FDA U.S. FOOD & DRUG ADMINISTRATION

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Purchasing Process

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Course Prerequisites

- Successful completion of the following MDSAP training module is a prerequisite to this course:
  - Introduction to the MDSAP Program
  - Overview of the MDSAP Audit Process
  - MDSAP: Management Process
  - MDSAP: Measurement, Analysis and Improvement Process
  - MDSAP: Design and Development Process
  - MDSAP: Production and Service Controls Process: Parts 1-3

Learning Objectives

- Explain the Purchasing Process
- Describe the purpose of auditing the Purchasing process
- Discuss the expected outcomes from audit of the Purchasing process
- Explain the audit tasks to include:
  - Description and related Clauses and Regulations
  - Country-specific requirements and assessment of conformity
  - Links to other MDSAP processes

Learning Objectives

- **Explain the Purchasing Process**
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Purchasing process

- Ensures that purchased, subcontracted, or otherwise received products and services conform to specified requirements
- Incorporates purchasing requirements and specifications
- Selects acceptable suppliers based on the capability of the suppliers

Purchasing process

- The organization is expected to establish and maintain documented controls for planning and performing purchasing activities
  - Controls depend on the effect of the purchased product or service .of the finished device
- Integral to other processes of the MDSAP audit sequence

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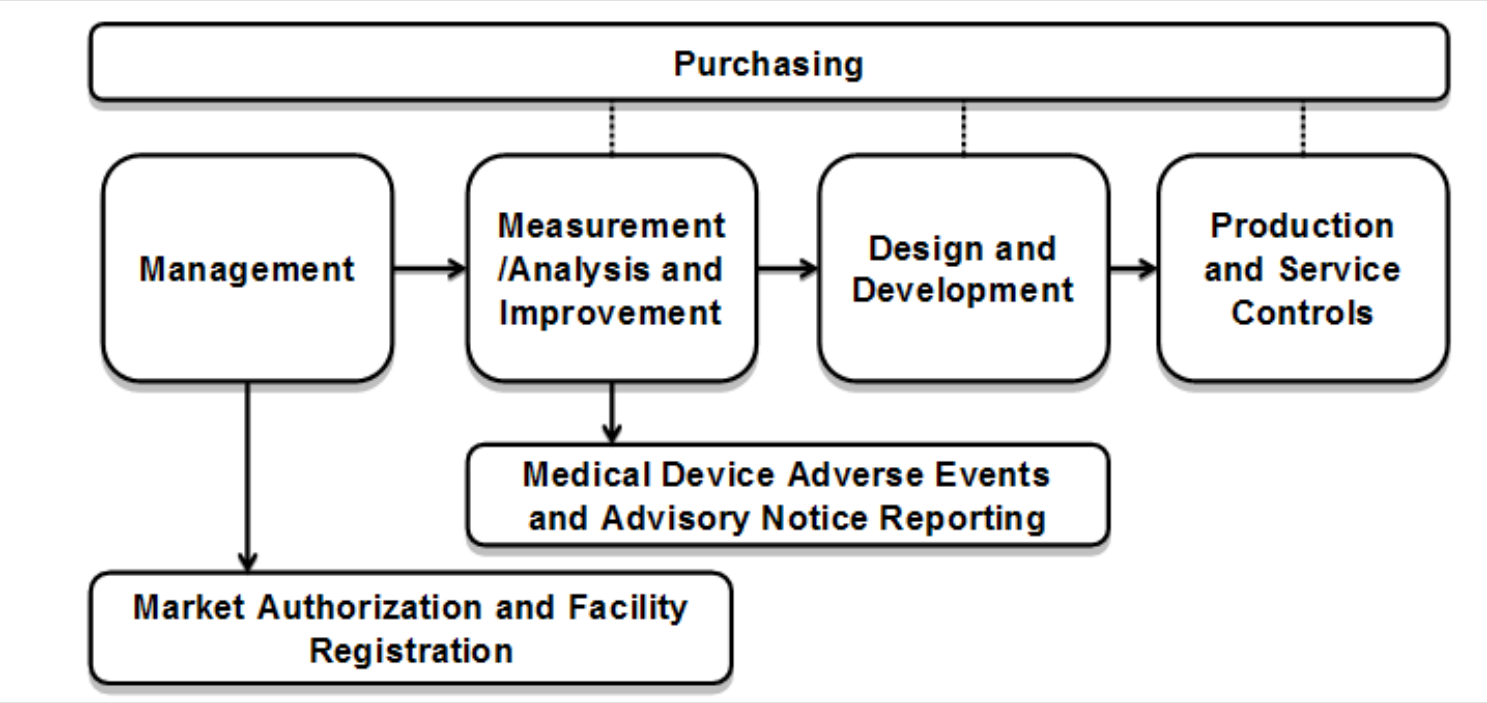
MDSAP Audit Sequence



Purpose of Auditing

- Purchasing Process is audited to:
  - Verify that the manufacturer's processes ensure that products are in conformity with specified purchase requirements
    - Products such as components, materials and services provided by suppliers, including contractors and consultants

Purpose of Auditing

- Suppliers include:
  - Providers of any product received from outside the manufacturer
    - Product has an effect on subsequent product realization or the final product

Learning Objectives

- Explain the Purchasing Process
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- **Discuss the expected outcomes from audit of the Purchasing process**
- Explain the audit tasks to include:
  - Description and related Clauses and Regulations
  - Country-specific requirements and assessment of conformity
  - Links to other MDSAP processes

Expected Outcomes

As a result of the audit of the Purchasing process, objective evidence will show whether the manufacturer has:

A. Defined, documented and implemented procedures

B. Established criteria for the selection, evaluation and re-evaluation of suppliers

Expected Outcomes

As a result of the audit of the Purchasing process, objective evidence will show whether the manufacturer has:

C. Performed the evaluation and selection of suppliers

D. Ensured the continued capability of suppliers to provide quality products that meet specified purchase requirements

E. Determined and implemented an appropriate combination of controls applied to suppliers in conjunction with acceptance verification activities

Learning Objectives

- Explain the Purchasing Process
- Describe the purpose of auditing the Purchasing process
- Discuss the expected outcomes from audit of the Purchasing process
- **Explain the audit tasks to include:**
  - **Description and related Clauses and Regulations**
  - **Country-specific requirements and assessment of conformity**
  - **Links to other MDSAP processes**

Task 1

1. **Verify that planning activities describe or identify products to purchase and processes to outsource, the specified requirements for purchased products, the requirements for purchasing documentation and records, purchasing resources, the activities for purchased product acceptance, and risk management in supplier selection and purchasing.**

Clause and Regulation: [ISO 13485:2016: 4.1.2, 4.1.3, 4.1.5, 7.1, 7.4.1, 7.4.2, 7.4.3; TG(MD)R: Sch1 P1 2, Sch3 P1 Cl1.4(5)(d)(ii); RDC ANVISA16/2013: 2.5.1, 2.4; MHLW MO169: 5-2, 5-3, 5-5, 26, 37, 38, 39 (Old: 5, 26, 37, 38, 39); 21 CFR 820.20, 820.50]

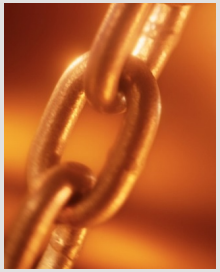
MDSAP Audit Approach

Task 1

- Additional country-specific requirements: None
- Assessing conformity:

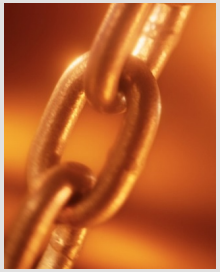
  Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 7: Purchasing under Task 1

Task 1



- *Links:*
  - *Design and Development*
    - Confirm that the organization has considered the effect of purchased product on the essential design outputs
      - The degree of purchasing controls necessary is commensurate with the effect of the supplied product on the proper functioning of the finished device.
      - During the audit of the Purchasing process, confirm when necessary that the degree of control over suppliers of purchased product has been made.

Task 1



- *Links:*
  - *Management*
    - Confirm when necessary that the quality objectives related to the purchased product were considered for inclusion in management review.

Task 2

2. Select one or more supplier evaluation files to audit.

Priority criteria for selection:

- 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

MDSAP Audit Approach

Task 2

2. Select one or more supplier evaluation files to audit.

Priority criteria for selection:

- 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

Clause and regulation: None

MDSAP Audit Approach

Task 2

- Additional country-specific requirements: None
- Assessing conformity: None

Task 3

3. **Verify that procedures for ensuring purchased product conforms to purchasing requirements have been established and documented.**

Clause and regulation: [ISO 13485:2016: 7.4.1; TG(MD)R Sch3 P1 Cl1.4(5)(d)(ii); RDC ANVISA 16/2013: 2.5.1; MHLW MO169: 37; 21 CFR 820.50]

MDSAP Audit Approach

Task 3

- Additional country-specific requirements: None
- Assessing conformity:

  Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 7: Purchasing under Task 3

Task 4

4. **Verify that the procedures assure the type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or on the final product.**

Verify that criteria for the selection, evaluation and re-evaluation of suppliers have been established and documented.

Clause and regulation: [ISO 13485:2016: 7.4.1; RDC ANVISA 16/2013: 2.5.2, 2.5.3; MHLW MO169: 37; 21 CFR 820.50]

MDSAP Audit Approach

Task 4

- Additional country-specific requirements: None
- Assessing conformity:
  - Be mindful or organizations that use a “one-size fits all” approach to managing their suppliers

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 7: Purchasing under Task 4

Task 5

5. **Verify that suppliers are selected based on their ability to supply products or services in accordance with the manufacturer's specified requirements.**

   Confirm the degree of control applied to the supplier is commensurate with the significance of the supplied product or service on the quality of the finished device, based on risk.

   Verify that records of supplier evaluations are maintained.

   Clause and regulation: [ISO 13485:2016: 4.2.1, 7.1, 7.4.1; TG(MD)R: Sch1 P1 2; RDC ANVISA 16/2013: 2.3.3, 2.5.3, 2.4; MHLW MO169:6, 26, 37 (Old: 6, 26, 37); 21 CFR 820.50(a)]

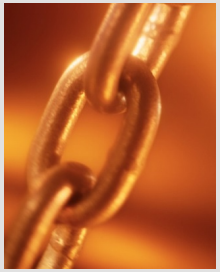
MDSAP Audit Approach

Task 5

- Additional country-specific requirements: Australia (TGA); Canada (HC); Japan (MHLW)
- Assessing conformity:
  - Confirm that the selection of the supplier was based on defined criteria commensurate with the risk posed
  - Confirm that the evaluation was made according to defined criteria

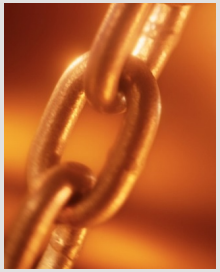
  Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 7: Purchasing under Task 5

Task 5



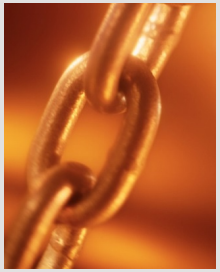
- *Links:*
  - *Design and Development*
    - Ensure the establishment of the necessary purchasing controls and required acceptance activities as a design output
    - Ensure the degree of the purchasing controls necessary and extent of acceptance activities is based on risk

Task 5



- *Links:*
  - *Production and Service Controls*
    - Auditors may encounter situations where the organization outsources processes that require validation.
    - During the review of the Purchasing process, review (when necessary) the controls the organization has instituted over suppliers that perform validated processes.
    - Confirm that the finished device manufacturer has reviewed the process validation data.

Task 5



- *Links:*
  - *Production and Service Controls*
    - Consider reviewing the purchasing controls and requirements for suppliers of products that undergo minimal acceptance activities at the device manufacturer.

Task 6

6. **Verify that the medical device organization maintains effective controls over suppliers and product, so that specified requirements continue to be met.**

   Clause and regulation: [ISO 13485:2016: 7.4.1; RDC ANVISA 16/2013: 2.5.3; MHLW MO169: 37; 21 CFR 820.50(a)]

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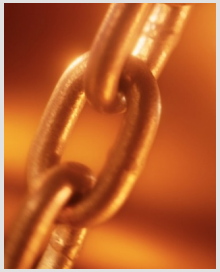
Task 6

- Additional country-specific requirements: None
- Assessing conformity:
  - Confirm that the supplier monitoring is documented and reviewed by appropriate individuals
  - Be mindful of instances were supplied product has caused complaints and/or product nonconformities
  - Verify that the organization has performed the appropriate monitoring

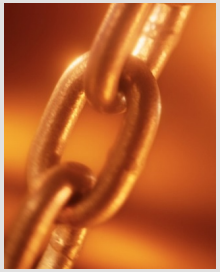
Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 7: Purchasing under Task 6

Task 6



- *Links:*
  - *Production and Service Controls*
    - Confirm when necessary that the appropriate acceptance activities have been implemented and monitored to ensure that the received product meets specified requirements.

Task 6



- *Links:*
  - *Measurement, Analysis and Improvement*
    - Confirm that analysis of supplier performance data has been performed and considered for corrective or preventive action when necessary.

Task 7

7. ***Confirm the re-evaluation of the capability of suppliers to meet specified requirements is performed at intervals consistent with the significance of the product on the finished device.***

   Clause and regulation: [ISO 13485:2016: 7.4.1; TG(MD)R: Sch1 P1 2; RDC ANVISA 16/2013: 2.5.2, 2.4; MHLW MO169: 37; 21 CFR820.50(a)]

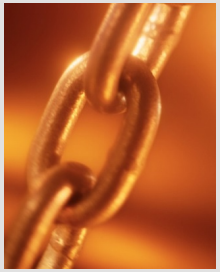
MDSAP Audit Approach

Task 7

- Additional country-specific requirements: None
- Assessing conformity:
  - Confirm that the re-evaluation of the supplier was performed commensurate with the risk the supplied product poses to the ability of the finished device to meet specifications

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 7: Purchasing under Task 7

Task 7



- *Links:*
  - *Measurement, Analysis and Improvement*
    - The frequency and extent of supplier re-evaluation activities may be based on the performance of the supplier demonstrated by:
      - statistical monitoring of the supplier,
      - monitoring of complaints and nonconformities related to supplied product
      - corrective or preventive actions related to the supplier

Task 8

8. **Verify that the medical device organization assures the adequacy of purchasing requirements for products and services that suppliers are to provide, and defines risk management activities and any necessary risk control measures.**

   Confirm that the medical device organization ensures the adequacy of specified purchase requirements prior to their communication to the supplier and that a written agreement with the supplier is established in which suppliers has to notify the organization about changes in the product.

Clause and regulation: [ISO 13485:2016: 4.2.1, 7.4.2, TG(MD)R: Sch1 P1 2; RDC ANVISA 16/2013: 2.4, 2.5.4, 2.5.6; MHLW MO169: 6, 38; 21 CFR 820.50(b)]

MDSAP Audit Approach

Task 8

- Additional country-specific requirements: Brazil (ANVISA)
- Assessing conformity:
  - Confirm that risk control measures have been identified when appropriate
  - Confirm that the risk control measures have been implemented and are effective

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 7: Purchasing under Task 8

Task 9

9. **Verify that the medical device 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.**

   Confirm that documents and records for purchasing are consistent with traceability requirements where applicable.

   Clause and regulation: [ISO 13485:2016: 7.4.2, 7.5.9 ; RDC ANVISA 16/2013: 2.3.3, 2.5.4, 2.5.5, 6.4; MHLW MO169: 38, 48, 49: 21 CFR 820.50(b), 820.65, 820.160]

MDSAP Audit Approach

Task 9

- Additional country-specific requirements: None
- Assessing conformity:

  Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 7: Purchasing under Task 9

Task 10

10. **Confirm that the verification (inspection or other activities) of purchased products is adequate to ensure specified requirements are met.**

    Confirm that the manufacturer has implemented an appropriate combination of controls applied to the supplier, the specification of purchase requirements, and acceptance verification activities that are commensurate with the risk of the supplied product upon the finished device. Verify that records of verification activities are maintained.

    Clause and regulation: [ISO 13485:2016: 4.2.1, 7.1, 7.4.3; TG(MD)R: Sch1 P1 2, Sch3 1.4(5)(e); RDC ANVISA 16/2013: 2.4, 2.5.2, 3.35.3.1, 5.3.2, 5.3.3; MHLW MO169: 6, 26, 39; 21 CFR 820.50, 820.80(b)]

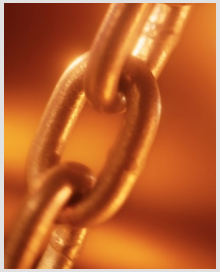
MDSAP Audit Approach

Task 10

- Additional country-specific requirements: Brazil (ANVISA)
- Assessing conformity:
  - Confirm the medical device organization has appropriately handled the nonconformity according to the medical device organization's established procedures
  - Confirm the records of verification activities have been maintained
  - Confirm the acceptance activities have been documented

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 7: Purchasing under task 10

Task 10



- *Links:*
  - *Production and Service Controls*
    - Confirm the organization has taken the appropriate action to determine the suitability of the acceptance activities.

Task 11

11. Verify that data from the evaluation of suppliers, verification activities, and purchasing are considered as a source of quality data for input into the Measurement, Analysis and Improvement process.

Clause and regulation: [ISO 13485:2016: 8.4; RDC ANVISA 16/2013: 7.1.1.1; MHLW MO169: 61; 21 CFR 820.100]

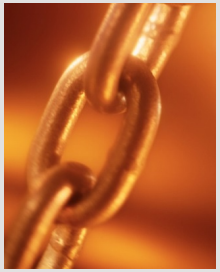
MDSAP Audit Approach

Task 11

- Additional country-specific requirements: None
- Assessing conformity:

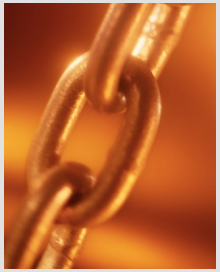
  Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 7: Purchasing under Task 11

Task 11



- *Links:*
  - *Design and Development*
    - Confirm, as necessary, that supplied product was evaluated as to the effect on the essential design outputs.
    - Verify the appropriate acceptance activities were implemented

Task 11



- *Links:*
  - *Measurement, Analysis and Improvement*
    - Confirm that the analysis of supplier performance data from the evaluation and monitoring of supplier process activities has been performed and considered for corrective or preventive action when necessary.

Task 12

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

Clause and regulation: [ISO 13485:2016: 4.1.3, 4.1.5, 5.2; RDC ANVISA 16/2013: 2.2.1; MHLW MO169: 5-3, 5-5, 11 (Old: 5, 11]

MDSAP Audit Approach

Task 12

- Additional country-specific requirements: None
- Assessing conformity:

  Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 7: Purchasing under task 12

Conclusion

- This concludes the training for MDSAP process: Purchasing Process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