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
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MDSAP Auditor Prerequisites

MDSAP Auditor is expected 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
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MDSAP Audit Process

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

• It is expected that the auditor is proficient in auditing to ISO 13485:2016 and is familiar with specific requirements of:
  – Australia's Therapeutic Goods Administration,
  – Brazil’s ANVISA,
  – Health Canada
  – Japan’s MHLW
  – United States’ Food and Drug Administration
MDSAP Audit Process

• Australia requirements
  – Therapeutic Goods Act 1989
  – Therapeutic Goods (Medical Devices) Regulations 2002
  – Uniform Recall Procedure for Therapeutic Goods (URPTG)

• Brazilian Medical Device Regulation
  – Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013)
MDSAP Audit Process

• Health Canada requirements
  – Medical Device Regulations (SOR/98-282)

• Japan 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

- United Sates Food and Drug Administration requirements
  - Labeling (21 CFR 801)
  - Quality 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)
MDSAP Audit Process

• Audit Tasks
  – The auditor assesses the organization's conformity to the applicable clause of ISO 13485:2016
  – The auditor assesses any additional country-specific requirement
  – Incorporate the requirements of the applicable ISO 13485:2016 clause and aspects of country-specific requirements
MDSAP Audit Process

• Why not just perform an audit to ISO 13385:2016?
  – Not all of the regulatory authorities have adopted ISO 13485:2016 as their regulatory requirement
  – There are additional requirements contained in Brazilian Good Manufacturing Practices (RDC ANVISA) and FDA Quality System Regulation (21 CFR Part 820)
MDSAP Audit Process

• Why not just perform an audit to ISO 13485:2016?
  – There are specific 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 red box)
- Tasks involving risk management and risk based decisions are also indicated (in blue font)
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 introduced. 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 ANVIS 16/2013: 2.4, 5.6, 7.1.1.4; MHLW MO169: 5, 6, 26, 45, 46; 21 CFR 820.100(a)(4), 820.100(a)(5), 820.70(b), 820.75(c )]
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:
      o Complexity and interaction of the organization’s processes and quality management system elements
      o 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
Learning Objectives

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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

• Generating audit findings
  – 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 ISO13485:2016
  - 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 (ISO/IEC 17021:2015)
References

- MDSAP AU P0002.5: MDSAP Audit Approach
- MDSAP AU P0008: Audit Time Determination Procedure
- MDSAP AU F0008.2: Audit Duration Calculation Form (Audit Model 2017)
- 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
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 16/2013)
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)
References

- United States (FDA)
  - Labeling (21 CFR 801)
  - Quality 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)
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Conclusion

• There are 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
Conclusion

This concludes the Overview of the MDSAP Audit Process training module.