Overview Of The MDSAP Audit Process

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Learning Objectives

- List the prerequisites for a Medical Device Single Audit Program (MDSAP) Auditor
- Describe the MDSAP Audit process and provide examples
- Review requirements for writing nonconformity statements and the final report

Learning Objectives

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- Describe the MDSAP Audit process and provide examples
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MDSAP Auditor Prerequisites

MDSAP Auditor is required to:

-Be affiliated with an MDSAP recognized auditing organization or

- Be employed by one of the MDSAP participating regulatory authorities

- Be proficient in auditing to the International Organization for Standardization (ISO) 13485: 2016 standard

- Be familiar with the specific requirements of participating regulatory authorities

- Successfully complete the MDSAP training program

MDSAP Audit Process

- MDSAP Auditor should be familiar with:
  - Australia's Therapeutic Goods Administration requirements
    - Therapeutic Goods Act 1989
    - Therapeutic Goods (Medical Devices) Regulations 2002
    - Uniform Recall Procedure for Therapeutic Goods (URPTG)
  - Brazil's ANVISA Medical Device Regulation requirements
    - Brazilian Good Manufacturing Practices (RDC ANVISA 665/2022)

MDSAP Audit Process

- MDSAP Auditor should be familiar with:
  - Health Canada requirements
    - Medical Devices Regulations (SOR/98-282)
  - Japan MHLW requirements
    - Japan Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (MHLW Ministerial Ordinance No. 169)

MDSAP Audit Process

- MDSAP Auditor should be familiar with:
  - United States Food and Drug Administration requirements
    - Labeling (21 CFR 801)
    - Quality Management System Regulation (21 CFR 820)
    - Medical Device Reporting (21 CFR 803)
    - Medical Devices: Reports of Corrections and Removals (21 CFR 806)
    - Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices (21 CFR 807)
    - Medical Device Tracking Requirements (21 CFR 821)
    - Unique Device Identification (21 CFR 830)

Learning Objectives

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MDSAP Audit Process

- Each MDSAP Audit process contains:
  - A purpose
  - A number of anticipated outcomes or objectives broken down into specific tasks
- The audit tasks are based on:
  - clauses in ISO 13485:2016 and
  - regulatory requirements of the participating Regulatory Authorities
- Each task has associated audit criteria

MDSAP Audit Process

- Audit Tasks
  - Auditor assesses the organization's conformity to the applicable clause of ISO 13485:2016
  - Auditor assesses any additional country-specific requirements

MDSAP Audit Process

- Why not just perform an audit to ISO 13485:2016?
  - All of the regulatory authorities have not adopted ISO 13485:2016 as their regulatory requirement
  - There are additional requirements for each MDSAP participating regulatory authority
    - Medical device adverse event reporting
    - Advisory notice reporting
    - Device marketing authorization
    - Facility registration

MDSAP Audit Process

- Audit tasks within an MDSAP audit process
  - Are flexible
  - Are arranged in a logical order
  - May be performed in any order to facilitate a thorough and efficient audit of the process

MDSAP Audit Process

- Linkages and interactions between the MDSAP processes are indicated throughout the process (in the box)
- Tasks involving risk management and risk-based decisions are also indicated (in italics)

MDSAP Audit Process

- The audit team will be asked to be mindful of “linkages”
- Quality management system has to identify and manage numerous interrelated (linked) processes
- The output of one process often directly forms the input of other processes
- The activities of a supporting process are relevant to other processes

MDSAP Audit Process

Linkages:

- Built into the MDSAP audit sequence and audit tasks
- Remind the audit team of the interactions between the processes
- Assist auditors in making appropriate selections when moving to the next process

MDSAP Audit Process

Risk Management:

- Assessed by the audit team during the audit
- An integral aspect of an organization's quality management system
- Top management provide the necessary commitment and resources for risk management activities

MDSAP Audit Process

- Effective risk management
  - Usually starts in conjunction with the design and development process
  - Proceeds through product realization, including the selection of suppliers
  - Continues until the time the product is decommissioned
- Risk-based decisions occur throughout the various quality management system processes
- Each organization must decide how much risk is acceptable

MDSAP Audit Process

- Guidance on assessing conformity is available in the MDSAP Audit Approach document
- Reference the MDSAP Audit Approach document as you complete the MDSAP training modules

Example 1 : MDSAP process

Auditing the Measurement, Analysis and Improvement Process

- Purpose:
  - Verify that the manufacturer's processes ensure that information related to products, processes, or the quality management system is collected and analyzed
  - Identify actual and potential product, process, or quality management system nonconformities
  - Ensure that problems and potential problems are investigated
  - Ensure that appropriate and effective corrective actions and preventive actions are taken

Example 1: MDSAP Process

Auditing the Measurement, Analysis and Improvement Process

- Outcomes: objective evidence that demonstrate whether the organization has:
  A. Defined, documented, and implemented procedures for measurement, analysis and improvement
  B. Identified, analyzed, and monitored appropriate sources of quality data and determined the need for corrective or preventive action

Example 1: MDSAP Process

Auditing the Measurement, Analysis and Improvement Process

- Outcomes: objective evidence will demonstrate whether the organization has:
  - C. Ensured investigations are conducted to identify the underlying causes of nonconformities and potential nonconformities, where possible
  - D. Implemented appropriate corrective action or preventive action

Example 1: MDSAP Process

Auditing the Measurement, Analysis and Improvement Process

- Outcomes: objective evidence will demonstrate whether the organization has:

E. Reviewed the effectiveness of corrective action and preventive action,

F. Utilized information from the analysis of production and post-production quality data to amend the analysis of product risk, as appropriate

Example 1: MDSAP Process

- Linkages to other MDSAP processes:
  - Design and Development process
  - Production and Service Controls
  - Purchasing
  - Medical Device Adverse events and Advisory Notice Reporting
  - Management

Example 1: MDSAP Process

Audit Task 7

When a corrective or preventive action results in a process change, confirm that the process change is assessed to determine if any new risks to the product are introduces. Verify the manufacturer has performed revalidation of processes where appropriate.

Clause and regulation:[ISO 13485: 2016; 4.1.2, 4.1.4, 4.1.6, 4.2.1, 7.1, 7.5.2, 7.5.6, 7.5.7; TG(MD)R Sch1 P1 2; Sch3 P1 1.5(4); RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 106, Art. 120; MHLW MO169: 5-2, 5-4, 5-6, 6, 26, 41, 45, 46]

Example 1: MDSAP Process

Audit Task 7

- Additional country-specific requirements (see MDSAP Audit Approach):
  - Australia (TGA): [TG(MD)R Sch3 P1 1.5(2)]
  - Canada (HC): [CMDR 1, 34]
  - Japan (MHLW): [MHLW MO169: 29]

Example 1: MDSAP Process

Audit Task 7

- Links:
  - Production and Service Controls and Purchasing processes
- The audit team considers:
  - Selecting changed production processes for evaluation during Production and Service Control audit
  - Selecting suppliers who performed changes to production processes for evaluation
  - Re-validation, when the organization makes a change to a validated process performed by a supplier
- If re- validation is required, confirm the results show the process meets the planned results

Example 1: MDSAP Process

- Managing the linkage
  - The Purchasing process may be reviewed in conjunction with:
    - The Measurement, Analysis and Improvement process
    - The Design and Development process, and
    - The Production and Service Controls process

Example 1: MDSAP Process

- Managing the linkage:
  - Consider if corrective or preventive action resulted in process change
  - Consider selecting those processes or suppliers to audit involving the process change that was made as a result of corrective or preventive actions

MDSAP Audit Process

- Sampling Records:
  - Judgement-based sampling
    - Flexible
    - Generally, fewer records sampled
  - Statistical sampling
    - Demonstrates conformity or nonconformity

MDSAP Audit Process

- Sampling Records:
  - Judgement-based sampling
    - Often the most-appropriate sampling methods to achieve the MDSAP audit outcomes
    - Takes into account:
      - Complexity and interaction of the organization's processes and quality management system elements
      - Key risk areas

MDSAP Audit Process

- Sampling Records
  - Statistical sampling
    - May be appropriate in cases where no high risk nonconformities have been identified.
    - Helpful in making a statistical estimate of the effect of uncertainty in the findings of the audit and the conclusions reached
    - The level of sampling risk needs to be assessed by the auditor

MDSAP Audit Process

- Sampling products and processes
  - Assess all product families and significant processes during audit cycle
  - Degree of assessment depends on:
    - Risk of the product and process
    - Whether significant nonconformities can be attributed to the product or process
    - Whether any significant changes have been made to the products or processes

MDSAP Audit Process

- Design and implementation of an organization's quality management system is based on:
  - The needs of the organization
  - The size of the organization
  - The processes employed
  - The products provided
- If the organization does not perform certain processes, then:
  - The organization's quality management system does not need to address such a requirement
  - The corresponding MDSAP process does not need to be audited

MDSAP Audit Process

- Outsourcing
  - Much more common in the area of device design and manufacturing
  - Organizations can choose to outsource any processes related to the design and/or manufacture of medical devices
    - The suppliers of the processes **must** be controlled within the organization's quality management system
    - The supplied processes **must** be controlled within the organization's quality management system
  - Organizations cannot outsource responsibility for the device

MDSAP Audit Process

- Exclusions and Non-applicability
  - The organization may exclude the requirements of markets where the organization does not intend to supply product
  - The audit scope and audit criteria must take into account any justified exclusions or non-applications
  - Some MDSAP requirements may not be applicable when an organization claims an exclusion from the requirements of a target market
  - Exclusions must be clearly identified in the audit report

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Nonconformity Statements

- During the audit, auditors must be mindful:
  - Of any instances where the organization demonstrates failure to fulfill any of the requirements in ISO 13485:2016
  - Of any instances where the organization demonstrates failure to fulfill any portion of the requirements listed in the audit activities and tasks
  - That these nonconformities are recorded in appropriate detail

Nonconformity Statements

- Pay attention to the potential interrelationship of the nonconformities observed
  - For example:
    - Audit findings in both purchasing controls and acceptance activities
      - May indicate a significant nonconformity because control over suppliers, and the products they supply, depends on an effective combination of both these activities
      - Deficiencies in one or the other may affect the quality of the finished device

Nonconformity Statements

- Nonconformities should be:
  - Recorded along with supporting evidence
  - Reviewed with the auditee
- Nonconformities should include:
  - A reference number or identifier
  - The date
  - Identification of the organization
  - Grading
  - The requirement that is not met
  - Supporting audit evidence
  - The name of the auditor issuing the nonconformity

Nonconformity Statements

- Nonconformities regarding country-specific requirements
  - Written as an audit finding
  - Documented in the audit report
- Exceptions to nonconformities regarding country-specific requirements
  - Exclusions and non-applications permitted by ISO 13485:2016
  - Requirements of markets where the organization does not intend to supply product

Nonconformity Statements

- Document in the audit report:
  - Any observations related to device safety
  - Any observations related to the organization's
    - Failure to report individual adverse events
    - Advisory notices
    - Changes to device marketing authorization
    - Changes to facility registration

Final Report

- Report Format
  - Reports must be in the format described in the MDSAP AU P0019: Medical Device Regulatory Audit Reports Policy
  - Use the Fillable MDSAP Audit Report Form

References

- Medical device- Quality management systems- Requirements for regulatory purposes (ISO 13485:2016)
- Guidelines for auditing management systems (ISO 19011:2011)
- Conformity assessment-Requirements for bodies providing audit and certification of management systems (IS0/IEC 17021:2015)

References

- MDSAP AU P0002: MDSAP Audit Approach
- MDSAP AU P0008: Audit Time Determination Procedure
- MDSAP AU F0008.2: Audit Duration Calculation Form
- MDSAP AU P0019: Medical Device Regulatory Audit Reports Policy
- MDSAP AU F0019.1: Medical Device Regulatory Audit Report
- MDSAP AU F0019.2: NC Grading and Exchange Form
- MDSAP AU P0019.3: Medical Device Regulatory Audit Report Form Guidelines
- MDSAP AU G0019.4: NC Grading Exchange Form Guidelines

Medical Device Single Audit Program | Medical Device Single Audit Program (MDSAP)

References

- Australia (TGA)
  - Therapeutic Goods Act 1989
  - Therapeutic Goods (Medical Devices) Regulations 2002
  - Uniform Recall Procedure for Therapeutic Goods (URPTG)
- Brazil (ANVISA)
  - Brazilian Good Manufacturing Practices (RDC ANVISA 665/2022)

References

- Health Canada (HC)
  - Medical Devices Regulations (SOR/98-282)
- Japan
  - Japan Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (MHLW Ministerial Ordinance No. 169)
  - The Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Law No. 145, 1960)

Resources

Cited Resource	URL
Labeling (21 CFR 801)	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-801
Quality Management System Regulation (21 CFR 820)	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820?toc=1
Medical Device Reporting (21 CFR 803)	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-803
Medical Devices: Reports of Corrections and Removals (21 CFR 806)	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-806

Resources

Cited Resource	URL
Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices (21 CFR 807)	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807/subpart-E/section-807.81
Medical Device Tracking Requirement (21 CFR 821)	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-821
Unique Device Identification (21 CFR 830)	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-830

Summary

- There are several prerequisites for an MDSAP Auditor.
- The MDSAP Audit process includes:
  - A purpose
  - Expected Outcomes
  - Audit tasks
  - Final Report
- Nonconformities should be documented in the Final Report using the fillable MDSAP Audit Report Form.

Industry Education

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2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information across the device total product life cycle: **www.fda.gov/DeviceAdvice**

3. **Division of Industry and Consumer Education (DICE)**
   - Email: **DICE@fda.hhs.gov**
   - Phone: 1-800-638-2041 or (301) 796-7100 (Live Agents 9 am – 12:30 pm; 1 – 4: 30 pm ET)

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