

## SUPPLIER AUDIT CHECK LIST

General Information		
<b>Organization Name:</b>		
<b>Name and Contact Details for personnel filling this list:</b>		
<b>Quality Management</b>	<b>YES</b>	<b>NO</b>
Is there a quality leader/in charge in the organization?		
If yes, then please provide name and contact details		
Is there a Quality Management System in place that can be reviewed during an agreed audit visit?		
Is the organization ISO 9001 certified? If yes, please provide a copy.		
Is the quality system documented, controlled, and maintained to clearly describe current practice?		
Do you have internal audit procedure? Do you maintain records for results?		
Does executive management participate in periodic quality system reviews that address quality related feedback from customers and internal quality metrics?		
Did SFDA inspected your facilities during the last (2) years? If yes, provide a copy of last inspection report		
<b>Continuous Improvement</b>		
Is a corrective action system in place that provides root cause analysis and takes timely and effective action to prevent recurrence?		
Does the corrective action system cover customer, internal and supplier issues?		
<b>Education &amp; Training</b>		
Are the skills and education level required for each job documented and appropriate training provided?		
Are suitable methods used to verify training effectiveness, and suitable records are maintained?		
Does the organization have a periodic refresher training programs for established employees?		
<b>Health &amp; Safety</b>		
Does the health and safety management system address the requirement for emergency planning?		
Are procedures used for the on-going identification of hazards, the assessment of risks, and the implementation of necessary control measures?		
<b>Customer Documentation</b>		
Is there a record control system is in place for the identification, storage, protection, retrieval, retention time, and disposition of quality records?		
Are quality records maintained?		

<b>Supplier Relationship</b>	<b>YES</b>	<b>NO</b>
Does the supplier assurance system ensure that all purchased product or material conforms to defined identifications and applicable regulatory or customer requirements?		
Does a system exist for the identification, verification and protection of customer supplied product that includes notifying customer if product is damaged or lost?		
Do supplier corrective action requests requiring root cause investigation show responses are analyzed?		
<b>Nonconforming Materials</b>		
Are nonconforming products are segregated and identified to prevent unapproved use?		
Is product traceability maintained to facilitate problem evaluation and corrective action?		
Is there a recall system to notify customers of nonconforming product that has already been shipped?		
<b>Monitoring &amp; Measurement</b>		
Do you have temperature monitoring system in warehousing facilities?		
Are temperature measuring devices and gauges are routinely calibrated and controlled per documented procedures?		
Are temperature measuring devices and gauges calibrated against standards traceable to a recognized regulatory body or agency?		
Are appropriate controls are in place to verify the suitability and accuracy of computer software prior to initial use in checking product quality or control of processes?		
<b>Storage</b>		
Are areas around the facility clean and orderly and are tools and equipment properly stored and readily available for use and is lighting and air quality are adequate?		
Are documented procedures followed to ensure proper control and preservation of handling, storage (FIFO), packaging, and delivery of product?		
Are there separate areas for Quarantine products, expired products, and damaged products?		
Are there separate areas for in-bounds and out-bounds?		
<b>Maintenance</b>		
Is there a maintenance contract for Air-Conditioning Equipment?		
Is there a maintenance contract for Cold Chain items cold room?		
Is there a maintenance contract for the Fire Fighting System?		
Is there a maintenance contract for pest control?		
Do Temperature Controlled Vehicles have maintenance log book?		
Is there a back-up power generator in case of power break-down? If yes, is there a maintenance contract		
Is there a maintenance contract for power back-up generator?		