MDSAP: Management Process

Slide 1
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. I will be your instructor for this course.

In this training module, we will be reviewing the Management process for the Medical Device Single Audit Program (or MDSAP) and how to audit this process.

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The prerequisites for understanding this Management Process training module are the MDSAP training modules: "Introduction to the MDSAP Program" and the "Overview of the MDSAP Audit Process".

It is expected that the auditor is proficient in auditing to the Organization for Standardization 13485:2016, Medical Devices- Quality management systems- Requirements for regulatory purposes (or ISO 13485:2016) and is familiar with the specific requirements of the regulatory authorities participating in the MDSAP program in addition to the Successful completion of the listed prerequisites.

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In this training module, we will explain the Management process, describe the purpose of auditing the Management process, discuss the expected outcomes from audit of the Management 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 Management process to other MDSAP processes.

Successful completion of this training module will give the basic knowledge required to audit the Management process.

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Let's begin with explaining the MDSAP Management Process.

Slide 5
The intention of the Management process is to provide adequate resources for device design, manufacturing, quality assurance, distribution, installation, and servicing activities, to assure the quality management system is functioning properly and effectively, and to monitor the quality management system and make necessary adjustments.

A quality management system that has been implemented effectively and is monitored to identify and address existing and potential problems is more likely to produce medical devices that function as intended.

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The management representative plays an important role in the quality management system. The management representative is responsible for ensuring that the requirements of the quality management system have been effectively defined, documented, implemented, and maintained.

Prior to the review of any process, it may be helpful to interview the management representative, or the management representative's designee, to obtain an overview of the process and a feel for management's knowledge and understanding of the process.

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We will now move to discussion of the purpose of auditing the Management process.
So, why do we audit the Management process?

Slide 8
As you can see from this diagram, the Management process is the first process to be audited per the MDSAP audit sequence.

Slide 9
The purpose of auditing the Management process is to verify that top management ensures that an adequate and effective quality management system has been established and maintained and to determine whether top management demonstrated commitment for a quality management system and communicated that commitment to personnel.

Slide 10
A thorough assessment of the organization's Management process is most efficiently made by evaluating the management process both at the beginning of the audit and throughout the audit of the other processes. Therefore, the audit should commence and end with the management process.

This doesn't mean that the audit tasks are repeated, but only that the final conclusions on the appropriateness and effectiveness of management activities and commitment can only be reached at the end of the audit by considering all the audit evidence collected.

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We will now move to a discussion of the expected outcomes of auditing the Management process.
The next few slides will discuss these outcomes.

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As a result of the audit of the Management process, objective evidence will show whether the organization has identified processes needed for the quality management system, their application throughout the organization, and their sequence and interaction; and has defined, documented, and implemented procedures and instructions to ensure the development and maintenance of an effective quality management system.

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As a result of the audit of the Management process, objective evidence will show whether the organization has: established quality objectives at relevant functions and levels within the organization consistent with the quality policy and ensured that these are periodically reviewed for continued suitability; determined the criteria and methods needed to ensure the operation and control of quality management system processes, including the identification and management of interrelated processes; and committed the appropriate personnel and resources for infrastructure to the quality management system.

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Objective evidence will show whether the organization has: assigned responsibility and authority to personnel and established the organizational structure to ensure processes assuring quality are not compromised; and performed risk management planning and ongoing review of the effectiveness of risk management activities to ensure that policies, procedures and practices are established for analyzing, evaluating and controlling risk.

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As a result of the audit of the Management process, objective evidence will show whether the organization has: ensured the continued effectiveness of the quality management system and its processes and established a quality management system which is capable of producing devices that are safe, effective and suitable for their intended use.

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We will now move to a discussion of each audit task.

The next few slides will Explain 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 Management process to other MDSAP processes.

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Task 1. Confirm that quality management system planning is performed to ensure that all required processes are identified, documented, implemented, monitored and maintained in order to conform to the applicable requirements and meet quality objectives. Verify that changes to the quality management system are managed to maintain the conformity of the quality management system and of the devices produced. Verify that a quality manual has been documented.

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

Slide 18

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 1: Management, under task 1.

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This task has links to various other MDSAP processes, including: Measurement, Analysis and Improvement; Design and Development; Purchasing; Production and Service Controls; and Device Marketing Authorization and Facility Registration. This is because while quality management system planning begins in Management, it spans throughout the other MDSAP processes to include change controls throughout the quality management system.

During the audit, whenever a change is identified, verify that the organization has implemented appropriate change controls.

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Task 2: Confirm top management has documented the appointment of a management representative. Verify the responsibilities of the management representative include ensuring that quality management

system requirements are effectively established and maintained, reporting to top management on the performance of the quality management system, and ensuring the promotion of awareness of regulatory requirements throughout the organization.

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

Slide 21

There are no additional country-specific requirements for this task.

Assessing conformity includes confirming the appointment of, evaluating the responsibility and authority of, and verify the required training of the management representative. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management, under task 2.

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

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Task 3: Verify that a quality policy and objectives have been set at relevant functions and levels within the organization. Ensure the quality objectives are measurable and consistent with the quality policy. Confirm appropriate measures are taken to achieve the quality objectives.

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

Slide 23

There are no additional country-specific requirements for this task.

Assessing conformity includes asking for examples of quality objectives and the status of these objectives. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management, under task 3.

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

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Task 4: Review the manufacturer's organizational structure and related documents to verify that they include provisions for responsibilities, authorities (e.g., management representative), personnel, resources for infrastructure, competencies, and training to ensure that personnel have the necessary competence to design and manufacture devices in accordance with the planned arrangements and applicable regulatory requirements.

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

Slide 25

There are no additional country-specific requirements for this task.

Assessing conformity includes reviewing organizational charts, asking authority and responsibility questions, and asking the management representative to provide examples of recent requests for different types of resources. Detailed Information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management, under task 4

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

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Task 5: Determine the extent of outsourcing of processes that may affect the conformity of product with specified requirements and verify the proper documentation of controls in 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.

Slide 27

There are additional country-specific requirements for Australia and Canada.

Assessing conformity includes ascertaining the extent to which the medical device organization outsources processes that are essential for the proper functioning of the finished medical device. Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management, under task 5.

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This task has a link to Purchasing processes.

At this stage in the audit, the audit team should take stock of the level of outsourcing practiced by the organization and consider the risk involved with this outsourcing. The audit team should determine what the organization's policies regarding outsourcing and purchasing are and who has authority and responsibility for the approval and management of suppliers and supplied products.

During the audit of the Management process, the audit team should begin to assess whether the organization has committed sufficient resources to the management of outsourcing and suppliers; this determination can only be completed by completing the audit of MDSAP Purchasing process, but the ground work for this is laid during the audit of the management process. The integration of risk management activities in the purchasing process should also form part of this task at a high level to assess management's involvement in the management of product risk associated with outsourcing.

This preliminary work will allow the audit team to more effectively complete the audit of the organization's Purchasing process, verifying that management has assured the appropriate level of control over suppliers, including an assessment of the relationship between supplied products and product risk.

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Task 6: Confirm the medical device organization has determined the necessary competencies for personnel performing work affecting product quality, provided appropriate training, and made personnel aware of the relevance and importance of their activities on product quality and achievement of the quality objectives. Ensure records of training and competencies are maintained.

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

Slide 30
There are additional country-specific requirements for Brazil.

Assessing conformity includes reviewing employee training records. Detailed information on additional country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management, under task 6.

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There is a linkage between this task and the Productions and Service Controls process.

During the audit of the Production and Service Controls process, ensure that employees who are involved in key operations that affect product realization and product quality have been trained in their specific job tasks, as well as the quality policy and objectives. When appropriate, review the training records for those employees whose activities have contributed to process nonconformities.

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Task 7: Verify that management has committed to and has responsibility for overall risk management planning, including ongoing review of the effectiveness of risk management activities ensuring that policies, procedures and practices are established and documented for analyzing, evaluating and controlling product risk throughout product realization.

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

Slide 33
There are no additional country-specific requirements for this task.

Assessing conformity includes ensuring the provision of adequate resources, ensuring assignment of qualified personnel for risk management activities, and ensuring top management reviews the suitability of the risk management process. Detailed Information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management, under task 7.

Slide 34
There is a linkage between this task and the Design and Development process.

Risk management usually starts in conjunction with the Design and Development planning process at a point in the development when the results of risk analysis can affect the design process.
During audit of the Design and Development process, evaluate top management's commitment to risk management activities. Evidence of commitment to risk management may include the implementation of new or more stringent controls, external controls (e.g. additional supplier-related controls), or design changes to maintain an acceptable level of product risk.

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Task 8: Verify that procedures have been defined, documented, and implemented for the control of documents and records required by the quality management system. Confirm the organization retains records and at least one obsolete copy of controlled documents for a period of time at least equivalent to the lifetime of the device, but not less than two years from the date of product release.

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

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There are additional country-specific requirements for Australia, Brazil, Japan, and United States.

Assessing conformity includes ensuring at least one copy of obsolete controlled documents is maintained. Detailed information on additional country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management, under task 8.

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

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Task 9: Verify that procedures for management review have been documented, management reviews are being conducted at planned intervals, that they include a review of the suitability and effectiveness of the quality policy, quality objectives, and quality management system to assure that the quality management system meets all applicable regulatory requirements.

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

Slide 38

There are no additional country-specific requirements for this task.

Assessing conformity includes ensuring that the quality policy and objectives have been reviewed for continued suitability and ensuring that any changes to regulatory requirements have been identified. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management, under task 9.

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There is a linkage between this task and the Measurement, Analysis and Improvement process.

During audit of the Measurement, Analysis and Improvement process, confirm when necessary that action items resulting from Management review are considered for corrective or preventive action.

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Task 10: Confirm that the medical device organization has defined and implemented controls to ensure that only devices that have received the appropriate marketing authorization are distributed or otherwise offered for commercial distribution into the applicable markets.

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

Slide 41
There are no additional country-specific requirements for this task.

Assessing conformity includes verifying the identification and documentation of the responsibilities of employees and personnel, verifying obligations are carried out by competent personnel, and verifying controls to ensure appropriate market authorization. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 1: Management, under task 10.

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There is a linkage between this task and the Device Marketing Authorization and Facility Registration process.

During the accomplishment of audit task 10, you may choose to perform a preliminary review of Device Marketing Authorization and Facility Registration. In some instances, this preliminary review may allow for adequate coverage of Device Marketing Authorization and Facility Registration. In other instances, you may need to revisit the Device Marketing Authorization and Facility Registration process if you find that changes were made to marketed devices, facilities, or the quality management system that need to be reported to the regulatory authorities participating in the Medical Device Single Audit Program.

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Task 11: At the conclusion of the audit, a decision should be made as to whether top management has demonstrated the necessary commitment to ensure a suitable and effective quality management system is in place and being maintained and whether the effectiveness of the system has been communicated to personnel.

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

Slide 44
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 1: Management, under task 11.

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In summary, the Management process is the first process to be audited per the MDSAP audit sequence. The intent of the Management process is to provide adequate resources, to assure the quality management system is functioning properly and effectively and to monitor and make any necessary adjustments.
Finally, the purpose of auditing the Management process is to verify that top management ensures an adequate and effective quality management system has been established and maintained.

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This concludes the training module for the MDSAP process: Management.