FDA U.S. FOOD & DRUG ADMINISTRATION

MDSAP
Medical Device Single Audit Program

Introduction To The MDSAP

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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

Learning Objectives

- Give an overview of the MDSAP training
- Describe the MDSAP
- Review the MDSAP Audit Approach
- Explain the MDSAP Audit sequence and plan
- Explain how surveillance audits are planned and performed

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MDSAP Training

- MDSAP training will primarily focus on:
  - The assessment of the organization's entire quality management system
  - The assessment of additional country-specific requirements
- Complete assessment described as a "certification audit" in (ISO/IEC 17021-1:2015(E)) *Conformity assessment-Requirements for bodies providing audit and certification of management systems*
- Surveillance audits will assess only a portion of the organization's quality management system

MDSAP Training

The MDSAP training program is composed of the following modules:

- Introduction to the MDSAP (this current module)
- Overview of the MDSAP Process
- Management Process
- Measurement, Analysis and Improvement
- Design and Development Process

MDSAP Training

The MDSAP training program is composed of the following modules:

- Production and Service Controls Process: Parts 1-3
- Purchasing Process
- Device Marketing Authorizations and Facility Registration
- Medical Device Adverse Events and Advisory Notices Reporting Process

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MDSAP

MDSAP:

- Is the acronym for the Medical Device Single Audit Program
- Is a regulatory audit program
- Initially jointly developed by four jurisdictions
- Allows a medical device manufacturer to have a single quality management system audit
- Only requires a single audit report used by all participating jurisdictions

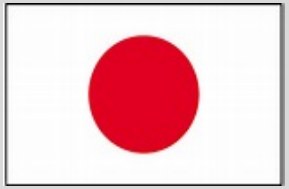
MDSAP

The current participating regulatory authorities (RAs):

Therapeutic Goods Administration (TGA)

Agencia Nacional de Vigilancia Sanitaria (ANVISA)

Health Canada (HC)



Japan (MHLW/ PMDA)

Food and Drug Administration (FDA)

MDSAP

MDSAP:

- Allows any medical device manufacturer to contract with an MDSAP recognized Auditing Organization
- Requires/allows each country to define how MDSAP outcomes are used within its jurisdiction

MDSAP

MDSAP:

- Developed to jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program
- Focused on the oversight of medical device manufacturers' quality management systems
- Goal is to create an international coalition of countries dedicated to pooling technology, resources, and services

MDSAP

MDSAP Objective is:

- To operate a single audit program that provides confidence in program outcomes
- To enable the appropriate regulatory oversight of medical device manufacturers' quality management systems
- To minimize regulatory burden on industry

MDSAP

MDSAP Objective is:

- To promote more efficient and flexible use of regulatory resources
- To respect the independence of each authority
- To promote greater alignment of regulatory approaches and technical requirements

Learning Objectives

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- **Review the MDSAP Audit Approach**
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MDSAP Audit Approach

- Has a total of seven processes
- Arranged in a set sequence
- Built on a foundation of risk management
- Document: MDSAP Audit Approach

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MDSAP Audit Approach

- The MDSAP audit sequence follows a process approach
- The MDSAP audit sequence has four primary processes:
  - Management
  - Measurement, Analysis and Improvement
  - Design and Development
  - Production and Service Controls
- Supporting process:
  - Purchasing

MDSAP Audit Approach

- The MDSAP audit process has two additional supporting processes:
  - Medical Device Adverse Events and Advisory Notices Reporting
  - Device Marketing Authorization and Facility Registration

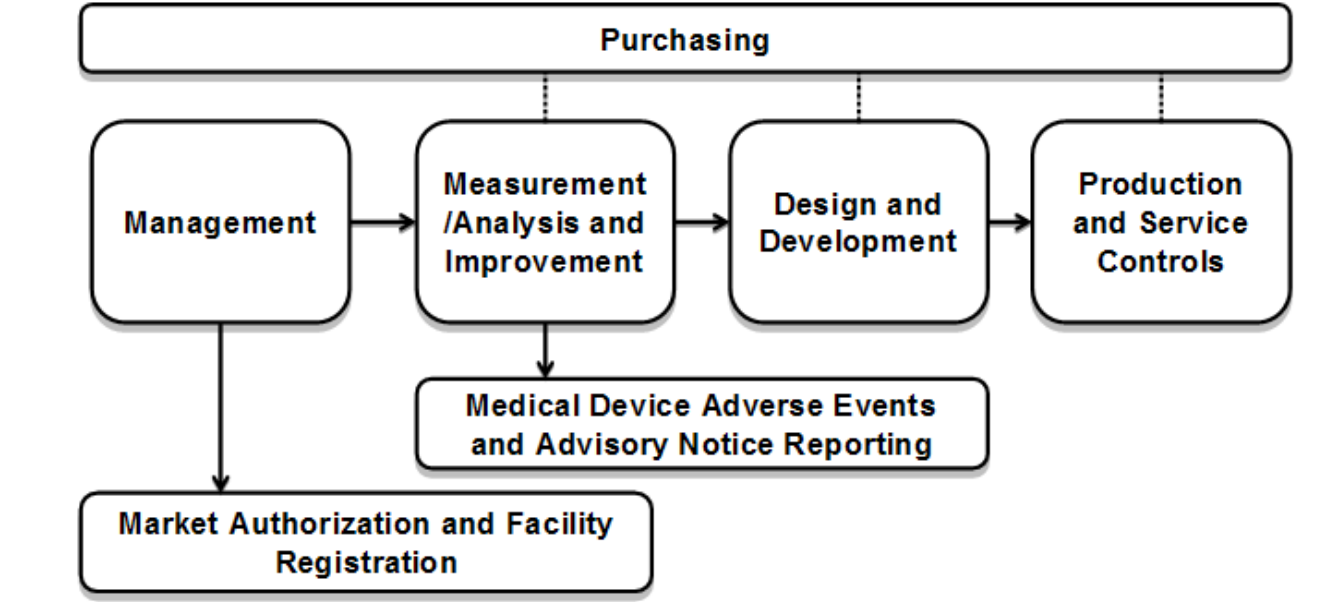
- These processes are necessary to fulfill specific requirements of the participating MDSAP regulatory authorities

MDSAP Audit Approach

- The five audit sequence processes are:
  - Built on a foundation of requirements for risk management
  - Comprise the requirements of a quality management system for medical device manufacturers according to:
    - Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
    - Quality Management System requirements of the Conformity Assessment Procedures of the Australian Therapeutic Goods (Medical Devices) Regulations (TG(MD)R Sch3)
    - Brazilian Good Manufacturing Practices (RDC ANVISA 665/2022)
    - Japan Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (MHLW Ministerial Ordinance No. 169)
    - Quality Management System Regulation (21 CFR Part 820)

MDSAP Audit Sequence

The MDSAP Audit Approach was designed for the audit of the MDSAP processes in the following sequence:



MDSAP Supporting Processes

- Purchasing process linked to:
  - Measurement, Analysis and Improvement process
  - the Design and Development process
  - Production and Service Controls process

- The Device Marketing Authorization and Facility Registration process linked to:
  - Management process
  - Design and Development processes as needed

- The Medical Device Adverse Events and Advisory Notices Reporting process linked to:
  - Measurement, Analysis and Improvement process

MDSAP Audit Sequence

- Designed and developed to allow for the audit to be:
  - Logical
  - Focused
  - Efficient
- Information learned during the audit of one process will be used to make decisions about what to select for audit during the next process

MDSAP Audit Sequence

- Use of the MDSAP audit sequence:
  - Assess the inter-relationship of processes and nonconformities
  - Avoid following unproductive audit trails while focusing on higher-risk areas

Example 1: Audit Sequence

- Nonconformances observed during audit of the Measurement, Analysis and Improvement process
- Use information observed regarding device and quality management system nonconformities to decide:
  - Design projects or design changes to assess during audit of the Design and Development process
  - Suppliers to evaluate during audit of the Purchasing process
  - Processes to review during audit of Production and Service Controls process.

Example 2: Audit Sequence

- Audit of the Design and Development process follows audit of the Measurement, Analysis and Improvement process
- Consider information regarding nonconformances observed during audit of the Measurement, Analysis and Improvement process
  - Decide design and development projects to be reviewed during audit of the Design and Development process
  - Decide design changes resulting from corrective actions to be reviewed during audit of the Design and Development process

Example 3: Audit Sequence

- Audit of the Production and Service Controls process follows audit of the Measurement, Analysis and Improvement process and the Design and Development process
- Decide production processes to be reviewed during audit of the Production and Service Controls process
  - Consider information regarding nonconformances observed during audit of the Measurement, Analysis and Improvement process
  - Consider information regarding nonconformities observed during audit of Design and Development process
  - Consider higher risk elements and essential design outputs from design projects reviewed

MDSAP Audit Plan

- The audit team will provide an audit plan per ISO/IEC 17021-1:2015
- The audit activities will follow the MDSAP audit sequence
- The audit plan will contain
  - the audit scope
  - objectives
  - roles and responsibilities of the audit team members
  - allocation of appropriate resources to the audit
  - other information.
- The audit plan will transpose the MDSAP audit sequence to the physical locations of the manufacturer

Example 1: Audit Plan

- Day 1 Morning:
  - Opening meeting
  - Plant/Facility Tour
  - Audit Management process
- Afternoon:
  - Review Device Marketing Authorization and Facility Registration
  - Conduct Daily Wrap-up

Example 1: Audit Plan

- Day 2 Morning:
  - Audit Measurement, Analysis and Improvement process
- Afternoon:
  - Continue auditing Measurement, Analysis and Improvement
  - Audit Medical Device Adverse Events and Advisory Notices
  - Conduct Daily Wrap-up

Example 1: Audit Plan

- Day 3 Morning:
  - Audit Design and Development process
- Afternoon:
  - Continue auditing Design and Development process
  - Audit Purchasing
  - Conduct Daily Wrap-up

Example 1: Audit Plan

- Day 4 Morning:
  - Audit Production and Service Controls
- Afternoon
  - Continue auditing Production and Service Controls
  - Write nonconformities
  - Conduct Closing Meeting

Example 2: Audit Plan

Day 1	Auditor 1	Auditor 2
Morning	Opening Meeting	Opening Meeting
	Plant/Facility Tour	Plant/Facility Tour
	Audit Management Process	Audit Device Marketing Authorization and Facility Registration process
Afternoon	Audit Measurement, Analysis and Improvement Process	Audit Adverse Events and Advisory Notices process
	Daily Wrap-up	Daily Wrap-up

Example 2: Audit Plan

Day 2	Auditor 1	Auditor 2
Morning	Audit Design and Development process	Audit Purchasing process
Afternoon	Audit Production and Service Controls process	Audit Production and Service Controls process
	Audit team meeting	Audit team meeting
	Closing Meeting	Closing Meeting

MDSAP Audit Cycle

- Consists of a three-year cycle as described in [ISO/IEC 17021-1:2015(E)]:
  - A full or “certification” audit initially
  - A partial or surveillance audit the following two years
  - A full “re-certification” or “re-audit’ in the third year

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Surveillance Audits

- Not complete audits and do not cover all the MDSAP processes
- Have a number of fixed tasks to be covered
- Have a variable component dictated by the circumstances of the audit

Surveillance Audits

- All surveillance audits must cover at least the following:
  - A review of changes to the manufacturer, QMS, or products since the last audit
  - The items described in MDSAP AU P0008: Audit Time Determination Procedure, Appendix 1

Surveillance Audits

- Audit evidence collected during the fixed tasks indicates existing or potential nonconformity:
  - The auditor follows audit trails into the Design and Development process
  - The auditor follows trails into the Production and Service Controls process as appropriate
- Audits tasks should be completed as applicable to the audit trails

Surveillance Audits

- Audit evidence collected during the fixed tasks does not indicate particular audit trails to follow
  - The auditor will complete either the Design and Development process or the Production and Service Controls process
- The Purchasing process can be audited as needed at any point during a surveillance audit

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 17021-1:2015(E)]

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
  - Procedure for Recalls, Product Alerts and Product Corrections (PRAC)
- Brazil (ANVISA)
  - Brazilian Good Manufacturing Practices (RDC ANVISA 665/2022)

References

- 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

- MDSAP training will focus on the assessment of the organization's entire quality management system and the assessment of additional participating country-specific requirements.
- MDSAP Audits allow a medical device manufacturer to have a single quality management system audit.
- MDSAP Audit approach has a total of seven processes arranged in a set sequence.
- MDSAP audits have a number of fixed tasks to be covered.

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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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