

MDSAP: Production and Service Controls Process: Part 2

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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. I will be your presenter for this module.

In this training module, we will be reviewing the second of three modules for the Medical Device Single Audit Program (MDSAP) process: Production and Service Controls.

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Successful completion of the following MDSAP training modules “Introduction to the MDSAP Program”, “Overview of the MDSAP Audit Process”, “Management Process”, “Measurement, Analysis and Improvement Process”, “Design and Development Process”, and Production and Service Controls Process: Part 1 are prerequisites to this training module.

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In this training module, we will review the purpose of auditing the Production and Service Controls process and continue with explaining the audit tasks for Production and Service Controls process: **Part 2** in terms of description and related Clauses and Regulations; country-specific requirements and assessment of conformity; and links to other MDSAP processes.

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We will begin with reviewing the purpose of auditing the Production and Service Controls process.

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The purpose of auditing the production and service controls process (including testing, infrastructure, facilities, equipment, and servicing) is to verify that the manufacturer’s processes are capable of ensuring that products will meet specifications.

Accomplishment of the outcomes for the Production and Service Controls process is accomplished through the completion of the audit tasks. We will now continue our discussion of the audit tasks and links to the interrelated MDSAP processes.

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We will now continue our discussion of the audit of the Production and Service Controls process by explaining the audit tasks for the Production and Service Controls process, Part 2 in terms of the description and related Clauses and Regulations; the country-specific requirements and assessment of conformity; and links to other MDSAP processes.

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Audit tasks 1-10 were discussed in MDSAP training Production and Service Controls: Part 1. Part 2 will commence with audit task 11.

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Task 11: Verify that the processes used in production and service are appropriately controlled, monitored, operated within specified limits and documented in the product realization records. In addition, verify that risk control measures identified by the manufacturer for production processes are implemented, monitored and evaluated.

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

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There are additional country-specific requirements for Australia.

Assessing conformity includes confirming that the procedures available to the production personnel are the most current approved revisions, comparing work instructions with what is actually being done, and comparing product acceptance criteria with acceptance activity results, and reviewing control charts against specified requirements.

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 11.

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This task has a link to Design and Development processes. The design outputs for a device include documents such as diagrams, drawings, specifications, procedures, and the production processes that are essential to the proper manufacturing of the device. Production processes can include not only the manufacturing instructions, but also internal controls, such as the type and extent of acceptance activities, equipment calibration and maintenance intervals, environmental controls, and personnel controls.

During audit of the Production and Service Controls process, consider reviewing production processes that have the highest risk or greatest effect on the essential design outputs.

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Task 12: Verify that personnel are competent to implement and maintain the processes in accordance with the requirements identified by the organization.

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

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There are no additional country-specific requirements for this task. Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 12.

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This task has a link to Management processes. 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 13: Confirm the organization has determined the monitoring and measuring devices needed to provide evidence of conformity to specified requirements. Verify that the monitoring and measuring

equipment used in production and service control has been identified, adjusted, calibrated and maintained, and capable of producing valid results.

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

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There are no additional country-specific requirements for Task 13. Assessing conformity includes confirming that the production and test equipment selected for review is suitable for its intended purpose and capable of giving valid results, reviewing the maintenance, control, and calibration procedures (and records) for the equipment selected for review, and verifying that the medical device organization made an assessment of the effect of the out-of-tolerance situation on in-process, finished, or released devices, based on risk.

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 13.

There are no links to other MDSAP processes for Task 13.

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Task 14: Confirm the organization assesses and records the validity of previous measurements when equipment is found not to conform to specified requirements and takes appropriate action on the equipment and any product affected. Verify that the control of the monitoring and measuring devices is adequate to ensure valid results. Confirm that monitoring and measuring devices are protected from damage or deterioration.

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

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There are additional country-specific requirements for Australia. Assessing conformity includes confirming that the organization has the proper procedures and controls in place to preserve the proper functioning of monitoring, measuring, and test equipment.

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 14.

There are no links to other MDSAP processes for Task 14.

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Task 15: If the selected process is software controlled or if software is used in production equipment or the quality management system, verify that the software is validated for its intended use. Software validation may be part of equipment qualification.

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

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There are no additional country-specific requirements for Task 15. Assessing conformity includes reviewing the software validation documents and records if the production process the audit team selected for review is controlled with software, and assessing the systems most likely to have an impact on the finished device's ability to meet specified requirements if multiple software driven systems are used in the production process.

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 15.

There are no links to other MDSAP processes for Task 15.

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Task 16: Determine if the medical device organization has established and maintained a file for each type of device that includes or refers to the location of device specifications, production process specifications, quality assurance procedures, traceability requirements, packaging and labeling specifications, and when applicable requirements for installation and servicing. Confirm that the manufacturer determined the extent of traceability based on the risk posed by the device in the event the device does not meet specified requirements.

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

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There are additional country-specific requirements for Australia. Assessing conformity includes confirming that the required records have been established

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 16.

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This task has a link to Design and Development processes. During the design and development of the device, the essential design outputs for the proper functioning of the device should have been identified. During audit of the Design and Development process, confirm that the essential design outputs for the proper functioning of the device have been identified. Raw materials, components, and subassemblies should have been considered for traceability if their nonconformity could result in the finished device not meeting its specified requirements and essential design outputs.

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Task 17: Determine if the medical device organization has established and maintained a record of the amount manufactured and approved for distribution for each batch of medical devices, the record is verified and approved, the device is manufactured according to the file referenced in Task 16, and the requirements for product release were met and documented.

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

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There are additional country-specific requirements for Brazil and the United States. Assessing conformity includes verifying that each batch of devices was manufactured in accordance with product and production specifications, being mindful that in some instances, a batch can be a single device. It includes confirming that the nonconformities were handled appropriately with input into the Measurement, Analysis and Improvement process when appropriate.

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 17.

There are no links to other MDSAP processes to Task 17.

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Task 18: If the medical device organization manufactures active or nonactive implantable medical devices, life-supporting or life-sustaining devices, confirm the manufacturer maintains traceability records of all components, materials, and work environment conditions (if these could cause the medical device to not satisfy its specified requirements) in addition to records of the identity of personnel performing any inspection or testing of these devices. Confirm that the organization requires that agents or distributors of these devices maintain distribution records and makes them available for inspection. Verify that the organization records the name and address of shipping consignees for these devices.

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

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There are additional country-specific requirements for Canada and the United States. Assessing conformity includes confirming that the medical device organization has the necessary systems in place to provide for tracking each device to the end user if the organization manufactures or distributes a device that falls under a tracking requirement.

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 18.

There are no links to other MDSAP processes to Task 18.

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Task 19: Verify that product status identification is adequate to ensure that only product which has passed the required inspections and tests is dispatched, used, or installed.

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

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There are no additional country-specific requirements for Task 19. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 19.

There are no links to other MDSAP process for Task 19.

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Task 20: Verify that the organization has implemented controls to identify, verify, protect, and safeguard customer property provided for use or incorporation into the product. Verify the organization treats patient information and confidential health information as customer property.

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

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There are no additional country-specific requirements for Task 20. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 20.

There are no links to other MDSAP processes for Task 20.

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In summary, production processes can include not only the manufacturing instructions, but also internal controls, such as the type and extent of acceptance activities, equipment calibration and maintenance intervals, environmental controls, and personnel controls

The purpose of auditing the production and service controls process (including testing, infrastructure, facilities, equipment, and servicing) is to verify that the manufacturer's processes are capable of ensuring that products will meet specifications.

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This concludes part 2 of the training module for MDSAP process: Production and Service Controls.

Please continue to part 3 to complete the discussion of the audit tasks for the Production and Service Controls process, as well as the links to other processes.

