

MDSAP – Purchasing Process

The Medical Device Single Audit Program, MDSAP, evaluates companies on their compliance to requirements based on ISO 13485:2016 and national regulations. An MDSAP audit looks at seven processes. This article deals with the Purchasing process in Chapter 7 of the Audit Model.

Purpose

The Purchasing process audit verifies that the manufacturer's processes ensure that products conform to the purchasing requirements including any quality management system requirements. Supplier include product providers that are outside the manufacturer's organization. This includes corporate functions and financial affiliates.

Outcomes

The audit produces objective evidence in five areas related to the manufacturer's purchasing process implementation.

- Defined, documented, and implemented procedures
- Established criteria for evaluation, selection, and re-evaluation of suppliers
- Supplier evaluation and selection performed
- Supplier re-evaluation performed
- Supplier controls determined and implemented

Audit Tasks

There are twelve audit tasks, summarized below. In some cases, the audit tasks include multiple requirements, but this article separates them to help clarify the presentation. Some of the tasks relate to QSR sections and ISO 13485:2016 clauses. In addition, some tasks link to other processes.

1. Verify that the planning activities describe or identify the:

- **Products to purchase**
- **Processes to outsource**
- **Specified requirements for purchased products**
- **Requirements for purchasing documentation and records**
- **Purchasing resources**
- **Purchased product acceptance activities**
- **Risk management activities in supplier selection**
- **Risk management activities in purchasing**

Relations:

21 CFR §820.20 Management responsibility

21 CFR §820.50 Purchasing controls

ISO 13485:2016 Clauses 4.1.2, 4.1.3, and 4.1.5; Part of 4.1 Quality management system
– General requirements

ISO 13485:2016 Clause 7.1 Product realization – Planning of product realization

ISO 13485:2016 Clause 7.4.1 Product realization – Purchasing – Purchasing process

ISO 13485:2016 Clause 7.4.2 Product realization – Purchasing – Purchasing information

ISO 13485:2016 Clause 7.4.3 Product realization – Purchasing – Verification of purchased product

Process Linkage:

Design and Development
Management

2. Select one or more supplier evaluation files to audit using the priority order:

- **Indications of problems with supplied products or processes from audit of the Measurement, Analysis, and Improvement process**
- **Suppliers of higher risk products or processes**
- **Suppliers who provide products or services that directly impact the design outputs required for proper functioning of the device**
- **Suppliers of processes that require validation or revalidation**
- **Newly approved suppliers of products or services**
- **Suppliers of products or services used in the manufacturing of multiple products**
- **Suppliers of components or services not covered during previous audits**

Relations: None

Process Linkage: None

3. Verify the establishment and documentation of procedures to ensure that the purchased product conforms to the purchasing requirements.

Relations:

21 CFR §820.50 Purchasing controls

ISO 13485:2016 Clause 7.4.1 Product realization – Purchasing – Purchasing process

Process Linkage: None

4-1 Verify the establishment and documentation of the criteria for supplier selection, evaluation, and re-evaluation.

4-2 Verify that the procedures assure that the type and extent of supplier control depends on the purchased product effect on either a) subsequent process realization or b) the final product.

Relations:

21 CFR §820.50 Purchasing controls

ISO 13485:2016 Clause 7.4.1 Product realization – Purchasing – Purchasing process

Process Linkage: None

5-1 Verify that supplier selection uses the supplier's ability to provide a product or service in accordance with the manufacturer's requirements.

5-2 Confirm that supplier control uses risk as a basis and is commensurate with the significance of the product or service effect on the quality of the finished device.

5-3 Verify the maintenance of records of supplier evaluation.

Relations:

21 CFR §820.50(a) Purchasing controls – Evaluation of Suppliers, Contractors, and consultants

ISO 13485:2016 Clause 4.2.1 Quality management system – Documentation requirements – General

ISO 13485:2016 Clause 7.1 Product realization – Planning of product realization

ISO 13485:2016 Clause 7.4.1 Product realization – Purchasing – Purchasing process

Process Linkage: Design and Development, Production and Service Controls

6. Verify that the manufacturer maintains effective controls over suppliers and product, to ensure meeting the specified requirements.

Relations:

21 CFR §820.50(a) Purchasing controls – Evaluation of Suppliers, Contractors, and consultants

ISO 13485:2016 Clause 7.4.1 Product realization – Purchasing – Purchasing process

Process Linkage: Production and Service Controls; Measurement, Analysis, and Improvement

7. Confirm the performance of the re-evaluation of supplier capability to meet requirements at intervals consistent with the significance of the product on the finished device.

Relations:

21 CFR §820.50(a) Purchasing controls – Evaluation of Suppliers, Contractors, and consultants

ISO 13485:2016 Clause 7.4.1 Product realization – Purchasing – Purchasing process

Process Linkage: Measurement, Analysis, and Improvement

8-1 Verify that the organization assures the adequacy of purchasing requirements for supplier provided products or services.

8-2 Verify that the organization defines risk management activities and any necessary risk control measures for supplier provided products or services.

8-3 Confirm that the manufacturer ensures the adequacy of the purchasing requirements before sending them to the supplier.

8-4 Confirm that the manufacturer has a written agreement with the supplier to notify the manufacturer of product changes.

Relations:

21 CFR §820.50(b) Purchasing controls – Purchasing data

ISO 13485:2016 Clause 4.2.1 Quality management system – Documentation requirements – General

ISO 13485:2016 Clause 7.4.2 Product realization – Purchasing – Purchasing information
Process Linkage: None

9-1 Verify that the organization documents purchasing information, including where appropriate the requirements for approval of product, procedures, processes, equipment, qualification of personnel, sterilization services, and other quality management system requirements.

9-2 Confirm that, where applicable, purchasing documents and records are consistent with traceability requirements.

Relations:

21 CFR §820.50(b) Purchasing controls – Purchasing data

21 CFR §820.65 Traceability

21 CFR §820.160 Distribution

ISO 13485:2016 Clause 7.4.2 Product realization – Purchasing – Purchasing information

ISO 13485:2016 Clause 7.5.9 Product realization – Production and service provision – Traceability

Process Linkage: None

10-1 Confirm that purchase product verification is adequate to ensure meeting the requirements

10-2 Confirm that the manufacturer implemented appropriate controls, commensurate with risk, on the supplier, the purchase requirements specification, and acceptance verification

10-3 Verify that the organizations maintains adequate records of verification activities

Relations:

21 CFR §820.50 Purchasing controls

21 CFR §820.80(b) Receiving, in-process, and finished device acceptance – Receiving acceptance activities

ISO 13485:2016 Clause 4.2.1 Quality management system – Documentation requirements – General

ISO 13485:2016 Clause 7.1 Product realization – Planning of product realization

ISO 13485:2016 Clause 7.4.3 Product realization – Purchasing – Verification of purchased product

Process Linkage: Production and Service Controls

11. Verify that data from supplier evaluation, verification activities, and purchasing are a source of quality data for the Measurement, Analysis, and Improvement process

Relations:

21 CFR §820.100 Corrective and preventive action

ISO 13485:2016 Clause 8.4 Measurement, analysis and improvement – Analysis of data
Process Linkage: Measurement, Analysis, and Improvement

12. Determine, based on the assessment of the overall purchasing, whether management provides the necessary commitment to the purchase process

Relations:

ISO 13485:2016 Clauses 4.1.3 and 4.1.5; Part of 4.1 Quality management system –
General requirements

ISO 13485:2016 Clause 5.2 Management responsibility – Customer focus

Process Linkage: None