FDA U.S. FOOD & DRUG ADMINISTRATION

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Management Process

CAPT Kimberly Lewandowski-Walker
Senior Regulatory Officer
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Course Prerequisites

- Successful completion of the following MDSAP training is a prerequisite to this course:
  - "Introduction to the MDSAP Program"
  - "Overview of MDSAP Audit Process"
- It is expected that the auditor is :
  - proficient in auditing to International Organization for Standardization 13485:2016, Medical Devices- Quality management systems- Requirements for regulatory purposes (ISO 13485:2016)
  - is familiar with specific requirements of the regulatory authorities participating in the Medical Device Single Audit Program (MDSAP)

Learning Objectives

- Explain the Management Process
- Describe the purpose of auditing the Management process
- Discuss the expected outcomes from audit of the Management 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

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Management Process

- Provides adequate resources for device design and manufacturing
- Assures the quality management system is functioning properly and effectively
- Monitors the quality management system and make necessary adjustments

Role of the management representative

- Responsibilities include:
  - Ensuring that the requirements of the quality management system have been effectively defined, documented, implemented, and maintained

- Interview the management representative (or designee) to obtain an overview of the process as needed

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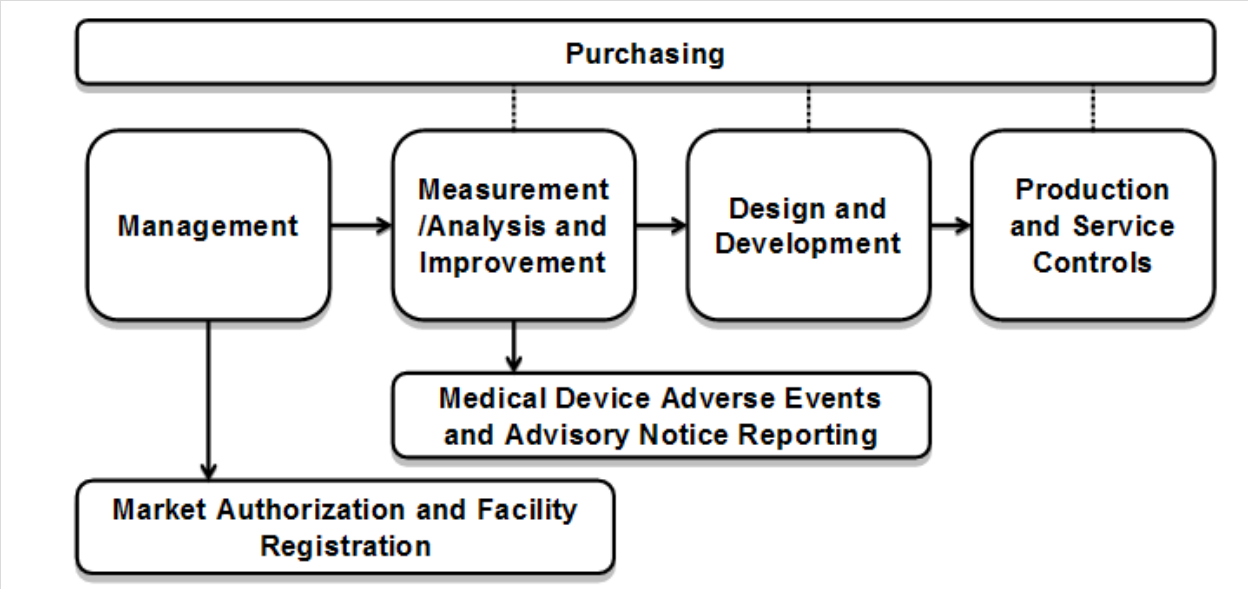
MDSAP Audit Sequence

- The Management process is the first process to be audited per the MDSAP audit sequence.



Purpose of Auditing

- The Management process is audited to:
  - Verify that top management ensure that an adequate and effective quality management system has been established and maintained
  - Determine whether top management demonstrated commitment for a quality management system and communicated that commitment

Purpose of Auditing

- The audit should:
  - Commence with management process
  - End with an assessment of management's control of the organization activities by quality management system

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Expected Outcomes

As a result of the audit of the Management process, objective evidence will show whether the organization has:

A. Identified processes needed for the quality management system, their application throughout the organization, and their sequence and interaction

B. Defined, documented, and implemented procedures and instructions to ensure the development and maintenance of an effective quality management system

Expected Outcomes

As a result of the audit of the Management process, objective evidence will show whether the organization has:

C. Established quality objectives at relevant function and levels within the organization consistent with quality policy and ensured that these are periodically reviewed for continued suitability

D. Determined the criteria and methods needed to ensure the operation and control of quality management system processes, including the identification and management of interrelated processes

E. Committed the appropriate personnel and resources for infrastructure to the quality management system

Expected Outcomes

As a result of the audit of the Management process, objective evidence will show whether the organization has:

F. Assigned responsibility and authority to personnel and established the organizational structure to ensure processes assuring quality are not compromised

G. Performed risk management planning and ongoing review of the effectiveness of risk management activities to ensure that polices, procedures and practices are established for analyzing, evaluation and controlling risk

Expected Outcomes

As a result of the audit of the Management process, objective evidence will show whether the organization has:

H. Ensured the continued effectiveness of the quality management system and its processes

I. Established a quality management system which is capable of producing devices that are safe, effective and suitable for their intended use

Learning Objectives

- Explain the Management Process
- Describe the purpose of auditing the Management process
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- **Explain the audit tasks to include:**
  - **Description and related Clauses and Regulations**
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  - **Links to other MDSAP processes**

Task 1

1. **Confirm that quality management system planning is performed to ensure that all required processes are identified, documented, implemented, monitored and maintained in order to conform to the applicable requirements and meet quality objectives. Verify that changes to the quality management system are managed to maintain the conformity or the quality management system and of the devices produced. Verify that a quality manual has been document.**

Clause and Regulation: [ISO 13485:2016: 4.1.1, 4.1.2; 4.1.3; 4.2.2, 4.1.4; 5.4.2; TG(MD)R Sch3 P1 1.4(4); RDC ANVISA 16/2013: 2.1, 5.6; MHLW MO169: 5-1, 5-2, 5-3, 5-4, 7, 14; (Old: 5, 7, 14); 21 CFR 820.20]

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 1: Management under task 1

Task 1

- *Links:*
  - *Measurement, Analysis and Improvement*
  - *Design and Development*
  - *Purchasing*
  - *Production and Service Controls*
  - *Device Marketing Authorization and Facility Registration*
    - During the audit:
      - Verify that the organization has implemented appropriate change controls

Task 2

2. **Confirm top management has documented the appointment of a management representative. Verify the responsibilities of the management representative include ensuring that quality management system requirements are effectively established and maintained, reporting to top management on the performance of the quality management system, and ensuring the promotion of awareness of regulatory requirements throughout the organization.**

   Clause and Regulation: [ISO 13485:2016: 5.5.2; TG(MD)R Sch3 P1 1.4(5)(b)(ii); RDC ANVISA 16/2013: 2.2.5; MHLW MO169: 16; 21 CFR 820.20(b)]

MDSAP Audit Approach

Task 2

- Additional country-specific requirements: None
- Assessing conformity:
  - Confirm appointment of management representative
  - Evaluate responsibility and authority of the management representative
  - Verify training as required

  Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management under task 2

Task 3

3. **Verify that a quality policy and objectives have been set at relevant functions and levels within the organization. Ensure the quality objectives are measurable and consistent with the quality policy. Confirm appropriate measures are taken to achieve the quality objectives.**

Clause and Regulation: [ISO 13485:2016: 5.3, 5.4.1; TG(MD)R Sch3 P1 1.4(5)(a); RDC ANVISA 16/2013: 2.2.1; MHLW MO169: 12, 13; 21CFR 820.20(a)]

MDSAP Audit Approach

Task 3

- Additional country-specific requirements: None
- Assessing conformity:
  - Ask for examples of quality objectives and the status of these objectives

Detailed Information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management under task 3

Task 4

4. **Review the manufacturer's organizational structure and related documents to verify that they include provisions for responsibilities, authorities (e.g., management representative), personnel, resources for infrastructure, competencies, and training to ensure that personnel have the necessary competence to design and manufacture devices in accordance with the planned arrangements and applicable regulatory requirements.**

   Clause and Regulation: [ISO 13485:2016: 5.1, 5.5.1, 5.5.2, 6.1, 6.2; TG(MD)R Sch3 P1 1.4(5)(b)(; RDC ANVISA 16/2013: 2.2.2, 2.2.3. 2.2.4, 2.3; MHLW MO169: 10, 15, 16, 21, 22, 23; 21 CFR 820.20(b), 820.25]

MDSAP Audit Approach

Task 4

- Additional country-specific requirements: None
- Assessing conformity:
  - Review organizational charts
  - Ask authority and responsibility questions
  - Ask the management representative to provide examples of recent requests for resources

  Detailed Information on how to assess conformity for this audit ask can be found in the MDSAP Audit Approach, Chapter 1: Management under task 4

Task 5

5. **Determine the extent of outsourcing of processes that may affect the conformity of product with specified requirements and verify the proper documentation of controls in the quality management system.**

   Clause and Regulation: [ISO 13485:2016: 4.1.5, 4.2.1;TG (MD)R Sch3 P1 1.4(5) (b)(iii), (d)(ii); RDC ANVISA 16/2013: 2.5; MHLW MO169: 5-5, 6; (Old: 5, 6); 21 CFR 820.50]

MDSAP Audit Approach

Task 5

- Additional country-specific requirements: Australia (TGA); Canada (HC)
- Assessing conformity:
  - Ascertain the extent the organization outsources essential processes

  Detailed Information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management under task 5

Task 5

- *Links:*
  - *Purchasing*
    - During audit of the organization's Purchasing process:
      - Ensure that management has assured the appropriate level of control over suppliers
      - Ensure management has assessed the relationship between supplied products and product risk

Task 6

6. **Confirm the medical device organization has determined the necessary competencies for personnel performing work affecting product quality, provided appropriate training, and made personnel aware of the relevance and importance of their activities on product quality and achievement of the quality objectives. Ensure records of training and competencies are maintained.**

   Clause and Regulation: [ISO 13485:2016: 4.2.1, 6.2; RDC ANVISA 16/2013: 2.2.3, 2.2.4, 2.3; MHLW MO169: 6, 22, 23, 25.4; 21 CFR 820.20(b)(2), 820.25]

MDSAP Audit Approach

Task 6

- Additional country-specific requirements: Brazil (ANVISA)
- Assessing conformity:
  - Review employee training records

  Detailed Information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management under task 6

Task 6

- *Links:*
  - *Production and Service Controls*
    - During the audit of the Production and Service Controls process:
      - Ensure that employees have been trained in their specific job tasks, as well as the quality policy and objectives
      - Review the training records for those employees whose activities have contributed to process nonconformities

Task 7

7. ***Verify that management has committed to and has responsibility for overall risk management planning, including ongoing review of the effectiveness of risk management activities ensuring that policies, procedures and practices are established and documented for analyzing, evaluating and controlling product risk throughout product realization.***

   Clause and Regulation: [ISO 13485:2016: 4.1.2 (b), 7.1; TG(MD)R Sch1 P1 2; RDC ANVISA 16/2013: 2.4; MO169: 5-2.1.2, 26; (Old: 26); 21 CFR 820.30(g)]

MDSAP Audit Approach

Task 7

- Additional country-specific requirements: None
- Assessing conformity:
  - Ensure the provision of adequate resources
  - Ensure assignment of qualified personnel for risk management activities
  - Ensure top management reviews the suitability of the risk management process

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

Task 7

- Links:
  - *Design and Development*
    - Risk management usually starts in conjunction with the design and development planning process
    - During audit of the Design and Development process:
      - Evaluate top management's commitment to risk management activities

Task 8

8. **Verify that procedures have been defined, documented, and implemented for the control of documents and records of both internal and external origin required by the quality management system. Confirm the organization retains records and at least one obsolete copy of controlled documents for a period of time at least equivalent to the lifetime of the device, but not less than two years from the date of product release.**

   Clause and Regulation: [ISO 13485:2016: 4.1.4; 4.2.1, 4.2.4, 4.2.5; TG(MD)R Sch3 P1 1.4(4); RDC ANVISA 16/2013: 3.1; MO169: 5-4, 6, 8, 9; (Old: 5, 6, 8, 9); 21 CFR 820.40, 820.180]

MDSAP Audit Approach

Task 8

- Additional country-specific requirements: Australia (TGA); Brazil (ANVISA); Japan (MHLW); and United States (FDA)
- Assessing conformity:
  - Ensure at least one copy of obsolete controlled documents is maintained

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management under task 8

Task 9

9. **Verify that procedures for management review have been documented, management reviews are being conducted at planned intervals, that they include a review of the suitability and effectiveness of the quality policy, quality objectives, and quality management system to assure that the quality management system meets all applicable regulatory requirements.**

   Clause and Regulation: [ISO 13485:2016: 5.6; TG(MD)R Sch3 P1 1.4(5)(b)(iii)(f); RDC ANVISA 16/2013: 2.2.6; MHLW MO169: 18, 19, 20; 21 CFR820.20(c)]

MDSAP Audit Approach

Task 9

- Additional country-specific requirements: None
- Assessing conformity:
  - Ensure that the quality policy and objectives have been reviewed for continued suitability
  - Ensure that any changes to regulatory requirements have been identified

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management under task 9

Task 9

- *Links:*
  - *Measurement, Analysis and Improvement*
    - During audit of the Measurement, Analysis and Improvement process:
      - Confirm when necessary that action items resulting from Management review are considered for corrective or preventive action

Task 10

10. **Confirm that the medical device organization has defined and implemented controls to ensure that only devices that have received the appropriate marketing authorization are distributed or otherwise offered for commercial distribution into the applicable markets.**

Clause and Regulation: [ISO 13485:2016: 4.1.1; 4.2.1, 5.2; 7.2.1;7.2.3]

MDSAP Audit Approach

Task 10

- Additional country-specific requirements: None
- Assessing conformity:
  - Verify identification and documentation of the responsibilities of employees and personnel
  - Verify obligations are carried out by competent personnel
  - Verify controls to ensure appropriate market authorization

  Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management under task 10

Task 10

- *Links:*
  - *Device Marketing Authorization and Facility Registration*
    - ➢ During audit of the Device Marketing Authorization ad Facility Registration process:
      - o Perform a preliminary review that may allow for adequate coverage

Task 11

11. **At the conclusion of the audit, a decision should be made as to whether top management has demonstrated the necessary commitment to ensure a suitable and effective quality management system is in place and being maintained and whether the effectiveness of the system has been communicated to personnel.**

    Clause and Regulation: [ISO 13485:2003: 5.1, 5.5.3; RDC ANVISA 16/2013: 2.2.1; MO169: 5-1, 5-4, 10, 17; (Old: 5, 10, 17); 21 CFR 820.20(a), 820.5]

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 1: Management under task 11

Summary

- The Management process is the first process to be audited per the MDSAP audit sequence.
- The intent of the Management process is to:
  - provide adequate resources,
  - assure the quality management system is functioning properly and effectively
  - and to monitor and make any necessary adjustments
- The purpose of auditing the Management process is to ensure a quality management system has been established and maintained.

Conclusion

This concludes the training module for the MDSAP process: Management Process.


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