FDA U.S. FOOD & DRUG ADMINISTRATION

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

# Device Marketing Authorization and Facility Registration

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# Course Prerequisites

- Successful completion of the following MDSAP training modules is a prerequisite to this course:
  - Introduction to the MDSAP Program
  - Overview of the MDSAP Audit Process
  - MDSAP: Management Process

# Learning Objectives

- Explain the Device Marketing Authorization and Facility Registration process
- Describe the purpose of auditing the Device Marketing Authorization and Facility Registration process
- Discuss the expected outcomes from audit of the Device Marketing Authorization and Facility Registration 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

# Learning Objectives

- **Explain the Device Marketing Authorization and Facility Registration process**

- Describe the purpose of auditing the Device Marketing Authorization and Facility Registration process

- Discuss the expected outcomes from audit of the Device Marketing Authorization and Facility Registration process

- Explain the audit tasks to include:
  - Description, Clause and Regulation
  - Country-specific requirements and assessment of conformity
  - Links to other MDSAP processes

# Device Marketing Authorization and Facility Registration process

- May be audited as a linkage from:
  - The Management process
  - The Design and Development process

# Learning Objectives

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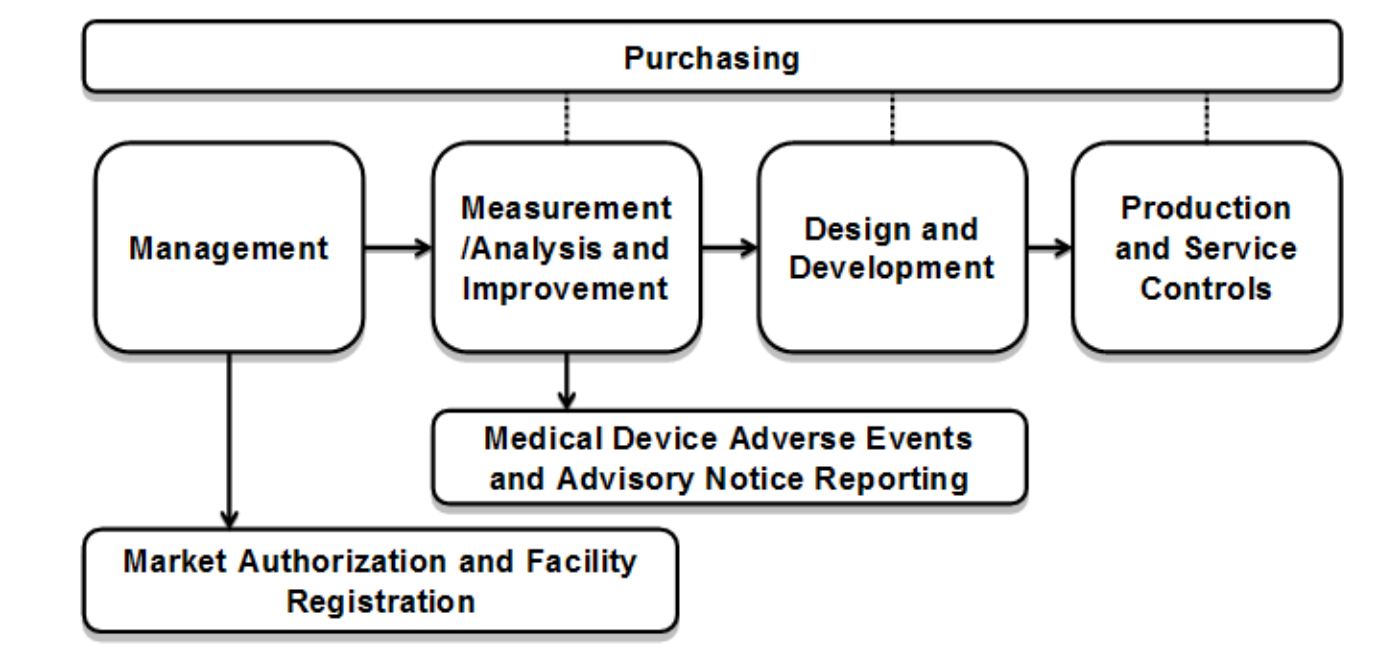
# MDSAP Audit Sequence



# Purpose of Auditing

- The Device Marketing Authorization and Facility Registration process is audited to:
  - Verify that the organization has performed the appropriate activities regarding device marketing authorization and facility registration with regulatory authorities participating in the MDSAP

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# Expected Outcomes

As a result of the audit of the Device Marketing Authorization and Facility Registration process, objective evidence will show whether the organization has:

(A) Complied with requirements to register and/or license device facilities

(B) Submitted device listing information to regulatory authorities when applicable

(C) Obtained device marketing authorization in the appropriate jurisdictions

(D) Arranged for assessment of changes (where applicable) and obtained marketing authorization for changes to devices or the quality management system which require amendment to existing marketing authorization

# Learning Objectives

- Explain the Device Marketing Authorization and Facility Registration process
- Describe the purpose of auditing the Device Marketing Authorization and Facility Registration process
- Discuss the expected outcomes from audit of the Device Marketing Authorization and Facility Registration process
- **Explain the audit tasks to include:**
  - **Description, Clause and Regulation**
  - **Country-specific requirements and assessment of conformity**
  - **Links to other MDSAP processes**

# Task 1

1. **Verify the organization has complied with regulatory requirements to register and/or license device facilities and submit device listing information in the appropriate jurisdictions where the organization markets or distributes their devices.**

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

MDSAP Audit Approach

# Task 1

- Additional country-specific requirements:

  Australia (TGA); Brazil (ANVISA); Canada (HC); Japan (MHLW); and United States (FDA)

- Assessing conformity:
  - Review labeling for product being supplied to a particular jurisdiction

  Detailed Information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 2: Device Marketing Authorization and Facility Registration under task 1

# Task 1

- *Links:*
  - *Management*
    - ➢ During audit of the Management process:
      - o Confirm that management is aware of and has made arrangements for device marketing authorization and facility registration

# Task 2

2. **Confirm the medical device organization has received appropriate marketing clearance or approval in the regulatory jurisdictions where the organization markets their devices.**

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

MDSAP Audit Approach

# Task 2

- Additional country-specific requirements: Australia (TGA); Brazil (ANVISA); Canada (HC); Japan (MHLW); and United States (FDA)

- Assessing conformity:

  Information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 2: Device Marketing Authorization and Facility Registration under task 2

# Task 2

- *Links:*
  - *Management*
  - *Design and Development*
    - During the audit of the Management and Design and Development processes:
      - Ensure that management is aware of requirements for device marketing authorization and facility registration,
      - Ensure that these are considered when designing the device.
      - Confirm that management obtains marketing authorization in the appropriate jurisdictions prior to commercial distribution of the device

# Task 3

3. **Verify the organization has identified changes to marketed devices or the quality management system which require notification to regulatory authorities.**

   **The audit team should pay special attention to situations observed in the audit of the Design and Development process (specifically design changes) that may require notification to the jurisdictions to which the changed devices are marketed.**

   *Clause and Regulation*: [ISO 13485:2016: 4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3, 7.3.9; ]

MDSAP Audit Approach

# Task 3

- Additional country-specific requirements: Australia (TGA); Brazil (ANVISA); Canada (HC); Japan (MHLW); and United States (FDA)

- Assessing conformity:

  Information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 5: Design and Development, under task 3.

# Task 3

- *Links:*
  - *–Design and Development*

- During the audit of the Design and Development process the audit team should:
  - Confirm the organization has considered regulatory requirements for device marketing authorization and facility registration
  - Confirm the organization has complied with requirements prior to marketing the changed device in the applicable regulatory jurisdictions

# Summary

- The Device Marketing Authorization and Facility Registration process may be audited as a linkage from the Management process or the Design and Development process.

# Conclusion

This concludes the training module for MDSAP process: Device Marketing Authorization and Facility Registration.


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