MDSAP: Measurement Analysis and Improvement 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 Measurement, Analysis and Improvement process for the Medical Device Single Audit Program.

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The prerequisites for understanding this Measurement, Analysis and Improvement process training module are the MDSAP training modules: 'Introduction to the MDSAP Program", "Overview of the MDSAP Process", "MDSAP: Management Process", and "MDSAP: Device Marketing Authorization and Facility Registration Process".

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

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We will begin with explaining the Measurement, Analysis and Improvement process.

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One of the most important activities in the quality management system is the identification of existing and potential causes of product and quality problems. Such causes must be identified so that appropriate and effective corrective or preventive actions can take place. These activities are carried out under the Measurement, Analysis and Improvement process.

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The purpose of an organization's Measurement, Analysis and Improvement process is to collect and analyze information, identify and investigate existing and potential causes of product and quality problems, and take appropriate and effective corrective or preventive action to prevent recurrence or occurrence. It is essential that an organization verify or validate these actions, communicate corrective and preventive action activities to responsible people, provide relevant information for management review, and document these activities. These activities will help the organization deal effectively with existing or potential product and quality problems, prevent their recurrence or occurrence, and prevent or minimize device failures or other quality problems.

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What is the purpose of auditing the Measurement, Analysis and Improvement process?

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As you can see from this diagram, the Measurement, Analysis and Improvement process is the second primary process to be audited per the MDSAP audit sequence. When applicable, 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, and processes to review during audit of the Production and Service Controls process.

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The purpose of auditing the Measurement, Analysis and Improvement process is to verify that the manufacturer's processes ensure that information related to products, processes, or the quality management system is collected and analyzed to identify actual and potential product, process, or quality system nonconformities, that problems and potential problems are investigated, and that appropriate and effective corrective actions and preventive actions are taken.

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We will now move to a discussion of the expected outcomes from the audit of the Measurement, Analysis and Improvement process.

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As a result of the audit of the Measurement, Analysis and Improvement process, objective evidence will show whether the organization has: defined, documented, and implemented procedures for measurement, analysis and improvement that address the requirements of the quality management system standard and participating MDSAP regulatory authorities and has identified, analyzed, and monitored appropriate sources of quality data to identify nonconformities or potential nonconformities and determined the need for corrective or preventive action.

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Additional outcomes include ensuring investigations are conducted to identify the underlying causes of nonconformities and potential nonconformities, where possible; and implementing appropriate corrective action to eliminate the recurrence, or preventive action to prevent the occurrence, of product or quality system nonconformities, commensurate with the risks associated with the nonconformities or potential nonconformities encountered.

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Objective evidence will show whether the organization has reviewed the effectiveness of corrective actions and preventive actions and utilized information from the analysis of production and post-production quality data to amend the analysis of product risk, as appropriate.

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We will now explain the audit tasks in terms of the description and related Clauses and Regulations, list country-specific requirements and assessment of conformity for each audit task, and indicate the links to other MDSAP processes.

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Task 1: Verify that procedures for measurement, analysis and improvement which address the requirements of the quality management system standard and regulatory authorities have been established and documented. Confirm the organization maintains and implements procedures to monitor and measure product conformity throughout product realization, as well as procedures that provide for mechanisms for feedback to provide early warnings of quality

The related clauses of ISO 13485:2016 are listed on this slide along with the related regulations for the participating countries.

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There are additional country-specific requirements for Brazil and the United States.
Detailed information on country specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 1.

There are no additional linkages for this task to other audit processes.

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Task 2: Determine if appropriate sources of quality data have been identified for input into the measurement, analysis and improvement process, including customer complaints, feedback, service records, returned product, internal and external audit findings, and data from the monitoring of products, processes, nonconforming products, and suppliers. Confirm that data from these sources are accurate and analyzed using valid statistical methods (where appropriate) to identify existing and potential product and quality management system nonconformities that may require corrective or preventive action. Information from the organization's analysis of quality data should be used to inform the audit team's decision as to specific complaint records to review in Task 12, and products and processes to audit during the Design and Development, Production and Service Controls, and Purchasing processes.

The related clauses of ISO 13485:2016 are listed on this slide along with the related regulations for the participating countries.

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There are no additional country-specific requirements for this task. Assessing conformity includes reviewing the previous audit report if there is one for the medical device organization, considering reviewing service records again to determine whether the previous deficiency was effectively addressed, and sampling raw quality data. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 2.

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This task has a link to Purchasing processes. During the audit of the Measurement, Analysis and Improvement process, the audit team may encounter data involving product nonconformities, including complaints involving finished devices, where the underlying cause of the quality problem has been traced to a supplied product. During the audit of the Purchasing process, the audit team should consider selecting suppliers to audit that have corrective action indicators of nonconformities with supplied components or processes.

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Task 3: Determine if investigations are conducted to identify the underlying causes of detected nonconformities, where possible. Confirm investigations are commensurate with the risk of the nonconformity.

The related clauses of ISO 13485:2016 are listed on this slide along with the related regulations for the participating countries.

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There are no additional country-specific requirements for this task. Assessing conformity includes selecting records of investigation where nonconformity has a higher risk of adversely affecting the ability of the finished device to meet its essential design outputs or the nonconformity affects the safety and efficacy of the product. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 3.

There are no additional linkages for this task to other audit processes.

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Task 4: Determine if investigations are conducted to identify the underlying causes of potential nonconformities, where possible. Confirm investigations are commensurate with the risk of the potential nonconformity.

The related clauses of ISO 13485:2016 are listed on this slide along with the related regulations for the participating countries.

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There are no additional country-specific requirements for this task. Assessing conformity includes selecting records of investigation where the potential nonconformity has a higher risk of adversely affecting the ability of the finished device to meet its essential design outputs or the potential nonconformity could affect the safety and efficacy of the product. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 4.

There are no additional linkages for this task to other audit processes.

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Task 5: Confirm that corrections, corrective actions, and preventive actions were determined, implemented, documented, effective, and did not adversely affect finished devices. Ensure corrective action and preventive action is appropriate to the risk of the nonconformities or potential nonconformities encountered.

The related clauses of ISO 13485:2016 are listed on this slide along with the related regulations for the participating countries.

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There are no additional country-specific requirements for this task. Assessing conformity includes confirming that the medical device organization's decision not to take corrective action has been made using appropriate risk based decision making including a determination that the finished device meets risk acceptability criteria and looking for product or quality problems or trends that continued or began after the actions were implemented. Detailed information on how to assess conformity for this audit

task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 5.

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This task has a link to Medical Device Adverse Events and Advisory Notices Reporting processes. Determine whether any of the organization's corrective actions require reporting to participating MDSAP authorities. The organization should be able to demonstrate to the auditor how it evaluates corrective actions to determine whether they require reporting to authorities. At this point in the audit, if you have found a number of corrective actions that require reporting to one or more of the regulatory authorities in the MDSAP, you can opt to move into the Medical Device Adverse Events and Advisory Notices Reporting process.

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Task 6: When a corrective or preventive action results in a design change, verify that any new hazard(s) and any new risks are evaluated under the risk management process.

The related clauses of ISO 13485:2016 are listed on this slide along with the related regulations for the participating countries.

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There are no additional country-specific requirements for this task. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 6.

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This task has a link to Design and Development processes. If the corrective action or preventive action involves changing the design, design controls should be applied to the change where applicable. When necessary, confirm that design controls were applied to the change according to the organization’s procedures. In addition, the organization should evaluate design changes as part of its risk management activities to ensure that changes do not introduce new hazards.

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Task 7: When a corrective or preventive action results in a process change, confirm that the process change is assessed to determine if any new risks to the product are introduced. Verify the manufacturer has performed revalidation of processes where appropriate.

The related clauses of ISO 13485:2016 are listed on this slide along with the related regulations for the participating countries.

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There are additional country-specific requirements for Australia, Canada, and Japan. Assessing conformity includes reviewing the medical device organization’s evaluation of the process change to determine if revalidation is needed. For changes to production processes that are performed by suppliers, consider selecting suppliers for evaluation during audit of the Purchasing process. Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 7.

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This audit task has linkages to the Production and Service Controls and Purchasing processes.
If the corrective action or preventive action involves changing a production process, the audit team should consider selecting this process for evaluation during the audit of Production and Service Controls. For changes to production processes that are performed by suppliers, the audit team should consider selecting those suppliers for evaluation during audit of the Purchasing process.

In cases where the organization makes a change to a validated process performed by a supplier, the audit team should evaluate when necessary if re-validation is required. If re-validation of production processes is required, confirm the results show the process meets the planned result.

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Task 8: Verify that controls are in place to ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. Confirm that an appropriate disposition was made, justified, and documented; and that any external party responsible for the nonconformity was notified.

The related clauses of ISO 13485:2016 are listed on this slide along with the related regulations for the participating countries.

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There are no additional country-specific requirements for this task. Review procedures and controls for preventing the unintended distribution of nonconforming product. Assessing conformity includes: selecting a sample of records involving nonconforming product that was in stock or returned to review how the procedures and controls were applied to control the nonconforming Product; confirming that the medical device organization's decision to use nonconforming product under concession has been made using appropriate risk-based decision making; and selecting records of nonconforming products to review where the nonconformity has a higher risk of adversely affecting the ability of the finished device to meet its essential design outputs or the nonconformity affects the safety and efficacy of the product. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 8.

There are no additional linkages for this task to other audit processes.

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Task 9: Confirm that when nonconforming product is detected after delivery or use, appropriate action is taken commensurate with the risk, or potential risks, of the nonconformity.

The related clauses of ISO 13485:2016 are listed on this slide along with the related regulations for the participating countries.

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There are no additional country-specific requirements for this task. Assessing conformity includes confirming that the medical device organization has determined the control and actions to be taken on nonconforming products detected after delivery or use, commensurate with the risk associated with a product failure and confirming that the decision is made using an adequate risk justification.

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 9

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This task has a link to Medical Device Adverse Events and Advisory Notices Reporting processes.
If the organization has taken field action on products already distributed, confirm that the appropriate MDSAP regulatory authorities have been notified, as necessary. At this point in the audit, if you have found a number of corrective actions that resulted in recalls or field actions that require reporting to one or more of the regulatory authorities in the MDSAP, you can opt to move into the Medical Device Adverse Events and Advisory Notices Reporting process if you haven't already completed this.

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Task 10: Verify that internal audits of the quality management system are being conducted according to planned arrangements and documented procedures to ensure the quality management system is in compliance with the established quality management system requirements and applicable regulatory requirements, and to determine the effectiveness of the quality system. Confirm the internal audits include provisions for auditor independence over the areas being audited, corrections, corrective actions, follow-up activities, and the verification of corrective actions.

The related clauses of ISO 13485:2016 are listed on this slide along with the related regulations for the participating countries.

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There are no additional country-specific requirements for this task. Assessing conformity includes interviewing auditors and ask how are audits conducted, how long audits typically last, and what documents are typically reviewed. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 10.

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 10

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This task has a link to Management processes. During the audit of the Management process, the audit team should confirm that the output of internal audits is an input to management review.

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Task 11: Determine if relevant information regarding nonconforming product, quality management system nonconformities, corrections, corrective actions, and preventive actions has been supplied to management for management review.

The related clauses of ISO 13485:2016 are listed on this slide along with the related regulations for the participating countries.

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There are no additional country-specific requirements for this task. Assessing conformity includes selecting a recent, significant corrective or preventive action and determine which records or information regarding the event was submitted for management review. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 11.

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This task has a link to Management processes. During the audit of the Management process, the audit team should have confirmed that the status of corrective and preventive actions is an input to management review. During the audit of the Measurement, Analysis and Improvement process, determine that top management is aware of higher-risk quality problems, as well as significant corrective and preventive actions, when necessary.

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Task 12: Confirm that the manufacturer has made effective arrangements for gaining experience from the post-production phase, handling complaints, and investigating the cause of nonconformities related to advisory notices with provision for feedback into the Measurement, Analysis and Improvement process. Select records of complaints for review that represent the highest risk to the user or have the largest impact on the ability of the device to meet its essential design outputs. Verify information from the analysis of production and post-production quality data was considered for amending the analysis of product risk, as appropriate.

The related clauses of ISO 13485:2016 are listed on this slide along with the 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. Assessing conformity includes reviewing complaints and customer feedback, reviewing the analysis of complaint data and postmarket surveillance activities, and selecting one or more complaint failure modes preferably failure modes associated with higher risk to the patient or user. Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 12.

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This task has linkages to Medical Device Adverse Events and Advisory Notices Reporting, Design and Development, and Production and Services Controls processes. During the review of complaints and feedback, confirm that individual medical device reports were made to the appropriate regulatory authorities when necessary. Information from reviewing post-production sources, including complaints and postmarket surveillance reports, should guide the audit team in selecting designs to review and production processes to audit.

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Task 13: Where investigation determines that activities outside the organization contributed to a customer complaint, verify that records show that relevant information was exchanged between the organizations involved.

The related clauses of ISO 13485:2016 are listed on this slide along with the related regulations for the participating countries.

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There are no additional country-specific requirements for this task. Assessing conformity includes confirming that information related to quality problems or nonconforming product, including complaints, is disseminated to those directly responsible for assuring the quality of product. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 13.

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This task has a link to Medical Device Adverse Events and Advisory Notices Reporting processes. During the audit of the Measurement, Analysis and Improvement process, if significant nonconformities are related to supplied product, the audit team should consider selecting those suppliers for evaluation during the audit of the organization's Purchasing process.

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Task 14: Verify that the medical device organization has defined and documented procedures for the evaluation of complaints for adverse event reporting. Confirm that decisions to not report complaints were made according to established procedures and a documented rationale.

The related clauses of ISO 13485:2016 are listed on this slide along with the related regulations for the participating countries.

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For additional country-specific requirements, refer to MDSAP process Medical Device Adverse Events and Advisory Notices Reporting. Assessing conformity includes assessing whether the complaint was evaluated to determine whether the criteria for reporting was met, confirming the appropriate reports and information was provided to the regulatory authority when appropriate, comparing the submitted reports to the associated complaint and complaint investigation, and confirming that reportable events were evaluated for corrective action when necessary. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 14.

There are no additional linkages for this task to other audit processes.

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Confirm that the manufacturer has made effective arrangements for the timely evaluation of quality problems involving distributed product for potential issuance and implementation of advisory notices. Select records for review of quality problems that were evaluated for potential issuance of advisory notices (include records where a decision was made not to issue an advisory notice as well as records of decision to issue advisory notices) and assess whether the organization has taken actions appropriately based on risk and documented the rationale.

The related clauses of ISO 13485:2016 are listed on this slide along with the related regulations for the participating countries.

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For additional country-specific requirements, refer to MDSAP process Medical Device Adverse Events and Advisory Notices Reporting. Assessing conformity includes selecting quality issues that were evaluated for potential advisory actions, assessing whether appropriate actions were taken and the organization's decisions were justified based on the risk of the quality problem to device users, and assessing whether the organization appropriately determined the scope of the quality issue. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 15.

There are no additional linkages for this task to other audit processes.

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Task 16: Determine, based on the assessment of the Measurement, Analysis and Improvement process overall, whether management provides the necessary commitment to detect and address product and quality management system nonconformities, and ensure the continued suitability and effectiveness of the quality management system.

The related clauses of ISO 13485:2016 are listed on this slide along with the related regulations for the participating countries.

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There are no additional country-specific requirements for this task. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 3: Measurement, Analysis and Improvement, under task 16.

There are no additional linkages for this task to other audit processes.

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In summary, the Measurement, Analysis and Improvement process is the second primary process to be audited per the MDSAP audit sequence. The identification of existing and potential causes of product and quality problems is one of the most important activities in the quality management system and is carried out under the Measurement, Analysis and Improvement process.

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This concludes the training for the MDSAP process: Measurement, Analysis and Improvement.