MDSAP: Production and Service Controls Process, Part 1

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

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The prerequisites for understanding this Production and Service Controls Process, Part 1 training module are the MDSAP training modules "Introduction to the MDSAP Program", "Overview of the MDSAP Process", "MDSAP: Management Process", "MDSAP: Measurement, Analysis and Improvement Process", and "MDSAP: Design and Development Process".

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In this Production and Service Controls Process, Part 1 training module, we will explain the Production and Service Controls process, describe the purpose of auditing the Production and Service Controls process, discuss the expected outcomes from the audit of the Production and Service Controls process, and explain the audit tasks for Production and Service Controls Process, Part 1 in terms of description and Clauses and Regulations, list country-specific requirements and assessment of conformity for each audit task in Part 1, and indicate the links to other MDSAP processes.

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We will begin this three-part training with first explaining the Production and Service Controls process.

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The intention of the Production and Service Controls process is to manufacture products that meet specifications. Developing processes that are adequate to produce devices that meet specifications, validating, or fully verifying the results of, those processes, and monitoring and controlling those processes are all steps that help to ensure that the result will be devices that meet specified requirements.

After completing the audit of the organization's Production and Service Controls process, the audit team will return to the Management process to make a final decision of whether top management ensures that an adequate and effective quality management system has been established and maintained at the organization.

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The organization must understand when deviations from device specifications could occur as a result of the production process or environment in order to meet the Production and Service Controls requirements of ISO 13485:2016, the Quality Management System requirements of the Conformity Assessment Procedures of the Australian Therapeutic Goods (Medical Devices) Regulations, the Brazilian Good Manufacturing Practices.

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The medical device organization must understand when deviations from device specifications could occur as a result of the production process or environment in order to meet the Production and Service Controls requirements also of the Japan Ordinance on Standards for Manufacturing Control and Quality

Control of Medical Devices and In Vitro Diagnostic Reagents, the US Quality System Regulation, and specific requirements of medical device regulatory authorities participating in the MDSAP program.

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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 audit of any process, it may be helpful to interview the management representative (or 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 a discussion of the purpose of auditing the Production and Service Controls process.

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Audit of the Production and Service Controls process will follow audit of the Measurement, Analysis and Improvement process and the Design and Development process per the MDSAP audit sequence. Information the audit team has learned about device and quality management system nonconformities during audit of the Measurement, Analysis and Improvement process, as well as higher risk elements and essential design outputs from the design projects reviewed during audit of the Design and Development process, should be used to make decisions regarding the production processes to be reviewed during the audit of 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.

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In this training, we will describe the purpose of the Design and Development process, discuss the expected outcomes from the audit of the Design and Development process, explain the audit tasks and links to other MDSAP processes, recognize country-specific requirements, and review the assessment of conformity for the audit tasks.

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As a result of the audit of the Production and Service Controls process, objective evidence will show whether the organization has: defined, documented and implemented procedures to ensure production and service processes are planned, developed, conducted, controlled, and monitored to ensure conformity to specified requirements; developed production and service process controls commensurate with the potential effect of the process on product risk.

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As a result of the audit of the Production and Service Controls process, objective evidence will show whether the organization has: ensured that when the results of a process cannot be verified by subsequent monitoring or measurement, the process is validated with a high degree of assurance to ensure that the process will consistently achieve the planned result; and Implemented procedures for the validation of the application of computer software for production and service processes that affect

the ability of the product to conform to specified requirements, including validation of computer software used in the quality management system.

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As a result of the audit of the Production and Service Controls process, objective evidence will show whether the organization has: maintained records for each batch of medical devices that provides information for traceability and confirmation that the batch meets specified requirements; and implemented controls to protect customer property, including intellectual property, confidential health information, and other forms of customer property that is used or incorporated into products.

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Accomplishment of the outcomes for the Production and Service Controls process is accomplished through the completion of the audit tasks. We will now discuss the audit tasks for the Production and Service Controls process Part 1 and the links to the interrelated MDSAP processes.

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Task 1: Verify that the product realization processes are planned, including any necessary controls, controlled conditions, and risk management activities required for the product to meet the specified or intended uses, the statutory and regulatory requirements related to the product, and when applicable, the unique device identifier requirements. Confirm that the planning of product realization is consistent with the requirements of the other processes of the quality management system and performed in consideration of the quality objectives.

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 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 6: Production and Service Controls, under Task 1.

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This task has a link to the Management process. During audit of the Management process, confirm when necessary that the quality objectives related to the product were considered for inclusion in management review.

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Task 2: Review production processes considering the following criteria. Select one or more production processes to audit. When selecting production processes for review, information the audit team has learned about device and quality management system nonconformities during audit of the Measurement, Analysis and Improvement process, as well as higher risk elements and essential design outputs from the design projects reviewed during audit of the Design and Development process should be used to make decisions as to the production processes to be reviewed.

There are no related Clauses and Regulations for Task 2.

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The audit team should consider the following priorities when selecting production processes for review: corrective and preventive action indicators of process problems or potential problems; use of production process for higher risk products; use of production processes that directly impact the ability of the device to meet its essential design outputs; new production processes or new technologies; use of the process in manufacturing multiple products; processes that operate over multiple shifts; processes not covered during previous audits.

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There are no additional country-specific requirements for this Task 2. Detailed information on how to assess conformity for this audit task are in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 2.

There are no links to other MDSAP processes for Task 2.

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Task 3: For each selected process, determine if the production and service process is planned and conducted under controlled conditions that include the availability of information describing product characteristics, the availability of documented procedures, requirements, work instructions, reference materials, reference measurements, and criteria for workmanship, the use of suitable equipment, the availability and use of monitoring and measuring devices, the implementation of monitoring and measurement of process parameters and product characteristics during production.

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In addition, for each selected process, determine if the production and service process is planned and conducted under controlled conditions that include the implementation of release, delivery and post-delivery activities, the implementation of defined operations for labeling and packaging, and the establishment of documented requirements for changes to methods and processes.

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 3. Detailed information on how to assess conformity for this audit task in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 3.

There are no links to other MDSAP processes for Task 3.

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Task 4: Determine if the organization has established documented requirements for product cleanliness including any cleaning prior to sterilization, cleanliness requirements if provided non-sterile, and assuring that process agents are removed from the product if required.

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. Assessing conformity includes confirming that the medical device organization has identified the cleanliness requirements for the finished device and the proper controls to achieve the required level of cleanliness. It includes confirming that the medical device organization has made effective arrangements to control the process agent (manufacturing material) in a manner commensurate with the risk the agent poses to the finished device. Detailed information on country-specific requirements and how to assess conformity for this audit task are in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 4.

There are no links to other MDSAP processes for task 4.

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Task 5: Verify that the organization has determined and documented the infrastructure requirements to achieve product conformity, including buildings, workspace, process equipment, and supporting services. Confirm that buildings, workspaces, and supporting services allow product to meet requirements. Verify that there are documented and implemented requirements for maintenance of process equipment, where important for product quality, and that records of maintenance are maintained.

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. Detailed information on country-specific requirements and how to assess conformity for this audit task are in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 5.

There are no links to other MDSAP processes for Task 5.

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Task 6: Verify documented requirements have been established, implemented and maintained for: health, cleanliness, and clothing of personnel that could have an adverse effect on product quality; monitoring and controlling work environment conditions that can have an adverse effect on product quality; training or supervision of personnel who are required to work under special environmental conditions; and controlling contaminated or potentially contaminated product (including returned products) in order to prevent contamination of other product, the work environment, or personnel.

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

There are no links to other MDSAP processes for Task 6.

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Task 7: Determine if the selected processes and sub-processes have been reviewed, including any outsourced processes, to determine if validation of these processes is required.

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 confirming that, when applicable, the medical device organization has identified processes which require validation, including validation requirements for any outsourced processes. Detailed information on country-specific requirements and how to assess conformity for this audit task are in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 7.

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There are links to Purchasing process for this task. The audit team may encounter situations where the organization outsources processes that require validation. During the review of the Purchasing process, review the controls the organization has instituted over suppliers that perform validated processes. This linkage can be particularly important for higher risk validated processes performed by suppliers, since the finished device manufacturer does not have immediate control over those processes.

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Task 8: Verify that the selected processes have been validated if the result of the process cannot be fully verified, or can be verified, but is not. Confirm that the validation demonstrates the ability of the processes to consistently achieve the planned result. In the event changes have occurred to a previously validated process, confirm that the processes were reviewed and evaluated, and re-validation was performed where appropriate.

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 country-specific requirements for Australia. Assessing conformity includes determining when applicable whether: the instruments used to generate the data were properly calibrated and maintained; predetermined product and process specifications were established; sampling plans used to collect test samples are based on a statistically valid rationale; data demonstrates predetermined specifications were met consistently; process tolerance limits were challenged; process equipment was properly installed, adjusted, and maintained; process monitoring instruments were properly calibrated and maintained; changes to the validated process were appropriately challenged (if applicable) and process operators were appropriately qualified.

Detailed information on country-specific requirements and how to assess conformity for this audit task are in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 8.

There are no links to other MDSAP process for Task 8.

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Task 9: If product is supplied sterile, verify that the sterilization process is validated, periodically re-validated, and records of the validation are available, that devices sold in a sterile state are

manufactured and sterilized under appropriately controlled conditions, and determine whether the sterilization process and results are documented and traceable to each batch of product.

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 country-specific requirements for Australia. Assessing conformity includes ensuring cleaning, packaging, and sterilization processes are validated and ensuring the medical device organization maintains appropriate controls over: routine monitoring and measure of the cleaning, packaging and sterilization processes; routine acceptance criteria of the cleaning, packaging and sterilization processes; requalification, reverification, recalibration and maintenance of the cleaning, packaging and sterilization equipment; environmental control of production areas (cleanroom design and monitoring); storage of device parts, components, and packaging material; storage of finished sterile product and management of shelf life; and handling processes for non-sterile devices for re-sterilization.

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 9.

There are no links to other MDSAP processes for Task 9.

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Task 10: Verify that the system for monitoring and measuring of product characteristics is capable of demonstrating the conformity of products to specified requirements. Confirm that product risk is considered in the type and extent of product monitoring activities.

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 country-specific requirements for task 10. Assessing conformity includes confirming that the control measures are suitable for detecting process or product nonconformities. Detailed information on how to assess conformity for this audit task are in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 10.

There are no links to other MDSAP processes for this task.

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In summary, the Production and Service Controls process is intended to manufacture products that meet specifications and the organization must understand when deviations from device specifications could occur as a result of the production process or environment in order to meet the Production and Service Controls requirements.

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This concludes part 1 of the training module for MDSAP process: Production and Service Controls. Please continue to part 2 to complete the discussion of the audit tasks for the Production and Service Controls process, as well as the links to other MDSAP processes.