Introduction to the MDSAP Audit Approach

Instructors

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Objectives

- Describe the purpose of the MDSAP program
- Discuss the MDSAP Approach
- Explain the MDSAP audit sequence
- Provide a real-time demonstration of the MDSAP Audit Approach

What is MDSAP?

What is MDSAP?

The Medical Device Single Audit Program (MDSAP) is a regulatory audit program that was initially jointly developed by four jurisdictions.

It allows a medical device manufacturer to have a single quality management system audit to satisfy the requirements of all participating regulatory authorities.

What is MDSAP?

The current participating regulatory authorities (RAs):

Therapeutic Goods Administration (TGA)

Agência Nacional de Vigilância Sanitária (ANVISA)

Health Canada (HC)

Japan (MHLW/PMDA)

Food and Drug Administration (FDA)

What is MDSAP?

As currently implemented, MDSAP allows any medical device manufacturer to contract with an MDSAP recognized Auditing Organization (AO) to have a single regulatory quality management system audit that meets the requirements of all participating Regulatory Authorities.

Each country defines how MDSAP outcomes are used within its jurisdiction in accordance with its legislation and regulatory framework.

Why was MDSAP developed?

MDSAP development

- 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.

- The overall goal is to create an international coalition of countries dedicated to pooling technology, resources, and services to improve the safety and oversight of medical devices in a more efficient manner that is also less burdensome for industry.

MDSAP development

The MDSAP objectives are:

- 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 while minimizing regulatory burden on industry

MDSAP development

The MDSAP objectives are (*continued*):

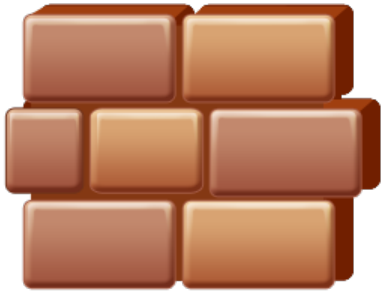
- To promote more efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among regulators while respecting the independence of each authority.

- To promote, in the longer term, greater alignment of regulatory approaches and technical requirements globally based on international standards and best practices.

What is the MDSAP Audit Approach?

MDSAP Audit Approach

- The MDSAP Audit Approach has a total of seven processes, arranged in a set sequence, and built on a foundation of risk management.



MDSAP Audit Approach

- The MDSAP audit sequence follows a process approach and has four primary processes:

  (1) Management

  (2) Measurement, Analysis and Improvement

  (3) Design and Development

  (4) Production and Service Controls

  And a supporting process:

  (5) Purchasing

MDSAP Audit Approach

- These five processes are built on a foundation of requirements for risk management and 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 16/2013)
  - Japan Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (MHLW Ministerial Ordinance No. 169)
  - Quality System Regulation (21 CFR Part 820)

MDSAP Audit Approach

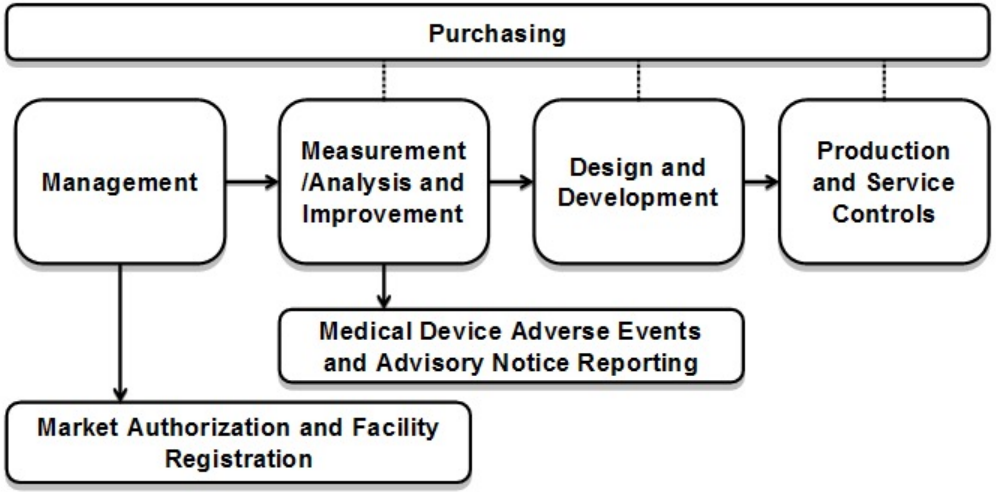
- The MDSAP audit process has two additional supporting processes:
  (1) Medical Device Adverse Events and Advisory Notices Reporting
  (2) Device Marketing Authorization and Facility Registration.

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

What is the MDSAP audit sequence?

MDSAP audit sequence

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



Why is there a prescribed MDSAP audit sequence?

- The MDSAP audit sequence was designed and developed to allow for the audit to be conducted in a logical, focused, and efficient manner

- Information learned during the audit of one process will be used to make decisions about what to select for audit during the next process

Why is there a prescribed MDSAP audit sequence?

- The use of the MDSAP audit sequence will assist the auditor in assessing the potential interrelationship of the nonconformities observed

Example

- Information regarding device or identified quality management system nonconformities observed during the audit of the Measurement, Analysis and Improvement process should be used to make decisions as to:
  - 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 the Production and Service Controls process

Example

- Audit of the Design and Development process will follow audit of the Measurement, Analysis and Improvement process per the MDSAP audit sequence.
  - Information regarding product or quality system nonconformities noted during audit of the Measurement, Analysis and Improvement process should be considered when making decisions as to the design and development projects, including design changes resulting from corrective actions, to be reviewed during the audit of the Design and Development process.

Example

- Audit of the Production and Service Controls process will follow audit of the Measurement, Analysis and Improvement process and the Design and Development process per the MDSAP audit sequence.
  - Information the audit team has learned about device and quality management system nonconformities during audit of the Measurement, Analysis and Improvement process, as well as higher risk elements and essential design outputs from the design projects reviewed during audit of the Design and Development process, should be used to make decisions as to the production processes to be reviewed during the audit of the Production and Service Controls process.

MDSAP audit sequence

- By following the MDSAP audit sequence:
  - Audits performed for MDSAP will be conducted in a consistent manner across auditing organizations
  - Audits will be conducted logically and efficiently, with attention to the interactions between processes
  - Auditors will be able to determine whether systemic quality management system nonconformities are present

MDSAP audit processes

MDSAP audit processes

- Each MDSAP process contains a purpose and a number of anticipated outcomes or objectives that are further broken down into specific tasks. Each task has audit criteria associated with it.

- The audit tasks are based on the clauses in ISO 13485:2016 and the regulatory requirements of the participating Regulatory Authorities.

MDSAP audit processes

- Australia
  - *Therapeutic Goods Act 1989*
  - Therapeutic Goods (Medical Devices) Regulations 2002
  - Uniform Recall Procedure for Therapeutic Goods (URPTG)

MDSAP audit processes

- Brazilian Medical Device Regulations
  - Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013)

MDSAP audit processes

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

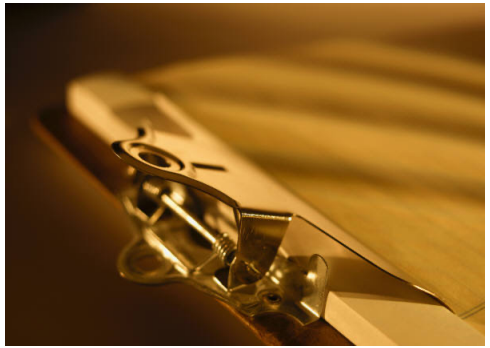
MDSAP audit processes

- Japan
  - 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 processes

- United States Food and Drug Administration
  - 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 tasks



MDSAP audit tasks

- During the accomplishment of the audit task, the auditor will be assessing:
  - Organization's conformity to the applicable clause of ISO 13485:2016
  - Any additional country-specific requirement

- The audit task is written to incorporate the requirement of the applicable ISO 13485:2016 clause and aspects of country-specific requirements

MDSAP audit tasks

- Why not just perform an audit to ISO 13485:2016?
  - Not all the regulatory authorities have adopted ISO 13485:2016 as their regulatory requirement
  - While the regulatory requirements of Brazil and the United States are aligned with the majority of ISO 13485:2016, there are additional requirements contained in Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013) and FDA Quality System Regulation (21 CFR Part 820)

MDSAP audit tasks

- Why not just perform an audit to ISO 13485:2016?
  - There are specific requirements for each MDSAP participating regulatory in terms of medical device adverse event reporting, advisory notice reporting, device marketing authorization, and facility registration

MDSAP audit tasks

- Is there any flexibility in the order that the audit tasks within an MDSAP audit process are performed?
  - Yes. While the audit tasks have been arranged in a logical order to conduct an audit of the MDSAP process, the audit tasks may be performed in any order to facilitate a thorough and efficient audit of the process

MDSAP audit tasks

- Linkages and interactions between the MDSAP processes are highlighted (in red).

- Tasks involving risk management and risk-based decisions are also singled out (in blue.)

Linkages

- During the audit of the firm's quality management system as identified in the seven MDSAP processes, the audit team will be asked to be mindful of "linkages"

- In order for an organization's quality management system to function effectively, it has to identify and manage numerous interrelated (linked) processes. The output of one process often directly forms the input of other processes, or the activities of a supporting process are relevant to other processes

Linkages

- Linkages were built into the MDSAP audit sequence and audit tasks to remind the audit team of the interactions between the processes.

- Linkages assist auditors to make appropriate selections when moving to the next process

Risk Management

- The audit team is also asked to assess risk management activities during the audit of the organization's quality management system processes

- Risk management is an integral aspect of an organization's quality management system, and it is the responsibility of top management to provide the necessary commitment and resources for risk management

Risk Management

- Effective risk management usually starts in conjunction with the design and development process, proceeds through product realization, including the selection of suppliers, and continues until the time the product is decommissioned

- Risk-based decisions occur throughout the various quality management system processes, and each organization must decide how much risk is acceptable to ensure medical devices are as safe as practical

Outsourcing, exclusions, and non-applicability

What about outsourcing?

- The design and implementation of an organization's quality management system is a strategic decision of an organization, based on the needs of the organization, the size of the organization, the processes employed, and the products provided.

- If the organization does not perform certain processes (e.g. Design and Development), then the organization's quality management system does not need to address such a requirement and the corresponding MDSAP process does not need to be audited.

- **However**, if the organization chooses to outsource any processes related to the design and/or manufacture of medical devices for which the organization has responsibility, these suppliers and supplied processes **must** be controlled within the organization's quality management system.

What about non-applicability and exclusions?

- In addition to the exclusions and non-applications permitted by ISO13485, 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

- When an organization claims an exclusion from the requirements of a target market, the auditor should use caution when applying the guidance provided in the MDSAP processes. Some requirements may not be applicable

MDSAP Audit Approach

- Demonstration
  - MDSAP Audit Approach is found on the MDSAP website, MDSAP Audit Procedures and Forms, under heading MDSAP AU P0002
  - https://www.fda.gov/medical-devices/medical-device-single-audit-program-mdsap/mdsap-audit-procedures-and-forms


MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM