EastBridge
The Science of Strategic Sourcing

供应商质量体系评估
Supplier Quality System Survey

Supplier:	Medical Device Supplier
Product & code:	Disposible Syringe
Address:	
Date:	October 24, 2017 - October 26, 2017
Audit:	首次稽核/first audit　例行稽核/rountine audit　关键问题稽核/special audit for critical problem　其他/others:
Auditor:	Eva Hu, Hill Miao

NO.	Item	Full Mark	N/A occupied	Efficient marks	Actual marks	Marks' rate/item
1	质量体系/Quality System Management	33	0	33	28	85%
2	内审/Internal Audit	18	0	18	14	78%
3	合约评审/Contract Review	15	0	15	5	33%
4	文件控制/Document controll	33	0	33	10	30%
5	供应商证书以及进料控制/Supplier certification & incoming control	42	0	42	30	71%
6	制程控制/process control	39	0	39	18	46%
7	检验和测试/Inspection and Testing / Status	30	0	30	19	63%
8	终检/Final verification measurement	24	0	24	11	46%
9	不良品控制/Control of Nonconforming Product	51	0	51	33	65%
10	仪器校验/ Calibration	24	3	21	10	48%
11	搬运，储存，包装和运输 Handling，Storage, Packaging, and Delivery	48	0	48	31	65%
12	教育训练/Training	15	3	12	9	75%
总分/**final marks**		372	6	366	218	60%

Audit Summary

Class：		
>80%	可以接受/acceptable	
80%>70%	有条件的接受/accept with some special requirements	**Improving before appr**
<70%	不能接受/unacceptable	

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On Site Comprehensive Audit Report
现场全面审核报告

1. Quality System Management		Rating				
		3	2	1	0	N/A
1.1	Has the supplier defined and documented its corporate quality policy, objectives and commitments to quality? Is the supplier ISO 13485 registered?Does the registration scope cover the entire manufacturing facility? 供应商是否有文件明确定义品质及其政策，目标与承诺? 供应商是否已通过ISO13485质量体系？若通过，该质量体系是否涵盖所有的生产场地?	3				
1.2	Are procedures in place to ensure this quality policy is understood, implemented and maintained at all levels in the organization? 供应商是否有程序书，使其保证组织內之各阶层均已了解该品质政策,并能有效实施及維持？		2			
1.3	Has the supplier defined the responsibility, authority and interrelation of all personnel who manage, perform and verify work that affects the quality of products, materials or services? (i.e. procedures, organization charts, quality manual) 凡担任会影响该产品，原料或服务质量的所有管理,执行以及验证的工作人员,其权责与相互关系,供应商是否加以定义?（程序书，组织图，质量手册）	3				
1.4	Has the supplier appointed a management representative who has responsibility and authority for ensuring that a quality management system has been implemented and maintained? 供应商是否有制订一管理代表并赋予其权力使其保证品质管理系统可以被执行与维持?	3				
1.5	Has the supplier established and maintained a documented quality system including procedures and work instructions? 供应商是否制定并维护品质系统的程序书与作业指导书?		2			
1.6	Have the procedures and work instructions been effectively implemented? (i.e. available to all personnel who need them) 其程序书与作业指导书是否有效地被執行（是否适合对所有需要的人）?		2			
1.7	Does the supplier conduct management reviews of the suitability and effectiveness of the quality management system at appropriate intervals? (i.e. does the quality system meet customer requirements?) 供应商是否在一定时期做管理评审以使其品质管理系统得以适切有效的被执行? (例如:品质系统是否符合客戶需求?)	3				
1.8	Are records maintained of these management reviews? 管理评审之纪录是否有保留?	3				

1.9	Are there statistics of quality cost? 有质量成本的统计数据吗?	3				
1.10	Is there evidence to show if the quality level reach the needed and the quality system is implemented effectively? 是否有证据可以显示质量水平可达到需求以及质量系统在有效地运行?		2			
1.11	Is there any project for continue improvement ? 有做持续改进吗?		2			
Attainec 28		18	10	0	0	0

2. Internal Audit						
2.1	Does the supplier carry out a comprehensive system of planned and documented internal quality audits? 供应商是否执行有计划，文件化的全面的内部质量审核系统?	3				
2.2	Do the internal quality audits verify compliance with quality objectives, customer/process requirements, and ISO elements? 内部质量审核结果是否符合公司的质量目标，客户和制程需求以及ISO标准要求?		2			
2.3	Do the internal quality audits verify effectiveness of the quality systems? (e.g., review SPC data and CLCA status) 内部质量审核是否能证明公司的质量系统的有效性（例如：审核SPC数据和CLCA的情况）?		2			
2.4	Are the internal quality audits scheduled on the basis of the status and importance of the activity? 内部质量审核计划是否依据基本情形和活动的重要性安排?	3				
2.5	Are the internal audits and follow-up actions carried out in accordance with documented procedures? 是否根据文件化的程序进行内部质量评审以及结果跟催的行动?	3				
2.6	Does the management personnel responsible for the area take timely corrective action on the deficiencies found by the audit? 当内审有发现不符合项时，管理人员是否负责该不符合区域及时采取的改善动作?			1		
Attainec 14		9	4	1	0	

3. Contract Review		Rating				
		3	2	1	0	N/A
3.1	Are there established procedures for contract review? (i.e. product specifications and quality requirements) 供应商是否有建立合约审查的程序书 ?(如: 产品规格和品质要求)			1		
3.2	Are such procedures reviewed to ensure that: a) Contract requirements are adequately defined and documented. 是否有制定一程序保证合同要求被充分定义和文件化。				0	
3.3	b) Contract requirements that differ from those in tender are resolved. 不同于合约之需求是否已被解决 ?			1		
3.4	c) Does the supplier have the capability to meet the contractual requirements. 供应商是否有能力符合合约之需求 ?			1		
3.5	Are there established procedures for new product introduction/transfer? (e.g., established work instructions, documentation checklist, equipment checklist, conduct pilot run, pre-production, first article review, etc.) 对新产品之介绍与产品线的转移是否有已制定程序 ? (例如 : 建立作业指导书，文件检查表，设备检查表，试产管理， 预先生产之管理，首件之审查 ……等等)		2			
Attainec 5		0	2	3	0	0

4. Document Control		Rating				
		3	2	1	0	N/A
4.1	Do these procedures ensure that pertinent documents are available to personnel at all locations? 相关程序是否可以确保有关文件适合在所有工作场中的员工 ?		2			
4.2	Do these procedures ensure that all obsolete documents are promptly removed from all points of issue or use? 这些程序是否可以确保其过时的文件能立刻从使用单位移开 ?			1		
4.3	Are quality documents reviewed and approved for adequacy by authorized personnel prior to issue? 品质文件在分发之前是否经授权人员适切的审查与核准 ?		2			
4.4	Is there a procedure to govern engineering changes? 是否有一程序去管理工程变更 ?				0	
4.5	Are engineering changes reviewed and approved by authorized personnel prior to implementation? 工程变更在实施之前,是否经授权人员的审查与核准 ?				0	
4.6	Are the engineering change notifications distributed to all affected functional areas once approved? 工程变更通知是否一经核准就会被分送至相关单位 ?				0	
4.7	Is there a system to ensure engineering change notifications are being implemented? 是否有一系統可确保其工程变更通知被執行 ?				0	

4.8	Is there a system to verify the effectiveness of engineering changes? 是否有一系统可验证其工程变更的有效性？				0	
4.9	Are the foreign document controlled into the document control system?(e.g. specification or customer drawing data) 文件控制系统中是否存在外部文件(例如客户规格和图纸）?	3				
4.10	Are the engineering changes to the spec from customer checked ,distributed and implemented in time? 关于客户提出的工程变更是否被及时的验证，分发并执行?		2			
4.11	If there is a full system to assure the engineering modification are implemented effectively? 是否有一个完整的系统可确保工程变更被有效的执行?				0	
Attainec 10		3	6	1	0	0

5. Supplier qulification & incoming control		Rating				
		3	**2**	**1**	**0**	**N/A**
5.1	Does the supplier have procedures to ensure that purchased product conforms to specified requirements? 是否有一程序可确保所采购的产品符合指定的要求？	3				
5.2	Are subcontractors selected on the basis of their ability to meet subcontract requirements, including quality requirements? 是否根据分包商合约所要求 (包括品质系统)之能力来选择分包商？			1		
5.3	Are up-to-date records kept of acceptable/approved subcontractors? 可接受/合格分包商是否保持最新的纪录？			1		
5.4	Does the supplier ensure that the subcontractors' quality system controls are effective? 供应商是否可确保其分包商之品质系统是有效的？			1		
5.5	Are the records for subcontractor approval properly maintained and kept according to the defined retention period? 分包商之合格记录是否适当的保存并依照所定义之保存期限保存？	3				
5.6	Does the supplier review and approve purchasing documents for adequacy of specified requirements prior to release? 供应商在采购文件发出前,是否就采购文件之规定要求审查,并核准其适切性？		2			

5.7	Is the customer allowed to verify at source, or upon receipt, that purchased product conformed to specified requirements? 是否允许客戶至分包商去验证其采购的产品是符合规定要求？	3				
5.8	Is there a procedure for part qualification? (i.e. tooling qualification, inspection method, inspection quantity, etc.) 对零件的承认是否有一程序？(即 工具承认、检验方法、数量，…等)				0	
5.9	Are First Article Inspections conducted in a production environment to ensure requirements are met prior to mass production? 在量产之前是否有執行首批检测, 以确保其生产环境是符合需求？		2			
5.10	Is there a procedure for identifying and tracing product to raw material source?Does this include a FIFO system? 是否有识别和追溯原物料到产品的程序? 该程序包含先进先出吗?	3				
5.11	If the procedure for IQC included the inpection method and sampling plan? 对于进料检验的程序是否包含检验方法和抽样计划?		2			
5.12	If the reason or quantity for acceptable , rejected are kept ? 进料检验中, 对于接受和拒收的原因或数量是否被适当保存?	3				
5.13	If the inspected or un-inspected are isolated correctly? 对于已检验和未检验的产品是否被正确的放置以利区分?	3				
5.14	If the record of IQC included the quantity of rejected or accpted ,or the reason for rejected? IQC的记录是否包含接受和拒收的数量或原因?	3				
Attainec 30		21	6	3	0	0

6. Process Control		Rating				
		3	**2**	**1**	**0**	**N/A**
6.1	Are there work instructions defining the manner of production and installation for each process/station? 是否有操作说明书对每个制程/每站定义生产和安装的方法？			1		
6.2	Do the work instructions clearly specify the machines, equipment, tools, fixtures, and program to be used? 是否有操作说明书清楚地说明机器, 设备, 工具, 制具和程序使用方法？			1		

6.3	Do the work instructions specify the materials to be used? (e.g., part number/name, assembly tools, inspection tools) 是否有操作说明书详细说明要使用哪些材料或工具? (例: 料号/品名, 组装工具, 检验工具) ?			1		
6.4	Do the work instructions indicate assembly specifications and machine setting? (e.g., solder temp, torque driver setting, and adjustment/test specifications) 是否有操作说明书指示组装规格和机器设定(焊接温度， 扭力计的设定，调整，测试）？			1		
6.5	Are quality documents (e.g., QC-flow/work instructions) revision controlled and approved by authorized personnel prior to issue? 品质文件修订 (例: QC 流程/工作手冊)在发行前是否有经授权人员的控制和核准？	3				
6.6	Is the environment in the cleanroom controlled? 无尘室的环境是否控制?			1		
6.7	Is the disinfectant used for the cleanroon and workers controlled? 用于无尘室和工人消毒是否有控制?			1		
6.80	Are out-of-control conditions noted on inspection data, with causes investigated, and actions provided? 对于检测报告上超出规格情况, 是否有原因调查和提出对策?			1		
6.90	Is there any follow actions/verification for the corrective action taken? 对于采取的改善措施是否有跟踪确认?		2			
6.10	When a process goes out-of-control and produces nonconforming product, are triggers defined and documented for the purpose of initiating a stop build, or stop shipment action? 当制程无法控制或生产出不合规定产品时,对于停线或停止出货指示是否有明确定义和文件说明？				0	
6.11	Are requirements for preventive maintenance defined and documented for activities that can influence the product quality? 是否有预防和影响产品品质的活动文件的定义？		2			

6.12	Are records of these activities maintained? 活动记录是否有被保存.	3				
6.13	Is there a effective system to track the raw material? 是否有一个有效的系统对原材料进行跟踪?			1		
Attainec	18	6	4	8	0	0

7. Inspection and Testing / Status		Rating				
		3	**2**	**1**	**0**	**N/A**
7.1	Are there documented procedures for defining inspection and test methods? 是否有定义检验和测试方法的程序？	3				
7.2	Does the supplier ensure that incoming product is not used or processed until it has been inspected and verified as conforming to specified requirements? 供应商可确保进料之产品在未经检验或验证之前，不得加以使用或处理吗？	3				
7.3	Does the supplier inspect, test and identify product as required by the quality plan or documented procedures? 供应商是否依照品质计划或规章来检验、测试和鉴定产品？			1		
7.4	Does the supplier utilize outgoing product inspection and testing such as Out of Box Audits? 供应商有作出货检验和测试吗? 例如开箱检查		2			
7.5	Does the inspection and test process assure outgoing products meet the customers goals? 所做的检验和测试可保证量产产品之品质符合客户目标吗？			1		
7.6	Are there procedures that address product inspection and test status? 对产品检验与测试状态是否有一程序？	3				
7.7	Are there procedures and practices in place to assure product traceability through all stages of production? 是否有程序可保证其产品的可追溯性?	3				
7.8	Is the conformance or nonconformance of a product's inspection or test status identified? (by markings, tags, inspection records, test software, physical location, etc.) 在检验或测试阶段，对良品和不良品是否加以识别? (做记号、标签、检查记录、测试软体)				0	
7.9	Does the system assure only material that has passed specified inspections or tests is utilized or sold? 是否有系统可保证所使用或出售的材料已通过指定的检验与测试？		2			

7.10	Are there records which give evidence that the product has passed inspection and/or test with defined acceptance criteria? 是否有纪录可证明其产品已通过检验与测试，且依照既定的允收标准？			1		
Attainec 19		12	4	3	0	0

8. Final verification measurement		Rating				
		3	**2**	**1**	**0**	**N/A**
8.1	Is there a sufficient outgoing sampling plan to ensure the acceptability of finished goods meet customer requirements(eg., c=0)? 是否有一个合理的出货抽验计划来确保成品可以满足客户的需求?				0	
8.2	If inspection and testing procedure have fully identified the acceptable parameters and tolerance? 是否有识别可接受的参数和公差的检验和测试的程序?			1		
8.3	Does the supplier formally indicate inspection status of parts? 供应商是否对检验状态作了正式标示?			1		
8.4	Are controlled customer drawings/specifications readily available and used at Final Test? 受控的客户图纸和规格是否被用于最终检验中?	3				
8.5	If the sampling plan include the frequency, sampling size and acceptable standard? 抽样检验方法是否包括检验的频率，样本大小以及接受标准?				0	
8.6	If the inspection and testing standard are identified(by instruction, mark , test record, test software and so on)? 是否有检验和测试标准供识别参考？（如指导书，标示，测试报告，测试软件等）			1		
8.7	If the test items are fully recorded and kept for reference later? 为了便于后续参考，所有的检验是否被纪录和保存?	3				
8.8	Any reliability tests are needed? 是否有作过可靠性测试?		2			
Attainec 11		6	2	3	0	

9. Control of Nonconforming Product		Rating				
		3	**2**	**1**	**0**	**N/A**
9.1	Are there documented procedures for control of nonconforming material? 对不合格材料的控管是否有程序？	3				
9.2	Is failure analysis performed on product returned? 对被退回产品是否有执行失效分析？	3				
9.3	Is there a requirement to issue a correct Action sheet for RMA? RMA 是否有纠错报告?	3				

9.4	Is there a system to feedback failure analysis and action items to relevant departments (including mfg site)? 是否有回馈系统将失效分析与改善项目传递到相关部门(包含制造部)？		2			
9.5	Are the RMA records kept according to the defined retention period? RMA 纪录是否有定义保存期限？	3				
9.6	Is there a MRB procedure to review the disposition of nonconforming material? (e.g., "use as is", RTV, scrap, rework) 是否有 MRB 程序去审核不合格材料的处理方式？（如：正常使用，退回供应商，报废，返工）		2			
9.7	Are the criteria/guidelines for materials disposition defined? 材料之处理是否有标准/指导方针？			1		
9.80000	Is the responsibility and authority to review/approve disposition of nonconforming materials defined? (e.g., MRB roster) 不合格材料的处理审查 / 核准之责任与权责是否加以定义？			1		
9.9	Is there a requirement to issue a CAR for MRB materials? MRB 材料是否会发出纠正措施报告?		2			
9.10	Is action taken when progress/implementation of improvement actions is not satisfactory? 当改善的过程或結果不令人满意时会采取其他方案吗？		2			
9.11	Are all corrective actions and results documented? 所有改善方案与結果是否文件化？	3				
9.12	Are all necessary details included in the corrective action request? (P/N, lot #, inspection date, lot size, sample size, reject qty, etc.) 改善行动方案是否包含详细资料？(料号、批号、检验日期、检验批量、检验数量、退货数量...等)	3				
9.13	Does the corrective action request include short term/preventive action? 改善行动方案是否包含短期与预防性行动？			1		
9.14	Does the corrective action request include long term/root cause action? If defect is supplier related, is there any system to feedback to IQC for actions? 改善行动方案是否包含长期/主要原因的对策？若问题与厂商有关，是否有一机制回馈到IQC?		2			
9.15	Is there a system to track status of corrective action requests? 改善行动方案是否有追踪系统？			1		

9.16	Are the contents of the responses/corrective actions appropriate to prevent future occurrences? 改善行动方案內容是否能防止未来不再发生？				0	
9.17	Are corrective actions monitored for effectiveness in preventing similar nonconformance? 为了有效的预防相同问题发生其改善行动是否加以监测？			1		
Attainec 33		18	10	5	0	

10. Calibration		Rating				
		3	**2**	**1**	**0**	**N/A**
10.1	Are there documented procedures for control of inspection, measuring and test equipment? 对仪器的检验、测量与测试是否有一作业程序？	3				
10.2	Is equipment verified or re-calibrated at appropriate intervals? 仪器设备的验证或校正是否于适当的期间执行校正？			1		
10.3	Is there an official approval control system for all equipment to determine accuracy and precision? 对所有仪器设备的准确度与精密度是否有一控管系统？				0	
10.4	Are devices that are exempt from inspection clearly marked as such? 对免校验的仪器是否有清楚的标示？				0	
10.5	Are the reference devices (standard equipment) used for base-point calibrations (0 point, maker's scale, etc.) correctly stored, managed and calibrated to national standards? 仪器校验之标准件是否正确地储存,管理与校验？					NA
10.6	Is an appropriate method set up for storing measuring equipment, tools, and jigs? 仪器设备、工具之储存是否有一适当的方法？	3				
10.7	Are measuring and test equipment re-calibrated when found not meeting the requirement? 测量与测试设备当发现未符合校验规格时是否有重新再校验？	3				
10.8	Is there a process for dispositioning product that has been built/tested with equipment found to be out of calibration? 当发现仪器已超过校验周期是否有一处理产品的程序？				0	
Attainec 10		9	0	1	0	

11. Handling, Storage, Packaging, and Delivery		Rating				
		3	**2**	**1**	**0**	**N/A**
11.1	Are there procedures for handling, storing, packaging and delivery of product? 对产品搬运,储存, 包装与交货是否有一作业程序？	3				
11.2	Are the material control records maintained per the procedures defined? 材料控制纪录之维护是否加以定义？	3				
11.3	Does the supplier provide methods and means of handling that prevent damage or deterioration? 供应商是否提供产品搬运方法以预防损伤或变质？	3				

11.4	Are flammable, corrosive, and toxic materials properly stored and segregated? 对可然性的、腐蚀性的与有毒性的材料是否适当的储存与隔离?			1		
11.5	Does the supplier provide secure storage areas to prevent damage or deterioration of product, pending use or delivery? 供应商是否提供安全的储存区域以避免产品在待用或交货期间损伤或变质？		2			
11.6	Are temperature and humidity monitored in these storage areas on a regular basis? 储存区域之温度与湿度是否加以监测？				0	
11.7	Is the condition of product in stock assessed at appropriate intervals in order to detect deterioration? 对库存品之状况是否于适当的期间加以评估以发现变质的产品?				0	
11.8	Does the supplier control packing, preservation and marking processes to ensure conformance to specified requirements? 为了确保产品符合指定需求，对包装、保存与标识之流程是否加以控制？	3				
11.9	Is there an arrangement for the protection of the quality of product after final inspection and test? 产品最终的检验与测试后,供应商对其品质是否加以防护？	3				
11.10	Are the materials issued according to FIFO? 材料的发放是否依照先进先出管制？	3				
11.11	If the valid date are checked for some special materials? 对于一些特殊材料是否对其有效期加以确认?				0	
11.12	If the stock is contorlled to prevent material are taken but no permission? 是否库存有被管制防止材料未经许可就被领用?	3				
11.13	Are there procedures defining product identification requirements for all products? 有程序定义对所有产品识别的需求吗?				0	
11.14	Are in-stock and in-process materials properly identified and controlled? 库存原材料和在制原材料都被适当地识别和控制吗?	3				
11.15	Where traceability is a specified requirement, do individual products or batches have a unique identification? 如有特别要求其产品的追溯性时，对其产品或者批号有作唯一的识别吗?	3				
11.16	Are properly marked and tracked through the process to ensure no steps in the process flow are missed? 是否在制程中有标示和追溯信息来确保在生产流程没有步骤被遗漏?			1		
Attainec 31		27	2	2	0	

12. Training		Rating				
		3	**2**	**1**	**0**	**N/A**
12.1	Is there a system that identifies training requirements for all personnel affecting the quality of the product? 是否有系统定义对影响产品质量的所有人员进行培训的需求?	3				

12.2	Does a system exist for determining which personnel are qualified for a job function? 是否有系统定义哪些人员具有上岗资格?	3				
12.3	Is there a system to disqualify and re-qualify personnel in a job function? 是否有定义取消上岗资格和重新获得上岗资格的系统?				0	
12.4	Are accurate training records maintained? 准确的培训纪录是否被保持?	3				
12.5	Is there any key job station and the job qualification distinguished ? 是否有针对一些关键的工作站和工作条件加以区分定义?					N/A

Attainec 9	9	0	0	0	

Supplier should provide following, as to set up the supplier database:

Quality Manual
Organization chart/Head count
Measure Instruments List(with preci
Certification
Key Customers/Suppliers List
Product Management Plan (PMP)
Key Employee Training Plan(Quality

Remarks
The supplier received ISO13485 qualification on March 11, 2015. Yes, the supplier defined their quality policy, objectives and commitments in the Quality Manual JDCA-02/0-2014. Yes, the registration scope covers the entire manufacturing facility.
The Incoming Inspection Procedure, Outgoing Inspection Procedure, Contract Review Procedure and Engineering Change Notification Procedure are missing.
Yes, the supplier does, it can be found in the quality manual, organization charts, written procedures, etc.
The management representative is appointed in the qualtiy manual.
For the customer's product: Work Instruction JK18/100 Inspection Card JK18/02 Process Flow Chart JK25-05 The detailed processes, materials and tools used during the assembly and other processes are missing.
There have WI for each station, however they are not available for all personnel. The WI are kept in a cabinet.
The supplier conducts a management review once a year and normally in January after the second internal audit.
Two years

The inspection content and inspected quantity are not clearly defined in all of the inspection reports. We couldn’t determine which dimensions were inspected, the quantiry inspcected, and etc.
Yes, the supplier carried out an internal audit and management review, however some of the corrective actions for the non-conforming items found then have not yet been corrected.

Twice a year, the first in June and the second in December.
There have twelve non-conforming items in June and eight in December.
The supplier needs to improve on the inspection data collection method, which was not recorded accurately. This is needed to improve quality, as the inspection content and quantity are not clearly defined in all of the inspection reports.
Some of the corrective actions are not valid and reasonable and the verification methodsdon't have true meaning. For example, for foreign matter, the corrective action is to clean the table, but the cleaning method and frequency are not defined, nor confirmation if the table is clean or not.

There isn't a procedure, but the supplier conducted a contract review for the sales order to verify the product procedures.
No procedures in place.
For the leakage issue, the supplier hasn't resolved it until October 25, 2017.
For the customer's product, the supplier doesn't currently meet the leakage requirementand and needs to improve on that aspect.
The supplier set up WI, inspection card and flow chart etc. for the customer's product: Work Instruction JK18/100 Inspection Card JK18/02 Flow Chart JK25-05

Some of the WI are kept in the cabinet, not applied to the work station.
Old and newly approved vendor list are mixed together.
The SOP for some of the test equipment have not been reviewed and approved.
No procedure.
No procedure.
No procedure.
No procedure.

No procedure.
There is no relevant procedure in place to ensure and record that engineeirng changes are checked, distributed and implemented. These processes are in place for the customer's product.
No procedure.

Purchasing Control Procedure, JDCB02011
The supplier has an audit template for the subcontractors, however it contained only basic company information. It doesn't include any quality evaluation.
No date shown on it, not sure if it is the latest version.
The supplier only tested the samples and if they pass, then three episodes of mass production are initiated. If the parts pass again, then the subcontractors are considered as qualified. No on-site quality evaluation is carried out before working with them.
No delivery requirement shown on the order.

No Procedure.
The supplier conducted a FAI, but the inspection contents are not clearly defined. We couldn't determine which dimensions were inspected, quantity, etc.
Traceability Control Procedure JDCB02018 The supplier controls FIFO from the material card.
For the cap, dimension is one of the key elements, however it isn't controlled in the inspection method.

For the customer's product, there is no detailed assembly process defined in their work instructions. There is no WI for entering the clean room and hand disinfecting.
For the customer's product, there are no equipment, tools, fixture, etc. defined in the WI.

For the customer's product, the components, silicone oil andinspection tools are not clearly defined in WI.
The functional and appearance specifications are not defined in the WI.
There is no record for the pressure differential between the cleanroom and outdoors. The recording requirement as defined in their WI for this metric is not reasonable (once per month) and should be recorded daily. There is no record for bacteria quantity. The temperature and humidity on October 25th was not checked and recorded before manufacturing. There is no record for hand disinfecting on Oct 25th, however the supplier carried out work during this period of time.
Based on the supplier's documents, the two disinfectants used for the cleanroom and workers should be changed every other month to avoid drug resistance, but they don't follow this procedure.
1.The dimensions shown in the supplier's reports are out of range, however the parts were passed. 2.There was an investigation and actions provided only after requested by the customer.
There is no data to prove that the foreign matter issue has been resolved.
No triggers defined and documented for that aspect.
The supplier has Preventive Control Procedure JDCB02029, but no FMEA.

Since the material for the customer's product is special and different from the supplier's common material, they can track it. For the common materials used for their standard products, there is no traceability.

Remarks
Incoming Quality Inspection Control Criteria,JK104
1.Warehouse Management Rule, JDCG/01/00-002 The supplier defines the different locations with the marks for the inspected and uninspected material. 2.Quality Management Rule, JDCG/01/00-013
The supplier hasn't an Outgoing Inspection Control Procedure.
For the customer's product, the supplier has provided an outgoing product inspection report for the customer. The dimensions failed but the result showed a pass.
For piston part, the dimension should be considered a key point to be controlled, but it is not. For barrel, some inspected dimensions fail to meet the specification, but the results still show a pass.
Quality Management Rule, JDCG/01/00-013
Product Traceability Control Procedure,JDCB02018
No marking for that.
The supplier has incoming and in-process control, but no outgoing process control.

For the customer's product, the supplier has provided outgoing product inspection reports to the customer displaying failed dimensions, but the result still show a pass.

Remarks
No out going sampling plan.
There is no inspection and testing procedure, but the supplier inspect the product based on the customer's requirement.
No marking for that, but the supplier used different locations to distinguish the inspection status.
For the customer's product, the controlled customer drawing is used to check their product.
No outgoing sampling plan
The supplier only has the inspection reports.
There is no high-low temperature and aging test, which should be required for the customer's product, to be discussed with the customer.

Remarks
Nonconforming Products Control Procedure,JDCB02024
The supplier performed failure analysis on the returned products.

The supplier held a meeting with the relevant departments to review failure analysis and action items for the customer's product and feedback, however there is no record for that.
Document/Record Control Procedure,JDCB02002 (two years) For Lot No.161216 product,the report number is JDCCRJ12005,
There is a MRB procedure, but no detailed method is included to define how to deal with them.
Only described as team review.
Based on the supplier's doucments, all decisions should be made by the QC department.
For the nonconforming material returned by the customer, the CAR is provided to the customer by the supplier. There is no requirment to publish a CAR.
For the product dimension improvement, even the supplier took the different action including mold modification and molding parameter adjustment etc. to improve it, but there still have problems.
For Lot No.161216 syringe, the corrective actions and results are shown in the report (report number:JDCCRJ12005).
No short term or preventive action shown in the corrective action plan.
For the defects related the subcontractor, the supplier simply informed their IQC, without suppporting records. As a result, we're not sure that all of the problems were clearly presented.
1.No tracking for the corrective action for the problem of the customer's product is in the supplier's report. 2. There is tracking for the corrective action for the non-conforming items found during the internal audit, the supplier were implemented and verified.

There were no preventive actions included in the corrective actions.
1.There is no record for monitoring the effectiveness for the quality issues that occurred during the manufacturing process. 2.For the internal audit, the supplier monitors the effectiveness for the corrective actions, but the method to monitor effectiveness is not correct. For example, foreign matter: to monitor if the corrective action results to determine if there has been defect rate decrease; and their method is to confirm if the table is clean or not.

Remarks
Inspection Equipment Management Rule,JDCG/01/0014 Inspection Equipment Maintenance Rule,JDCG/01/0015
The equipment which should be calibrated in August of 2017 hasn't been calibrated.
The supplier hasn't a MSA system.
The supplier uses tape measure and ruler which are considered exempt devices, however they are not marked as such.
no self-calibrated devices.
Inspection Equipment Management Rule,JDCG/01/0014 Inspection Equipment Maintenance Rule,JDCG/01/0015
No procedure or process to define this.

Remarks
Warehouse Management Rule,JDCG/01/00-002
Raw material card.

Alcohol, Ethyl acetate, Dilutent and other flammable materials are kept in a separate room, however they are not segregated from each other and the environment is not controlled.
The raw materials and finished goods are in same warehouse, no temperature and humidity control for that area.
No monitoring of this.
No assessment.
No valid control for Alcohol, Ethyl acetate, ink etc.
Warehouse Management Rule,JDCG/01/00-002 ERP system.
No procedures to define product identification requirement.
There is a process card to show the part name and the quantity, but no tracking to determine if any process is missing.

Human Resources Control Procedure,JDCB02005

The supplier has a document defining that element, however there is no evidence that is used.
The training record is until October 2017.

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No.	Process	Problem Description	Eval.
1	Quality System Management & Final verification measurement & Document Control & Contract Review	No procedure for Incoming Inspection, Outgoing Inspection, Contract Review and Engineering Change Notification.	D
2	Quality System Management &Process Control	The Work Instruction for the customer's product is not correct and complete, no detail process, material and tool etc. used defined during the assembly.	D
3	Quality System Management	There are many documents which are not belong to WI included in the WI list, for example risk management report and evaluation reports which should be removed.	D
4	Quality System Management	There have WIs for each station, but are kept in the cabinet.	M
5	Quality System Management&Supplier qulification & incoming control	1.The inspection content and inspected quantity are not clearly defined in all inspection reports, we don't know which dimension are inspected and the inspected quantity etc. 2.There only have part name shown in the report which can't be considered as sole identification for each product, need to add part number in all the inspection reports.	D
6	Internal Audit	Some of the corrective actions for the non-conforming items found during the internal audit are not correct and reasonable and the verification for those elements are not relevant. For example, for the foreign matter issue, the corrective action was to clean the table, but how to clean and the frequency of the cleaning were not defined, nor building in a verification that the table was cleaned.	D
7	Document Control	Old and new approved vendors list are melded together.	D

8	Document Control	The SOP for some of the testing equipment used in the laboratory was not reviewed or approved.	**D**
9	Supplier qulification & incoming control	The supplier utilizes an audit template for their subcontractors, however it lists only basic company information not including any quality evaluation.	**D**
10	Supplier qulification & incoming control	The supplier test only pre-production samples and if they pass, three mass production events are triggered. If the production passes again, then the subcontractors are considered as qualified. No on site quality evaluation is carried out prior to authorizing volume production.	**D**
11	Supplier qulification & incoming control	No Part Qualification Procedure is utilized.	**D**
12	Supplier qulification & incoming control	For the cap, the dimension is one of the key points, however it isn't controlled through the inspection method.	**D**
13	Process Control	There is no record for pressure difference between the cleanroom and outdoor. The recording requirement of once per month as defined in their WI is inadequate. It should be monitored and recorded daily. There is no record for bacteria quantity. The temperature and humidity on October 25th was not checked and recorded before initiating manufacturing. There is no record for hand disinfecting on October 25th, however production was conducted during this period of time.	**D**
14	Process Control	Based on the supplier's documents, the two disinfectants used for the cleanroom and the workers should be changed every other month to avoid drug resistance. They do not follow this guideline.	**D**
15	Process Control	The supplier recorded the date that the the disinfectant is mixed, however there is no record for the length of time that it is used.	**D**
16	Process Control	1.The dimensions shown in the supplier's report are out of specification, but the parts were passed nonetheless. 2.The supplier's internal nvestigation and corrective action were provided to the customer only after their request.	**D**

17	Process Control	No triggers defined and documented for initiating a stop build or stop shipment action.	**D**
18	Process Control	There is no traceability from raw material to the finished products. There is also no traceability to ensure that individual processes were not missed during production.	**D**
19	Inspection and Testing / Status	There was no marking for conforming and non-conforming products.	**D**
20	Inspection and Testing / Status	The specification didn't match the production results. The date showed that the parts were out of tolerance, but the results showed a pass.	**D**
21	Final verification measurement	There is no upper/lower temperature and aging test, which is required for the customer's product.	**D**
22	Control of Nonconforming Product	There is no system to review and provide feedback of the failure analysis and action items.	**D**
23	Control of Nonconforming Product	There were no preventive actions included in the corrective action report, no tracking and no monitoring for the effectiveness of the recommended changes.	**D**
24	Calibration	The supplier hasn't a MSA system to determine accuracy and precision for all testing equipment.	**D**
25	Calibration	There is no marking for the devices that are exempt from inspection.	**D**
26	Handling, Storage, Packaging, and Delivery	The flammable, corrosive, and toxic materials are not segregated from one another other and the environment is not controlled.	**D**

27	Handling, Storage, Packaging, and Delivery	The temperature and humidity are not monitored in the storage areas.	**D**
28	Handling, Storage, Packaging, and Delivery	The condition of product in stock is not assessed at appropriate intervals in order to detect deterioration.	**D**
29	Handling, Storage, Packaging, and Delivery	The validity for Alcohol, Ethyl acetate, ink and etc. is not monitored.	**D**
30	Handling, Storage, Packaging, and Delivery	There is no procedure defining product identification requirements for all products.	**D**
31	Handling, Storage, Packaging, and Delivery	There is no marking or tracking through the process to ensure that no steps in the process flow were missed.	**D**
32	Training	The supplier has a document used to disqualify and re-qualify personnel in a job function, however there is no evidence that is used.	**D**

Notes: D- defect,needs action immediately; M- minor defect,needs improvement;S- Suggestion, may do better.

Signature of Supplier:

.IER AUDIT CORRECTIVE ACTION PLAN

Record by : Eva Hu&Hill Miao
Date: Oct 26, 2017

Root Cause Analysis	Corrective Action	Owner	Due time	Follow up	Target Date Closed ?

Signature of Eastbridge Business Service (SIP) CO,.LTD