Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

Title: Distributor Auditing Checklist

Authoring Group: Work Group 6, Quality Management System: Audit & Assessment

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Chair, Working Group 6

Note: Print 2nd page onwards for use

Distributor Name:	Address & Contact:
Auditee name & contact:	Auditor name and contact:

Sl#	Category	Auditable Item	Compliance Status	Remarks
1	7.0 General requirements for auditing organizations			
2	7.1 Legal responsibility	Entity registration with country authority(s), where required		
		Legal agreement with the manufacturer with agreed terms, conditions, liabilities and clear responsibilities		
		Power Of Attorney/ Legal manufacturer/ Authorised Representative/ Reselling/ Repackaging responsibility		
		Foreign trade and also Foreign trade agreements between local and other outside countries		
		Register with the Ministry of Trade and Commerce and acquire Importer/ Exporter Code before starting with the business License by competent authority(s) to run the business		
		Be aware about the notifications issued by Ministry of Trade and Commerce/ Competent Authority related to imports/ Exports		
		Be aware of Import duties/ Bill of Entry/ Green Channel facility/ AntiDumping, etc		
		All relevant/ applicable regulatory approvals, Export controls, etc in the country to place product in that market		
		identify the legal formalities involved in trading of various classified items (free trade/ restricted/ Prohibited/ licensed/ regulated/ samples, etc) in both the countries and also the integrity of the overseas Manufacturer		
3	7.2 Independence and impartiality	Compliance to local laws/ regulations, being impartial, managing conflict of interests due to Multi-manufacturer/ competitor products/ any other sources creating conflict of interests		
4	7.2.1 Management of impartiality			
5	7.3 Confidentiality, due professional care and code of ethics	• Compliance wrt ethical conduct of business, preventing market monopoly, pricing, ensuring complete confidentiality and required care towards products • Ensure utmost privacy and security of all relevant documents/ records		
6	7.3.1 Management of confidentiality			

Sl#	Category	Auditable Item	Compliance Status	Remarks
7	7.4 Liability and financing	Clear alignment, liabilities and any other obligations shall be documented. The compliance, documentation/ records and practices shall not be compromised due to commercial/ financial/ any other pressures		
8	8.0 Management	Overall linkage to the manufacturer's organisation		
9	8.1 Structural requirements	• Structural alignment with the manufacturing organisation with clear roles and responsibilities, also to address the local laws and regulations • Customer helpdesk and contacts shared with end users		
10	8.2 Quality management system	• Certification to ISO 9001 • Maintaining all relevant communications/ documents/ record evidences & in local language where necessary, for the period defined in QMS and/ or as required by the local regulation • Retention policy and retention method • Disposal method after retention period/ obsolescence of document/ record • IT data backup and recovery • End customer trace and batch record		
		• Conformance to applicable procedures wrt manufacturer's Business ethics/ principles/ Policy & QMS • Inclusion of 3rd parties in Quality Manual/ approved list • Customer focus, • Sales & distribution • Maintain status across Packaging/ handling/ storage, preservation, installation/ commissioning/ servicing/ maintenance • Spare parts management • Training & Monitoring • Labelling & packaging • Field corrections • Handling recalls • Hold shipment • Advisory Notice • Adverse Event Reporting • Medical Device Reporting • Customer complaints and feedback to manufacturer (pricing/ market/ product/ competition, etc) • Investigations, CAPA & audit findings disposition		
		Participate in periodic manufacturer audits		
		Handling customer property, Non-conforming product(s), deviations, field corrections/ upgrades, etc		

Sl#	Category	Auditable Item	Compliance Status	Remarks
11	8.3 Consistency	The approach and depth of audit depends on the contract scope/ terms and applicable QMS		
12	9.0 Resources	Resources with relevant qualifications, Product/statutory/ regulations/ laws knowledge, skill and competency shall be made available		
13	9.1 Resources			
14	9.2 Audit team competence	Training matrix, training records, skill matrix, competency profiling		
15	9.3 Outsourcing	Activities under the scope of agreement including roles/ responsibilities when outsourced to 3rd parties		
16	10.0 Audit Process	Participate in internal/ external audits arranged by manufacturer and certification body/ notified body/ competent authority		
17	10.1 Audit objectives and scope	The objectives & scope of audit as relevant / defined by the Distributor		
18	10.2 Types of audits	Identify and apply the right audit type		
19	10.4 Roles, responsibilities and authorities	As per contractual terms and applicable QMS/ regulations/ statutory/ laws		
20	10.5 Audit team composition	Audit Plan		
21	10.6 Audit activities	Availability of audit plan & report, action on the relevant disposition sections of the audit report, retention mechanism and storage period of audit records		
22	10.7 Adequacy of audit documentation	Maintain all applicable QMS and audit documentation and make it available to regulatory authorities when required		
23	10.8 Follow-up activities	Participate in disposition of audit findings and support in any followup actions		

Summary of the audit:
Audit conclusions:

Signed by:
Name , desgination