PROQC INTERNATIONAL

Global Quality Control and Engineering Solutions

GMP Audit Report

** Example Report **

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PRO QC INTERNATIONAL	GMP Audit Report	Rev.
	SUMMARY	0

Supplier Name	Audit Date	Report No.
xxx	xx-xx-xxxx	xxx

SUPPLIER'S INFORMATION	CLIENT'S INFORMATION
NAME :	NAME :
ADDRESS :	ADDRESS :
CITY :	CITY :
COUNTRY :	COUNTRY :
PHONE :	PHONE :
FAX :	FAX :

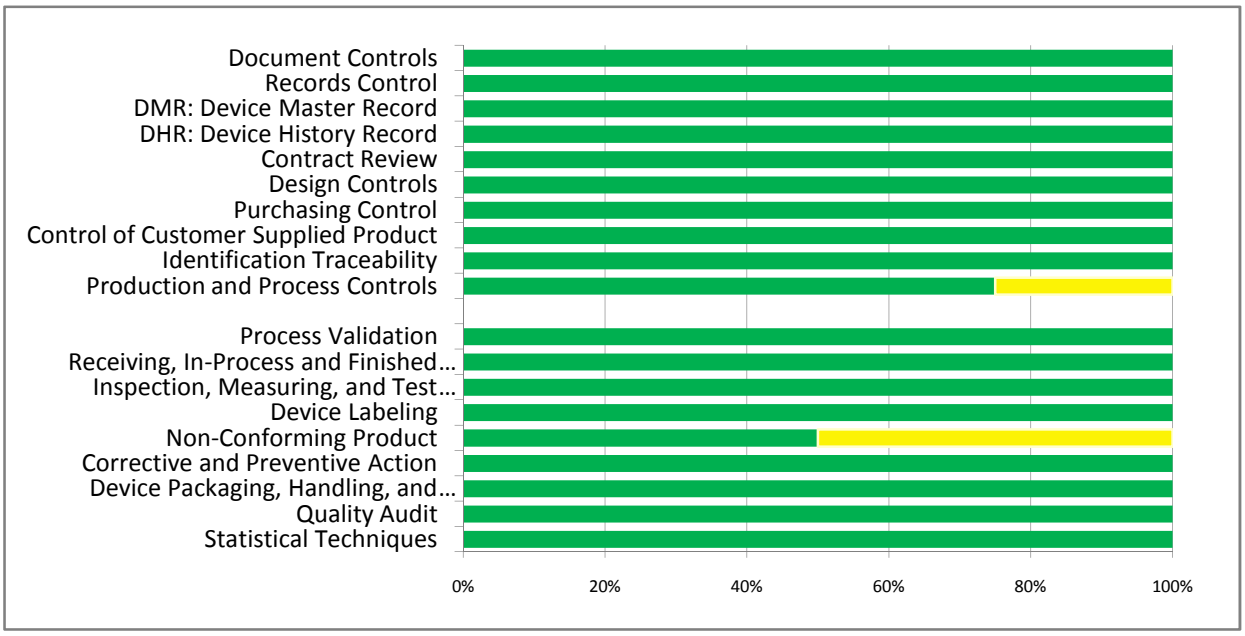
SUPPLIER'S PERSONNEL PARTICIPATING

Mr./Mrs.	Title:	Email:
Mr./Mrs.	Title:	Email:
Mr./Mrs.	Title:	Email:
Mr./Mrs.	Title:	Email:

Pro QC PERSONNEL

Mr./Mrs.	Title:
Mr./Mrs.	Title:

AUDIT RESULTS



JUDGMENT & RECOMMENDATIONS

- ☐ **Passed - T**he QMS is effective; you could use this supplier as a reliable business partner.
- ☑ **Passed - T**he QMS is acceptable with minor ncf (see **Audit Report**); you could use this supplier as a reliable business partner, but keep pushing them for improvement to reduce risk.
- ☐ **On-Hold** - The QMS presents few major ncf (see **Audit Report**); you could request them to provide a CAPA before you engage in any business.
- ☐ **Failed - T**he QMS presents serious major ncf (see **Audit Report**) that could impact your your business. The better solution is to source from another supplier.

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Scope of Audit:

The intent of conducting a quality system audit based on QSR 820 requirements is to provide the client with information useful for making an initial assessment regarding business viability and reducing their sourcing risks.

Summary/Recommendation:

The audited factory has XX production sites on a total land of XXXXXXX square meters. Production areas are distributed among XX different workshops / buildings, including a 100000 Class Room of XXXXX square meters at the workshop A11 where the product XXXXXXXXXX will be produced.

The factories also have a ETO Sterilization Chamber under a different business license. XXX% of product to USA market is sterilized here. Products are sent to those chambers under a sub-contract external service. The audited factory maintains record of process validation of those chambers, including production record linked to DHR files.

The factory has ~XXX workers, but with around X or less focused in the production of XXXXXXX. The factory is certified to ISO 13485 and CE, Registered to FDA and compliant to GMP.

DMR files are maintained for project developed and fully compliant to the requirement of 820.181.

DHR files are maintained per lot produced, with all records of IQC, IPQC, FQC both in product are process, training of operators, environmental check…etc, fully compliant to 820.184.

Traceability in product and related records is reliable, even that it is manually controlled. However, the factory should make more effort to ensure the space limitation in the last step of packaging to avoid not affecting proper identification and traceability of packaging boxes.

We also recommended the factory maintain a cleanliness schedule visible on-site on a daily basis. Same recommendation will apply to the environmental check plan and record.

Strengths:

1) Certified to ISO 13485, CE, registered to FDA with quality management fully documented.
2) Have a dedicated personnel to ensure conformity to requirements related to medical devices.
3) Very large manufacturing center with 11 workshops in the same place.

Opportunities for Improvement:

1) Should manage sufficient space at the packaging area to ensure proper position and identification of packaging material.
2) Should keep a record of cleanliness, as well as record of environment control up-to-date and readily available on site, with the purpose to enhance employees in their effort to ensure compliance in this aspect.

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C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRES / EVIDENCES	FINDINGS	SCORE
1	**Quality System (ISO 4.1, 4.2, 5.1, 5.3, 5.5 / QSR 820.5, 820.20)**		
1.1	Is there evidence that the quality policy is understood by all personnel? Public posted, record of training, etc.	The quality policy is written in page 23 of Quality Manual (XXXXXXX) which was approved and published in xxxx-04-11. In addition to regular training, the same content of the quality policy is posted at various place of workshop, including in the employee ID card.	C
1.2	Is an organizational chart documented and accurate?	Yes, the organization chart is accurate and documented in the 13th page of the Quality Manual (XXXXXXX). See photo #8.	C
1.3	Are responsibility & authorities defined?	Yes, responsibilities / authorities are detailed in the 17th page of Quality Manual (XXXXXXX), See photo #9.	C
1.4	Is there a person nominated as Management Representative? Is the nomination in written and approved by company authorities?	Mr. XXXXXXX is nominated as Management Representative since xxxx, with nomination letter attached to Quality Manual in page 4. See photo #10.	C
1.5	Is a Management Review conducted on regular basis? Are records of the last management meeting available?	The management review is conducted following the procedure (XXXXXXX), record of last management review meeting conducted in Jan 15th , xxxx are available as following: - Management review plan in form XXXXXXX - Record of opening meeting in form XXXXXXX - Report of management review XXXXXXX	C
1.6	Are required Quality System procedures developed and up-to-date?	Yes, the factory has developed 41 procedures as guidance to compliant to requirements of ISO 13484, FDA 21 CFR 820, MDR etc. Theses procedures are listed in the annex of page 58 and 59 of the Quality Manual. See photo #6.	C
2	**Personnel (ISO 6.2.2 / QSR 820.25)**		
2.1	Are training needs identified, planned and completed? Are traning records available?	Yes, training is conducted according to the procedure (XXXXXXX). Training plan of year xxxx is documented. See photo #11. It includes few training records been implemented saved in the sheet# XXXXXXX. For example, training code # XXXXXXX conducted in xxxx-06-15 about requirement of ISO 13485 / YY0287 / QSR 820. See photo #12.	C
2.2	Do qualified people who need a CV have one?	All Internal Auditors have CV, including people working on site.	C
3	**Document Controls (ISO 4.2.3 / QSR 820.40)**		
3.1	Is there a system or procedure to organize the edit, update, revision, distribution of quality system documents?	Yes, documents are controlled according to the procedure (XXXXXXX).	C

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3.2	Are up-to-date or current revisions of SOP's and data sheets used on site?.	Any change in documents are required to be applied in form (XXXXXXX) with record of others documents to be affected by the change, then submit to the original person who created the document for approval. See photo #13.	C
3.3	Is there a Master list of document under control showing change status?	The factory maintains up-to-date a master list of all documents, including title, doc# and status of current revision.	C
3.4	SOP's are up-to-date? Cross check with SOP on site.	Reviewed onsite work instruction at the Injection process: - Work Instruction (XXXXXXX) on machine ##### - Work Instruction (XXXXXXX)	C
3.5	Are technicians familiar with the SOPs that affect quality?	Operators are familiar with SOPs.	C
4	**Records Control (ISO 4.2.4 / QSR 820.180)**		
4.1	Are records stored properly?	Yes, records are controlled according to the procedure (XXXXXXX).	C
4.2	Is restricted access practiced?	Production record is saved to the central place per each PO, together with all DHR files involved. The central place is maintained by the responsible of compliance.	C
4.3	Check log books, notebooks, binders, folders, cross-documentation practices (cross-outs, whiteouts, white-out, etc.)	Records are properly identified with folders, cross-referenced when needed. During the audit, it only takes them around 1 to 2mns to get the record the auditor needed.	C
5	**DMR: Device Master Record (QSR 820.181)**		
5.1	Are device specifications included in the DMR?	Yes, device specification are documented in the file #######, see photo#14. It includes: - Product drawing ####### - Packaging list and requirements - Label printing requirement for small / external carton box. - Manual printing	C
5.2	Are all SOP's for production in the DMR.	Yes, all SOPs for the production are documented in the file (XXXXXXX).	C
5.3	Are inspections, labels, and tags identified?	Yes, inspection instructions are defined in the file (XXXXXXX) . Label, tags requirements are documented in the file (XXXXXXX) . List of inspection equipment to use are listed in the file (XXXXXXX).	C

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18	**Non-Conforming Product (NCP)**		
18.1	Is rejected product properly labeled, and or quarantined?	Yes, NCP are identified, by isolation in red boxes as indicated in the procedure (XXXXXXX) . Every machine at Injection workshop, at the welding process room, and packaging has Red boxes available to store NCP, see photo #31. Red boxes are located around blues boxes in which GOOD parts should be putted. There is opportunity to mix parts.	I
18.2	Has NCP been properly evaluated?	All NCP will be collected in daily basis, and categorized to each type of defect, such injection, welding process etc; this data will be use for root cause evaluation as required in the procedure (XXXXXXX) .	C
19	**Corrective and Preventive Action (QSR 820.100)**		
19.1	Check log sheets to ensure out of specification (OOS) temperatures have a CAR.	The CAPA is conducted as per procedure (XXXXXXX), the factory maintains a list of 34 CAPAs, which include NCF issues from internal audit, on site observation such as process parameter deviation, NCP, client's complaint.	C
19.2	Check CAR log to see if the department has any CAR's that are not resolved.	Each CAPA has number, responsible department in charge for investigation or root cause, and corrective action and preventive action written a separate CAPA report.	C
19.3	Check corrective actions for effectiveness.	Basically all CAPA are effective and closed, for example of CAPA # 4C6161212CO.	C
20	Device Packaging, Handling, and Storage Distribution (QSR 820.130, 820.140. 820.150, 820.160)		
20.1	Are sterile items stored to prevent contamination?	Yes, sterile items are maintained and stored at the sterilization work place, totally separated to others product that are in workshop A4, as required in the procedure (XXXXXXX)	C
20.2	Is media that is supposed to be stored in the dark, stored properly?	No such requirement for the audited factory, no media product	C
20.3	Are accepted raw materials and test articles kept separate from product that has not been accepted?	Yes, accepted materials are identified and kept separate.	C
20.4	Look for documentation demonstrating customer's original requirements were met.	The file DMR and DHR of product ###### under lot#####A provide enough evidence demonstrating compliance to customer's original requirement.	C
21	**Quality Audit (QSR 820.22)**		
21.1	Is there a procedure as guidance for the execution of internal audit? Is it conducted on a regular basis?	Yes, the audit is conducted at least once per year. The last internal audit was planned and conducted between xxxx -08-16 ~ xxx-08-25, according to the procedure (XXXXXXX) .	C

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21.2	Does the factory has qualified internal auditors? Do they execute the internal audit independently?	Yes, 5 independent Internal auditor (Mr. YYYY # 07 1355, Mr. ZZZZZ # 05 706) attended to this internal audit, all certified to ISO 13485 and MDD 93/42/EEC.	C
21.3	Is the scope of internal audit documented amd cover all element of ISO 13485, QSR 820, including MDD?	The scope covers requirement of ISO 13485, 21 CFR 820 as written in the audit plan sheet (XXXXXXX) .	C
21.4	Are findings of audit identified and corrective action from previous audit completed?	Minor NCF were found specifically in the issue affecting requirement and safety, and which required to update document (XXXXXXX) , (XXXXXXX) about rules to enforce in the laboratory, training were provided to 4 members working in the laboratory as evidence of correction.	C
	Statistical Techniques (QSR 820.200)		
22.1	Are there any requirements for statistical techniques?	Requirement for statistical techniques are defined in the procedure (XXXXXXX) , and mainly applied to define proper sample plan and acceptance AQL during incoming Inspection (IQC), In-process Inspection (IPQC) and Final Inspection (FQC).	C
22.2	Statistical techniques can be found in: - Customer specifications - SOP's - Reference Standards - Acceptance Criteria (i.e. sampling plan)	Every inspection work instruction has defined statistic method to use and the number of sample randomly (ie. GB2828) selected is mentioned in the record. Statistic methods are used to categorize failure and calculate defect rate in monthly basis.	C

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INSERT PHOTO HERE	INSERT PHOTO HERE
Photo 1: Main Gate	Photo 2: External View of Workshop
Photo 3: Record of Opening / Closing Meeting	Photo 4: Integrity Declaration
INSERT PHOTO HERE	INSERT PHOTO HERE

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Photo 5: Documentation (Procedure, QM)	Photo 6: List of 41 procedures
Photo 7: Record of cument change / distribution	Photo 8: Organization Chart

INSERT PHOTO HERE
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INSERT PHOTO HERE	INSERT PHOTO HERE
Photo 31: NCF stored in red boxes	Photo 32:
INSERT PHOTO HERE	INSERT PHOTO HERE
Photo 32: Performance of FQC	Photo 32: Customer Complaint
INSERT PHOTO HERE	NO PHOTO
Photo 32: Supplier Performance	

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