



**Factory Quality Audit Tool**  
**Amazon Private Brand Supplier Quality Management**

**Audit Basic Information:**

Audit Number: _____	Audit Requester : _____	Business Model: _____
Auditor Name: _____		Product Line: _____
Auditor Organization: _____	Audit Type: _____	Factory Contact Name: _____
Oversea Auditor Name: _____	Audit Occurrence: _____	Factory Contact email: _____
Audit Start Date: _____ MM/DD/YYYY	Cost Center: _____	Vendor Contact Name: _____
Audit Manday: _____	QM Product Line Owner: _____	Vendor Contact email: _____
Sourced Products: _____	Vendor Name: _____	
Factory Name (EN): _____	Factory Name (CN): _____	
Factory Address (EN): _____	Factory Address (CN): _____	

<b>Overall</b> <b>0.00%</b>
<b>Disqualified for 0 risk 0</b>
Factory can apply re-audit after factory internal improvement is done.
<b>Failed section</b> Overall does not meet requirement (em. Req.)

**Factory Capability Evaluation Summary**

Put a "x" in one of the rating columns for each element, to give your evaluation rating to that element, by comparing its level in the industry benchmark.

No.	Elements	Evaluation Ratings				Weight	Comments
		Good	Average	Marginal	Not Acceptable		
1	Management organization					4	
2	Workforce and capacity					3	
3	Product / Pkg Development					4	
4	Experiences in the category					8	
5	Production / Mfg Capability					8	
6	Material Control (incl. regulatory req.)					4	
7	Quality Functions					4	
8	In-house Test Capability (Product)					5	
9	In-house Test Capability (Package)					2	
10	Communication					3	



Quality Management System Audit Checklist(质量体系审核清单)

No.	Questions(问题点)	Weight Factor (from 1 to 5, for levels)	Put a "x" in 1 of "score columns" for each question, and provide necessary comments.						Comments(意见/发现)	Score (分数)	Adjust Availab leScore (调整后分数)
			Fully Comply (完全符合)	Majority Comply (大多数符合)	Partial y Comply (部分符合)	A Few Rough Works( 一点符合)	Not At All (完全没有)	N/A (不相关)			
<b>Section 1: Factory Facilities &amp; Environment(第一部分:工厂设施和环境)</b>											
1.1	Does factory look <b>clean, organized, and secured</b> in: production lines, storage of materials and products, rework / repair areas, inspection, and packing areas? Is the overall production process flow organized in an efficient way? (工厂整体是否干净, 整洁, 安全: 包括生产线,原料仓和成品仓, 重工返修区,检查和包装区? 总体的生产流程设置高效?)	3									
1.2 CCP	Does factory have the <b>right facilities</b> (incl. production equipment, tooling) <b>for manufacturing of the products being sourced</b> ? Are the maintenances / status of the facilities look good? (工厂是否有合适的设施(包括生产机器和工装用具)用于生产所采购产品? 这些设施的维护保养是否在好的状态?)	4									
1.3	Does factory have and maintain <b>sanitation and/or pest controls</b> in certain production workshops and / or warehouses, as necessary, to ensure products' quality and compliance? (必要时,工厂是否在特定的生产车间和仓库设立并执行卫生及虫害防治, 以确保产品质量和合规?)	3									
<b>Section Summary Line :-</b>		Total Available S	40.00	<b>Total Compliance Percentage:</b>		<b>0.00%</b>			0.00	0	
<b>Section 2: Quality System, Documentation Control, Training(第二部分:质量体系, 文件管理, 培训)</b>											
2.1	Does factory have a documented <b>quality manual</b> to define the factory's quality policy, quality objectives, organization, roles and responsibilities in quality management, and, outline the high level quality operations? Have the quality manual contents been clearly <b>communicated and understood</b> by factory's management staff? (工厂是否有文件化的质量手册来确定工厂的质量方针, 质量目标, 组织结构及质量管理的权责, 并且概述出质量运作要求, 并且质量手册的相关内容在内部进行充分的沟通并被管理层理解)	2									
2.2	Does factory have documented <b>operation procedures and necessary work instructions</b> to guide people to operate consistently and effectively achieve results as expected, and the procedures and work instructions have been <b>communicated and understood</b> by related employees? (工厂是否有文件化的操作指引和必要的工作指引去指导员工一致性操作并有效地达到期望的结果, 并且程序和工作指引被相关员工充分了解)	4									
2.3	Does factory <b>control documents</b> properly, i.e. review and approval, distribution, change control, etc.? The controlled documents should include external standard documents, and technical documents like spec., drawing, BOM, standard samples, etc.. (工厂是否正确地进行文件控制,像文件审核,批准,分发,变更控制等?受控文件应该包括外部标准文件; 内部规格,图纸,物料清单,标准样板等技术文件)	3									
2.4	Does factory clearly define <b>quality records needs</b> in various quality operations, and the <b>retention</b> time of those records? (工厂是否清晰的规定了哪些质量控制位需要质量记录以及记录的保存时间)	2									
2.5	Does factory <b>properly keep</b> the quality records, that includes identification, keeping in righth environment, easy retrieval of records, etc.? (工厂是否正确地保存质量记录,包括标识,保存环境以及易于取得等)	2									
2.6 CCP	Does factory have an <b>independent Quality Department</b> , with QA/QC personnel authorized to inspect products and materials, and take necessary actions to assure quality? (工厂是否有独立的质量部门, 有授权的QA/QC人员检验产品和原料,并采取必要的质量保证措施。)	5									
2.7	Does factory have a well planned and implemented <b>training program for workforces and QA/QC personnel</b> , that includes training of product knowledge, production processes, inspection & testing, and, right operations of production, testing, and measuring equipment in production and in-house lab? (工厂是否很好地规划和执行全体员工及QA/QC人员培训体系,内容包括产品知识,生产流程,检查和测试,正确的操作生产线和实验室的生产,计量和测试等设备)	3									



Quality Management System Audit Checklist(质量体系审核清单)

No.	Questions(问题点)	Weight Factor (from 1 to 5, for levels)	Put a "x" in 1 of "score columns" for each question, and provide necessary comments.						Comments(意见/发现)	Score (分数)	Adjust Availab leScore (调整后分数)
			Fully Comply (完全符合)	Majority Comply (大多数符合)	Partially Comply (部分符合)	A Few Rough Works( 一点符)	Not At All (完全没有)	N/A (不相关)			
		4	3	2	1	0	X				
2.8	Do factory's on-job production and QA/QC personnel have <b>adequate knowledge</b> of quality requirements for the product categories being sourced, relevant materials, and the production processes? (工厂员工和QA/QC人员对相关产品,原料的质量要求以及生产流程是否有足够的知识)	4									
<b>Section Summary Line :-</b>		Total Available S	100.00	<b>Total Compliance Percentage:</b>		<b>0.00%</b>			0.00	0	
<b>Section 3: Product Development Control (第三部分: 产品设计开发控制)</b>											
3.1	Does factory have <b>right knowledge, experiences</b> and competent engineers / technicians to develop the type of products being sourced? (工厂是否有具备正确的知识,经验和能胜任的工程师/技术员去开发客户需要的产品)	5									
3.2	Does factory have a process to <b>review with customers to define product requirements</b> , that should include certain spec., product performance, safety, durability, etc. for product development? (工厂是否有相应的流程规定在确定产品要求前和客户充分沟通,沟通开发过程中的产品标准,表现,安全,可靠性等)	4									
3.3	Does factory have <b>product development plans</b> to outline product development stages, covering development of product (construction, functions, materials etc.), prototype / sample making, review / verification arrangement for the product developed, etc.? Does factory conduct necessary reviews, verifications at various stages of product development according to the plan? (工厂是否有详细的开发计划去定义好以下开发进程, 包括产品结构/功能, 需要的物料, 手板样本制作, 产品设计的审核/确认等? 工厂是否按产品开发计划安排了必要的产品开发检讨, 验证?)	5									
3.4	Does factory's product development <b>output</b> right / updated product spec., drawings, and/or samples, to provide data, requirements, and instructions for production, purchasing, and quality controls? (工厂设计开发阶段是否有以下输出:正确的产品规格,图纸,样板,并为生产,采购,质量控制提供相应的资料, 要求, 和指引)	5									
3.5	Does factory have competent engineer / technician, and a process in place to <b>develop, review / verify package</b> construction which is sufficient to protect the type of products? (工厂是否有能胜任的工程师/技术员, 及相关工作流程去开发,审核/确认产品包装结构)	4									
3.6	Does factory have in-house capability to <b>develop, review / verify User Manual, Assembly Instruction, etc.</b> for the type of products? (工厂是否有能力自己开发,审核/确认用户手册,装配说明书等).	3									
3.7 CCP	Does factory conduct <b>right and complete tests</b> (incl. submission to 3rd party test) to verify that <b>final product complies</b> to the customer's and regulatory requirements before release for production? (在量产前,工厂是否进行正确的产品测试(或第三方测试)去确认产品对于客户要求 and 法规要求的符合性)	5									
3.8	Does factory hold <b>Pre-Production Meeting</b> to communicate product quality requirements to production teams before mass production starts? (在量产前,工厂是否举行产前会议交接产品质量要求给生产部门)	4									
3.9	Does factory have a process to <b>control</b> (evaluate, approve, communicate) <b>changes</b> to product / package after product / package has been approved, that includes communicating the changes to customer's approval? (工厂是否有相应的流程去管控产品/包装工程变更, 包括通知客户并得到客户的批准)	5									
<b>Section Summary Line :-</b>		Total Available S	160.00	<b>Total Compliance Percentage:</b>		<b>0.00%</b>			0.00	0	
<b>Section 4: Purchasing Control &amp; Materials Control (第四部分: 采购控制和原材料(外包)控制)</b>											



Quality Management System Audit Checklist(质量体系审核清单)

No.	Questions(问题点)	Weight Factor (from 1 to 5, for levels)	Put a "x" in 1 of "score columns" for each question, and provide necessary comments.						Comments(意见/发现)	Score (分数)	Adjust Availab leScore (调整后分数)
			4	3	2	1	0	X			
4.1	Does factory have a method / process to <b>evaluate and select its suppliers</b> (incl. subcontractors) based on their abilities to meet quality and on-time delivery requirements? (工厂是否有建立评估和选择供应商(包括分包商)的流程。基于供应商满足质量和准时交货要求的能力)	3									
4.2	Does factory have a mechanism to <b>measure suppliers' quality performances</b> to ensure right suppliers are being used to consistently supply right quality materials / components? (工厂是否有评估供应商质量水平的机制去保证正确的供应商稳定地提供正确的物料/零件.)	3									
4.3	Does factory have a method / process to <b>evaluate and approve the materials / components</b> before purchase? (在采购之前工厂是否有方法/流程去评估和确定原材料/零件)	5									
4.4	Does factory clearly <b>communicate quality requirements</b> to its suppliers <b>when purchase</b> materials or <b>outsource</b> any production processes? (当采购原物料或者外购任何半成品时工厂是否清晰的与供应商沟通其质量要求).	3									
4.5	Does factory clearly <b>define inspection</b> and testing requirements for <b>incoming</b> materials / components, that should include sampling plan, inspection / test items, acceptance criteria? (工厂是否清晰地定义原材料和零件的检验和测试要求, 包括抽样计划, 检验/测试内容, 收货标准等)	3									
4.6 CCP	Does factory <b>conduct inspection / tests for incoming materials / compoents</b> according to the defined requirements, documented drawing / spec., product requirements, reference samples, and certain inspection / testing work instructions? Are IQC records kept? (工厂是否按照定义的要求进行原物料/零件的检验/测试, 定义的要求包括受控的图纸/标准, 产品要求, 客户样板, 以及检验/测试指导书等? 有保留IQC记录吗?)	5									
4.7	Does factory clearly <b>identify inspection status</b> for incoming goods, separate the goods that passed inspection, not inspected, failed inspection, so as to prevent unintended uses? (工厂是否清晰地定义来料的检验状态, 正确区分出检验合格, 待检验, 检验不合格, 避免混用和非预期使用)	2									
4.8	Does factory clearly <b>define and implement</b> processes / authorities for <b>disposition of nonconforming</b> incoming goods, that could be RTV, rework & reinspect, approved concession? Are disposition records kept? (工厂是否清晰地定义并执行来料不良品处理的流程/权限, 可能是退货, 重工, 重检验, 批准豁免, 有保留不合格品处理的记录吗?)	4									
4.9	Does factory <b>store the materials and components</b> in areas / warehouses with appropriate environment, stack and rotate stocks <b>properly</b> , like FIFO (First In First Out) to prevent materials / components from deterioration or over stock due date? (工厂的原物料/零件仓是否有合适的储存环境, 正确的储存和周转, 执行先进先出避免原物料/零件劣化或过期)	3									
4.10	Does factory <b>identify products / materials</b> properly with models, item #, receiving dates, etc., and, separate materials for specific markets, e.g.: CARB P2 for USA, REACH for EU, <b>to prevent unintended use</b> of wrong quality materials / products? And the identifications facilitate traceability? (工厂是否用型号, 物料编号, 来料日期等正确地识别物料/产品, 包括区分不同目标市场物料, 比如区分CARB, REACH 物料, 以避免非预期使用错误的物料/产品? 标识能提供追溯性?)	4									
4.11	Does factory <b>handle, transport</b> materials, components and WIPs appropriately to prevent products from damages, scratches, etc.? (工厂是否正确地处理, 运送相关原料, 零件和半成品而避免损坏和刮花等)	3									
<b>Section Summary Line :-</b>			Total Available S	152.00	<b>Total Compliance Percentage:</b>		<b>0.00%</b>		0.00	0	



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			4	3	2	1	0	X			

Section 5: Production and In-process Quality Control (General Part) (第五部分: 生产和过程质量控制)										
5.1	Does factory <b>plan productions</b> properly for customers' orders, by considering purchasing and production lead time, workforces, available capacity, etc., and have means to manage productions in peak seasons? Does factory maintain a good record of <b>on-time delivery</b> ? (工厂能否基于工厂的采购及生产周期, 人力和产能, 合理按客户订单安排生产, 并有能力在高峰期管理好生产? 工厂是否保持良好的(90%)准时交货率?)	3								
5.2	Does factory <b>plan its manufacturing processes</b> for types of products with consideration of risks and necessary controls (e.g.: from PFMEA outputs), to outline process steps (incl. outsourced ones), identifying key areas of risks, define process requirements and execute quality controls, to effectively <b>eliminate risks to quality of products</b> in the productions? Where product quality can't be verified by subsequent inspection/ testing, the process has been validated? (工厂是否考虑风险及控制的要求(比如, 依据“制程失效模式分析”的输出结果)来规划生产制程(包括外发制程), 对识别出来的制程关键质量控制点安排和执行有效的控制, 以消除生产中导致产品质量问题的风险。当某工位产品质量不能被后续检验/测试证实时, 此工位必须是被验证过的)	5								
5.3	Does factory <b>arrange manufacturing processes according to the plans</b> , with right allocation of material / component, equipment, work forces, in-process inspection / tests, etc. for the type of products? (工厂是否正确地安排生产, 恰当地分配物料/零件, 设备, 人力, 过程检验/测试等)	4								
5.4	Does factory prepare and provide <b>necessary work instructions</b> , reference samples, etc. with defined working methods, quality acceptance criteria, and/or defects classifications, at certain workstations for production or inspection use? (工厂是否准备好必要的工作指引, 参考样板等, 在确定的工位有已经定义好的工作方法, 质量接收标准, 以及不良分类等支持生产和检验)	3								
5.5	Does factory's Production / QC inspect and sign off the <b>first articles</b> of WIPs and finished products at appropriate process steps to ensure that they meet the requirements with regard to specification, quality & safety? (工厂生产/QC是否在过程和成品阶段审核及签发首件来保证产品满足规格, 质量及安全方面的要求)	4								
5.6	Does factory use appropriate <b>jigs / fixtures</b> as necessary to control consistency of positions, directions, level, gaps etc. in relevant production processes? (在相关的生产制程, 工厂是否应用适当的工装夹具控制位置, 方向, 水平面, 缝隙的一致性)	3								
5.7	Does factory <b>control process parameters</b> (like: temperature, humidity, speed, torque, pressure, drying time, etc.) in production to ensure product quality is achieved and consistent? (工厂是否控制关键制程参数(温度, 湿度, 速度, 扭力, 压力, 时间等)来确保质量的达成及一致)	4								
5.8	Does factory production <b>select right quality materials / components</b> , and/or <b>control recycle materials</b> ratio (e.g.: plastic injection materials) for production use, to ensure the outcome products having right quality? (工厂是否选择正确的原料/零件, 以及控制再生料的比率(注塑塑胶料), 以达到产品质量)	3								
5.9	Does factory production always <b>apply sufficient auxiliary materials</b> (like glue, paint), and use proper production <b>reference samples (like color panels)</b> to control production consistency, ensure product construction integrity and finish conformity? (工厂是否经常应用足够的辅助物料(胶水, 颜料), 并且应用适当的参考样板(色版)去控制生产过程, 以达到产品结构和成品的符合性)	3								



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		4	3	2	1	0	X				
5.10	Does factory plan and conduct <b>production equipment maintenances</b> properly, to ensure precision and good conditions of the production equipment? (工厂是否适当策划和执行生产设备保养, 以确保生产设备的精确度和好的状态)	3									
5.11	Does the factory clearly <b>identify</b> products / components in production, <b>segregate and isolate non-compliant materials and products</b> in all areas to prevent unintended usage and cross contamination? (工厂是否在生产过程中, 清晰地标识产品和零件, 及将合规的产品/材料与非合规的产品/材料隔离开, 以防止它们的误用及交叉污染?)	3									
5.12	Does factory have method to <b>control and prevent</b> risks of physical, chemical and biological (such as: molds, needles, RoHS/non-RoHS materials) <b>contaminations</b> in the production processes that may damage the products and/or personnel? (工厂是否有方法控制和预防 生产制程中物理、化学及生物污染等可能造成产品/人员的损坏, (比如, 发霉, 断针, RoHS和非RoHS物料混用))	5									
5.13	Does factory define, communicate, and correctly follow the <b>package</b> requirements (package materials, package method, labeling, packing list, etc.) in production? (生产中工厂是否定义、沟通并且正确地遵照包装要求(包装材料, 包装方法, 标签, 包装清单等))	3									
5.14	Does factory clearly <b>define in-process inspections</b> , include inspection needs at various stages, frequency / sampling plan, inspection and testing methods, equipment to use, quality requirements and acceptance criteria, etc.? (工厂是否清晰地定义过程检验, 包括检验点, 检验频率/抽样计划, 检验和测试方法, 检验仪器, 质量要求及接收标准)	4									
5.15	Does factory <b>conduct in-process inspections</b> according to the defined requirements, at appropriate stations, against the defined product spec., drawing, sample, etc.? (工厂是否按照确定的要求进行过程检验, 包括检验点, 确定的产品规格, 图纸, 样板等)	5									
5.16	Does factory <b>record</b> inspection results and findings, feedback / review with productions as appropriate? (工厂是否记录检验结果和发现, 并恰当地向生产部门反馈)	3									
5.17	Does factory clearly <b>identify inspection status</b> of products in production lines, segregate nonconforming products properly? (工厂是否清晰地识别产品的检验状态, 正确地区分出不合格品)	2									
5.18	Does factory <b>define and implement</b> processes / authorities for <b>disposition of nonconforming</b> products in productions, that could be rework & reinspect, approved concession, etc.? (工厂是否定义和执行不良品处理流程和权限, 可能包括重工, 重检, 批准豁免)	4									
<b>Section Summary Line :-</b>		Total Available S	256.00	<b>Total Compliance Percentage:</b>		<b>0.00%</b>			0.00	0	

<b>Section 6: Final Inspection &amp; Test (第六部分: 最终成品检查及测试)</b>											
6.1	Does factory clearly define <b>inspection requirements for the finished products</b> , especially for critical features like, construction, performances, safety and serviceability, etc., and, define the inspection sampling plan, acceptance criteria? (工厂是否清晰地定义成品的检验要求, 特别是结构, 表现, 耐用, 安全和适用性等, 定义检验抽样计划和接收标准)	3									
6.2	Does factory train its QA/QCs to clearly <b>understand quality requirements for the final products, and understand inspection processes</b> (i.e.: inspection and test items / needs, methods & tooling, frequencies / sampling plan, acceptance criteria, etc.)? (工厂是否培训QA/QC人员理解产品和检验的质量要求(检验和测试项目, 方法, 测试设备, 频率, 抽样计划, 接收准则等))	4									



Quality Management System Audit Checklist(质量体系审核清单)

No.	Questions(问题点)	Weight Factor (from 1 to 5, for levels)	Put a "x" in 1 of "score columns" for each question, and provide necessary comments.						Comments(意见/发现)	Score (分数)	Adjust Availab leScore (调整后分数)
			Fully Comply (完全符合)	Majority Comply (大多数符合)	Partial y Comply (部分符合)	A Few Rough Works( 一点符)	Not At All (完全不符合)	N/A (不相关)			
6.3 CCP	Does factory <b>conduct final inspections</b> according to the defined process, against relevant drawings / specifications, product requirements, reference samples, and conduct adequate <b>tests</b> to verify products' safety, fit for use, durability, etc.? (工厂是否按照定义好的流程进行终检, 依据相关的图纸 / 规格, 特殊产品要求, 参考样板, 并进行足够的测试去验证产品的安全性, 使用功能, 耐用性等)	5									
6.4	Does factory <b>record</b> final inspection results and findings, feedback / review with productions for corrective actions / improvement opportunities? (工厂是否记录终检结果和发现, 并反馈给生产部门作为纠正和改善机会)	3									
6.5	Does factory clearly <b>identify inspection status</b> of final products, segregate nonconforming products properly? (工厂是否清晰地识别检验产品的状态, 隔离出不良品)	2									
6.6 CCP	Does factory define and implement a process, with necessary authorities, to <b>make dispositions for the inspection failed products</b> , dispositions could be: rework and re-inspection, accept on deviation, etc., and, communicate to customer's approval? (工厂是否有定义和执行不良品处理流程, 可能包括重工, 重检, 接收差异等, 并且得到客户的批准)	5									
6.7	Does factory have a correct shipping operation process in place to control that <b>products are NOT shipped until they have passed final inspection</b> ? (工厂是否有正确的出货流程, 确保产品通过终检合格后才能出货)	4									
<b>Section Summary Line :-</b>			Total Available S	104.00	<b>Total Compliance Percentage:</b>			<b>0.00%</b>	0.00	0	

Section 7: Control of Measuring and Testing Equipment (第七部分: 计量和测试设备的控制)										
7.1	Does factory have <b>right measuring and testing equipment (with right scale and range)</b> used in inspections and tests for incoming goods, products in production processes, and final products? Does factory maintain these measuring / test equipment always in a <b>good / usable condition</b> ? (工厂是否有合适对进料, 生产制程的产品, 及最终产品进行检验和测试的设备, 包括对的刻度和量程, 并保养测量仪器, 测量/测试设备以确保它们在好的可用的状态)	4								
7.2	Does factory have a <b>master list and calibration plan</b> for the measuring and test equipment that are used in production, inspections for receiving goods, in-process & final inspection and test operations? (工厂是否有测量/测试设备清单和校正计划, 包括生产使用/来料检验/过程检验/产品终检以及 测试阶段的测量测试设备)	3								
7.3	Does factory arrange <b>calibrations</b> for all measuring and test equipment at appropriate intervals to ensure the equipment are suitable and accurate to measure and verify products' acceptance, and the calibrations are traceable to national / international standards? (工厂是否在恰当时间间隔安排测量/测试设备的校正, 以保证设备恰当和精确地验证产品, 且相关校正追溯国家/国际标准)	5								
7.4	Does factory <b>record, identify calibrations</b> , define and implement a procedure to <b>recall</b> products when equipment is found not in calibration status? (工厂是否记录, 识别校正结果, 并有定义召回流程, 以在发现测量/测试设备失准时对其检验过的产品执行召回)	3								
<b>Section Summary Line :-</b>			Total Available S	60.00	<b>Total Compliance Percentage:</b>			<b>0.00%</b>	0.00	0

Section 8: CAP, Crisis Mgt, and Continuous Improvement (第八部分: 改正措施计划和持续改善)





Quality Management System Audit Checklist(质量体系审核清单)

No.	Questions(问题点)	Weight Factor (from 1 to 5, for levels)	Put a "x" in 1 of "score columns" for each question, and provide necessary comments.						Comments(意见/发现)	Score (分数)	Adjust Available Score (调整后分数)
			Fully Comply (完全符合)	Majority Comply (大多数符合)	Partially Comply (部分符合)	A Few Rough Works (一点偏)	Not At All (完全没有)	N/A (不相关)			
8.1	Does factory have a <b>CAP process</b> , that should define conditions to initiate CAP, and CAP work flow that should include containment, causes investigation, corrective actions to eliminate causes and prevent recurrence, and follow up / verify effectiveness? (工厂是否有纠正和预防措施流程,应该包括什么情况发行CAP,CAP流程应该包括围堵措施,原因调查,消除原因的纠正措施和预防措施,以及跟进/确认有效性)	3									
8.2	Does factory have a method to review and respond to <b>customer complaints / returns / claims</b> that includes customer's inspection / testing fails, and, the factory investigates causes, takes necessary corrective actions to prevent recurrence? (工厂是否有流程回复客户抱怨/退货/投诉(包括客户检验和测试不良,工厂是否调查原因,执行必要的纠正预防措施防止再次发生)	4									
8.3	Does factory take necessary corrective actions to fix problems with its suppliers, production processes, etc., when there are <b>significant quality issues</b> happening with materials / components from its suppliers, in factory's productions, or, with its final products, etc.? (当生产中或供应商产品有重大质量问题时工厂是否执行或要求必要的纠正预防措施)	4									
8.4	Does factory collect <b>quality data and analyze data</b> with certain quality analysis tools, so as to precisely identify quality problems and improvement opportunities? Does factory <b>initiate corrective actions and/or quality improvement projects</b> based on quality data analysis? (工厂是否有一些必要的质量数据收集和分析,以准确的识别质量问题和改善机会?工厂是否基于质量数据分析而启动一些纠正预防措施或质量改善项目)	3									
8.5	Does the factory conduct <b>internal audits</b> for its quality management according to internal procedures? Are the audit results captured and <b>CAPA</b> (Corrective Action and Preventive Action) properly executed and documented? (工厂是否对内部质量管理进行内审,并记录内审发现的问题,执行纠正预防措施并记录?)	4									
8.6	Does the factory have a process in place to <b>manage various crisis situations</b> , such as breakdown of production equipment or lines, fire and evacuation of the facility, major supplier bankruptcy, strike? (工厂是否有方法有效管理各种危机,比如,生产设备,生产线故障,火灾及工厂疏散,主要供应商破产,罢工,等等?)	3									
<b>Section Summary Line :-</b>			Total Available Score	84.00	<b>Total Compliance Percentage:</b>		<b>0.00%</b>		0.00	0	

Scoring Guideline

Score	Criteria / Explanation	Rating	CAP / Observation
4.0	There is documented procedure or well common understanding for the questioned requirement, all required operations are being effectively implemented and proven to be able to assure quality, provides full confidence to customers on QMS implementation.	Fully Comply	N/A
3.0	There is documented procedure or well common understanding for the questioned requirement, majority of required works are being carried out with certain effectiveness, providing confidence to customers. A few minor discrepancies may be found.	Majority Comply	No CAP, but observation point for improvement opportunity
2.0	To the questioned requirement, there are operation requirements defined (documented or commonly understood) in factory, and certain works have been carried out case by case, not able to provide customer good confidence that the works are effectively managed.	Partially Comply	CAP may be needed depends on findings





Quality Management System Audit Checklist(质量体系审核清单)

No.	Questions(问题点)	Put a "x" in 1 of "score columns" for each question, and provide necessary comments.						Comments(意见/发现)	Score (分数)	Adjust Available Score (调整后分数)
		Weight Factor (from 1 to 5, for levels)	Fully Comply (完全符合)	Majority Comply (大多数符合)	Partially Comply (部分符合)	A Few Rough Works (一点不符合)	Not At All (完全没有)			
			4	3	2	1	0	X		
1.0	Not acceptable. There are a few rough works done to the question's requirement, but not a planned work, not able to ensure compliance and effectiveness. Or, majority of required operations are not implemented, or, the failure could result in immediate quality concern.	A few rough Works								
0.0	Nothing has been done, or, being judged as Critical Failure, operations breakdown.	Not At All								
N/A	The question is not applicable to factory's operations at the moment.	Not Applicable								

Quality Evaluation Overall Scoring: -tal Available scc ##### Total compliance Percentage

0.00%

0.00 0

**Product Specific CTQ Audit Checklist(产品特性关键点审核清单)**

Category		Factor (from 1 to 5, for levels of)	Put a "x" in 1 of "score columns" for each question, and provide necessary comments. (标识"x" 在其中的一个框内, 并提供必要的阐述意见, 得分为2分及以下的问题一定要写意见)					Comments(意见/发现)	Score (分数)	Full Score (满分)
			Fully Comply 4	Majority Comply 3	Partially Comply 2	A Few Rough 1	Not At All(完全 不相关) 0			
No.	Questions(问题点)									
1										
2										
3										
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<b>Section Summary Line :-</b>		Total Available Sco			<b>Total Compliance Percentage:</b>			0	0	



Factory: January 0, 1900

Audit Requester =FQA Scoring!K10

The Audit Team's comments for the factory's capabilities and quality assurance:

Strength:	Weakness:
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The Factory's Pictures:

1. The Factory's Gate & Overall	2. The Showroom	3. Sourced Product Type(s)	

4. The Factory's 3 - 5 Major Production Processes, Equipment, and Facilities					

5. The Factory's Warehouses	6. Factory's QC Activities	7. Factory's in-house Lab / Calibration (	8. ISO 9001 certificate picture

Remark: Auditors can insert some more pictures when they can demonstrate the factory's status of capability, quality management, or discrepancies, etc..

