FDA U.S. FOOD & DRUG ADMINISTRATION

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Medical Device Adverse Events and Advisory Notices Reporting Process

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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 MDSAP Audit Process
  - MSDSAP: Management Process
  - MDSAP: Measurement, Analysis and Improvement Process

Learning Objectives

- Explain the Medical Device Adverse Events and Advisory Notices Reporting process
- Describe the purpose of auditing the Medical Device Adverse Events and Advisory Notices Reporting process
- Discuss the expected outcomes from audit of the Medical Device Adverse Events and Advisory Notices Reporting 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

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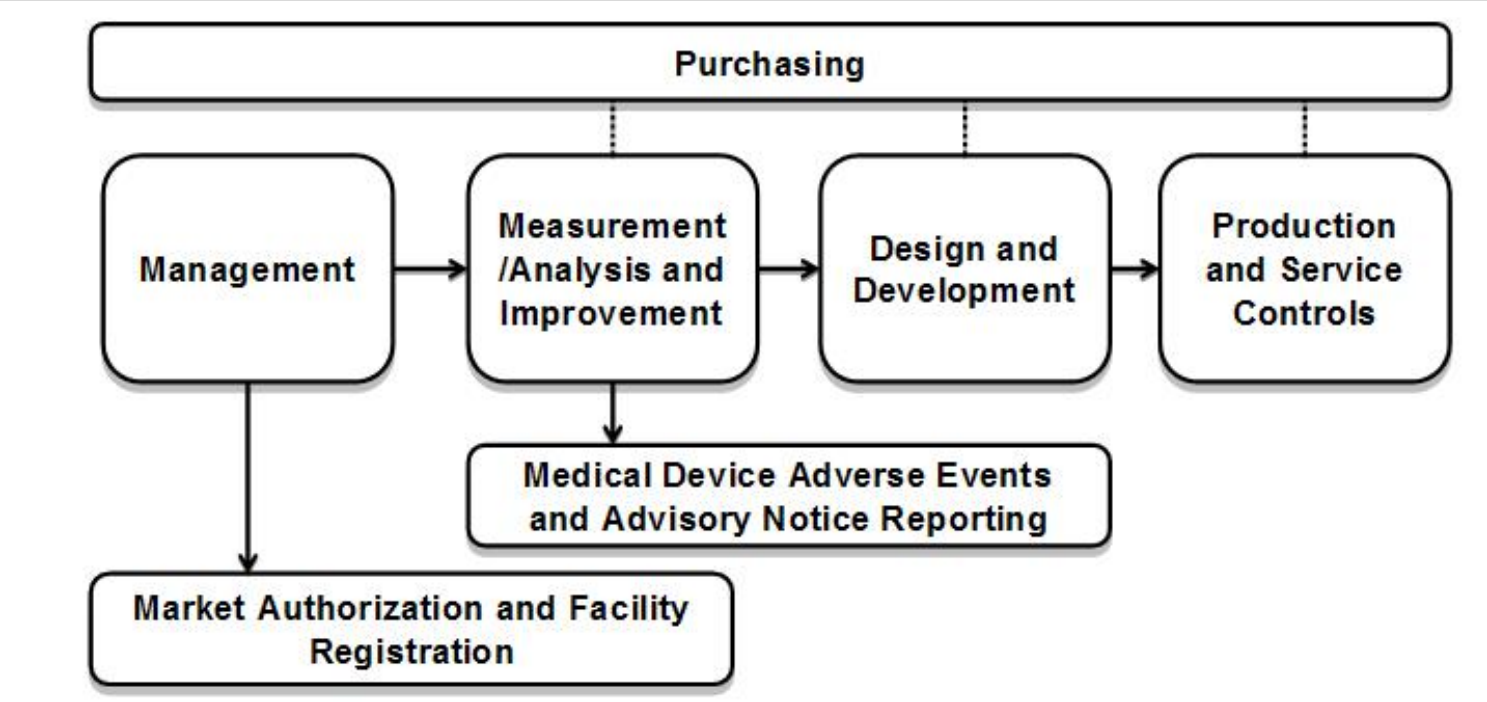
MDSAP Audit Sequence



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Purpose of Auditing

- The Medical Device Adverse Events and Advisory Notices Reporting process is audited to:
  - Verify that the organization's processes ensure that adverse events and advisory notices are reported:
    - To regulatory authorities
    - Within required timeframes

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Expected Outcomes

As a result of the audit of the Medical Device Adverse Events and Advisory Notices Reporting process, objective evidence will show whether the organization has:

A. Defined processes to ensure individual device-related adverse events are reported to regulatory authorities as required

B. Ensured that advisory notices are reported to regulatory authorities and authorized representatives when necessary

C. Maintained appropriate records of individual device-related adverse events and advisory notices

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Task 1

1. **Verify that the organization has a process in place for identifying device-related events that may meet reporting criteria as defined by participating regulatory authorities. Verify that the complaint process has a mechanism for reviewing each complaint to determine if a report to a regulatory authority is required. Confirm that the organization's processes meet the timeframes required by each regulatory authority where the product is marketed.**

   Clause and Regulation: [ISO 13485:2016: 4.2.1, 7.2.3, 8.2.2, 8.2.3]

MDSAP Audit Approach

Task 1

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

- Assessing conformity:

  Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 4: Medical Device Adverse Events and Advisory Notices Reporting Process, under task 1

Task 1

- *Links:*
  - *Measurement, Analysis and Improvement*
    - ➢ During the audit of the Measurement, Analysis and Improvement process:
      - Confirm that the organization has considered individual adverse events and trends of adverse events

Task 2

2. **Verify that advisory notices are reported to regulatory authorities when necessary and comply with the timeframes and recordkeeping requirements established by participating regulatory authorities.**

Clause and Regulation: [ISO 13485:2016: 4.2.1, 7.2.3,8.2.3, 8.3.3]

MDSAP Audit Approach

Task 2

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

- Assessing conformity:

  Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 4: Medical Device Adverse Events and Advisory Notices Reporting Process, under task 2

Task 2

- *Links:*
  - *Measurement, Analysis and Improvement*

➢During the audit of the Measurement, Analysis and Improvement process:

- Confirm the organization has taken appropriate correction regarding devices already distributed
- Confirm the organization has taken appropriate corrective action

Summary

- The Medical Device Adverse Events and Advisory Notices Reporting process is audited as a linkage from the Measurement, Analysis and Improvement process.

- When specified requirements or planned results are not achieved, correction and corrective action must be taken as necessary.

Conclusion

This concludes the training module for MDSAP process: Medical Device Adverse Events and Advisory Notices Reporting


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