scale for the date and result of the latest calibration.

Questions		Response
9.3	How do you dispose of your industrial waste?	By the city water company
10.0	**Miscellaneous:**	
10.1	What type of ongoing training programs do you have for;	
10.1.1	New employees	Yes, orientation training and following trainings according to the Master Training program. All training have records documented
10.1.2	Present staff	Yes, according to the Master Training Program, and yearly review and update the Master Training Program, All training have records and documented with attendance signed
10.2	Do you maintain a record of consultants and their qualifications?	Yes, the consultant is an industrial expert from the US: C&K Consulting, Atwater, California
10.3	Are there written job descriptions?	Yes, for everyone and also the key teams and their members posted on wall
10.4	How do you handle complaints and returned products?	According to relevant SOPs as described before. Customer complaints are also reviewed by upper management
10.5	Do you have a recall procedure in place?	Yes, and we do Mock Recall at least once a year
10.6	How many shifts do you usually have?	3 shifts
10.7	How many employees do you have?	250
10.8	What is the approximate square footage of your facility?	279,030 (33,000 M^2)

Questions		Response
10.9	Have you ever been inspected by FDA, EPA, DEA or OSHA? If so, provide the dates and their results?	We have not been inspected by the US organizations as mentioned in your questionnaire because the plant is in China,However, we have been inspected by various organizations and agents of quality assurance and 3th party quality audits by US customers .
10.10	Describe your safety record over the last five years.	Excellent