

MDSAP: Medical Device Adverse Events and Advisory Notices Reporting Process

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I am CAPT Kimberly Lewandowski-Walker, Senior Regulatory Officer at the Center for Devices and Radiological Health at the U.S. Food and Drug Administration. In this training module, we will be reviewing the Medical Device Adverse Events and Advisory Notices Reporting process for the Medical Device Single Audit Program.

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Successful completion of the MDSAP training modules "Introduction to the MDSAP Program," "Overview of the MDSAP Audit Process," "MDSAP: Management Process," and "MDSAP: Measurement, Analysis and Improvement" are prerequisites to this course.

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In this training module, we will explain the Medical Device Adverse Events and Advisory Notices Reporting process, describe the purpose of auditing this process, discuss the expected outcomes from audit of the process, and explain the audit tasks in terms of the description and related Clauses and Regulations for each audit task, the list of country-specific requirements and assessment of conformity for each audit task, and finally indicate the links of the Medical Device Adverse Events and Advisory Notices Reporting process to other MDSAP processes.

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We will first begin with explaining the Medical Device Adverse Events and Advisory Notices Reporting process.

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As you can see from this diagram, the Medical Device Adverse Events and Advisory Notices Reporting process is audited as a linkage from the Measurement, Analysis and Improvement process. The primary reason for this is that complaints, reportable adverse events, and nonconformities leading to recall are quality data sources for the Measurement, Analysis and Improvement process.

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We will now move to a discussion of the purpose of auditing the Medical Device Adverse Events and Advisory Notices Reporting process.

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The purpose of auditing the Medical Device Adverse Events and Advisory Notices Reporting process is to verify that the organization's processes ensure that individual device-related adverse events and advisory notices involving medical devices are reported to regulatory authorities within required timeframes.

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Let's discuss the expected outcomes from auditing the Medical Device Adverse Events and Advisory Notices Reporting process.

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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 defined processes to ensure individual

device-related adverse events are reported to regulatory authorities as required, ensured that advisory notices are reported to regulatory authorities and authorized representatives when necessary, and maintained appropriate records of individual device-related adverse events and advisory notices.

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Accomplishment of the outcomes for the Medical Device Adverse Events and Advisory Notices Reporting process is accomplished through the completion of the audit tasks. For this process, the primary means of accomplishing the audit tasks is by verifying the organization meets the regulatory requirements of the various jurisdictions participating in the Medical Device Single Audit Program.

We will now discuss the audit tasks in terms of the description and related Clauses and Regulations for each audit task, the Country-specific requirements and assessment of conformity, and the Links of the Medical Device Adverse Events and Advisory Notices Reporting process to other MDSAP processes.

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Task 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.

The related clauses of ISO 13485:2016 are listed on this slide. There are no related regulations for the participating countries.

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There are additional country-specific requirements for Australia, Brazil, Canada, Japan, and the United States. Detailed information on the country-specific requirements and how to assess conformity for this audit task are in the MDSAP Audit Approach, Chapter 4: Medical Device Adverse Events and Advisory Notices Reporting Process, under Task 1.

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This task has a link to Measurement, Analysis and Improvement processes. Reports of individual adverse events are a form of feedback and must be analyzed, as appropriate, for trends requiring improvement or corrective action.

During the audit of the Measurement, Analysis and Improvement process, confirm that the organization has considered individual adverse events and trends of adverse events in the analysis of data.

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Task 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.

The related clauses of ISO 13485:2016 are listed on this slide. There are no related regulations for the participating countries.

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There are additional country-specific requirements for Australia, Brazil, Canada, Japan, and the United States. Detailed information on country-specific requirements and how to assess conformity for this audit task are in the MDSAP Audit Approach, Chapter 4: Medical Device Adverse Events and Advisory Notices Reporting Process, under Task 2.

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This task has a link to Measurement, Analysis and Improvement process. It is important to remember that corrections and removals are indicative that the product or process does not meet specified requirements or planned results and the nonconformity was not detected prior to distribution.

When specified requirements or planned results are not achieved, correction and corrective action must be taken as necessary. During the audit of the Measurement, Analysis and Improvement process, confirm the organization has taken appropriate correction regarding devices already distributed, and taken appropriate corrective action to prevent recurrence of the conditions that caused the nonconformity.

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In 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.

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This concludes the training module for MDSAP process, Medical Device Adverse Events and Advisory Notice Reporting.