



Production and Service Controls Process, Part 1

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Course Prerequisites

- Successful completion of the following MDSAP training module is a prerequisite to this course:
 - Introduction to the MDSAP Program
 - Overview of the MDSSAP Audit Process
 - MDSAP: Management Process
 - MDSAP: Measurement, Analysis and Improvement Process
 - Design and Development Process

Learning Objectives

- Explain the Production and Service Controls process
- Describe the purpose of auditing the Production and Service Controls process
- Discuss the expected outcomes from audit of the Production and Service Controls process
- Explain the audit tasks for Production and Service Controls process, **Part 1** to include:
 - Description and related Clauses and Regulations
 - Country-specific requirements and assessment of conformity
 - Links to other MDSAP processes

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Production and Service Controls process

- The Production and Service Controls process:
 - Manufactures products that meet specifications by:
 - Developing processes that are adequate to produce devices that meet specifications
 - Validating (or fully verifying the results of) those processes
 - Monitoring and controlling those processes

Production and Service Controls process

- Organization must understand when deviations could occur to meet the requirements of:
 - Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016)
 - Quality Management System requirements of the Conformity Assessment Procedures of the Australian Therapeutic Goods (Medical Devices) Regulations (TG(MD)R Sch3)
 - Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013)

Production and Service Controls process

- Organization must understand when deviations could occur to meet the requirements of:
 - Japan Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (MHLW Ministerial Ordinance No. 169),
 - Quality System Regulation (21 CFR Part 820)
 - and specific requirements of medical device regulatory authorities participating in the MDSAP program

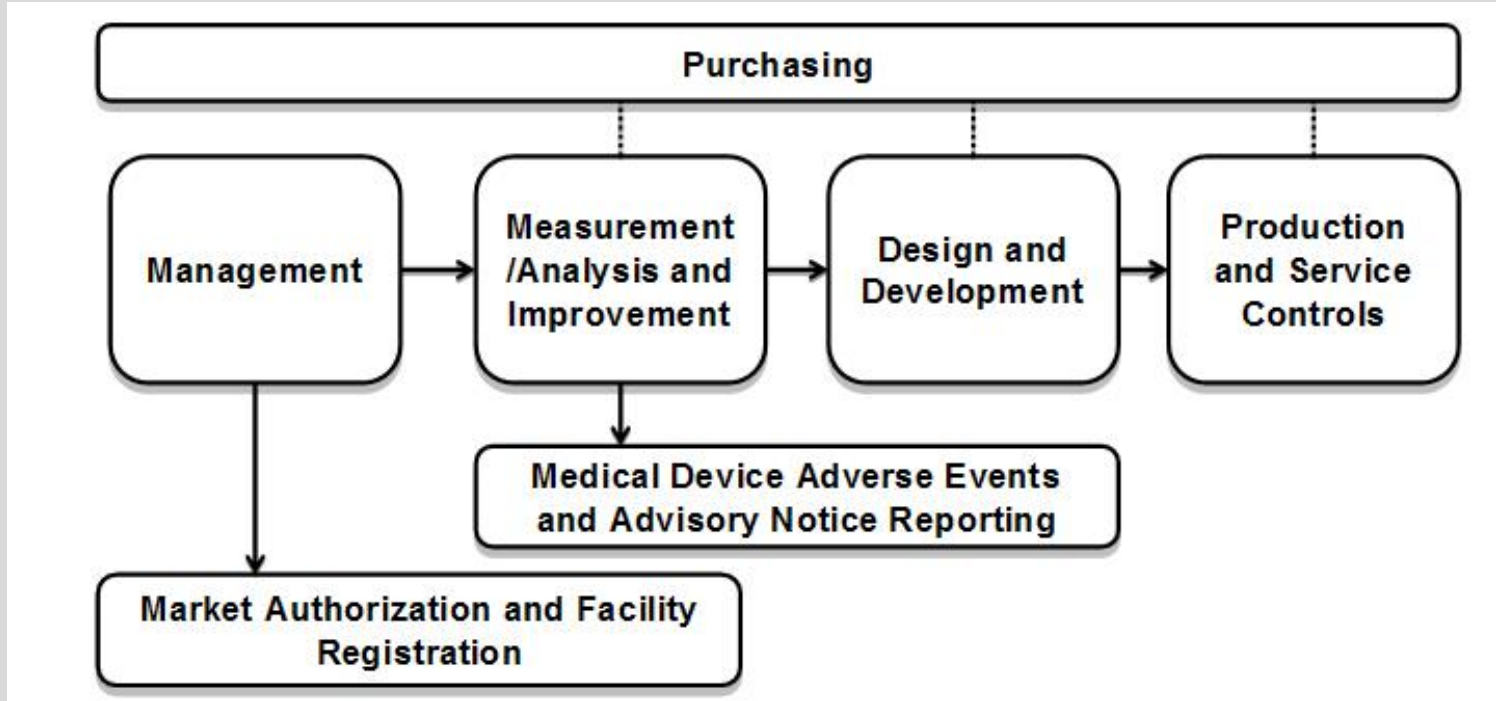
Role of the management representative

- The management representative:
 - Ensures that the requirements of the quality management system have been effectively defined, documented, implemented, and maintained
 - Interviewed to obtain an overview of the process and a feel for management's knowledge and understanding of the process

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MDSAP Audit Sequence



Purpose of Auditing

- The Production and Service Controls process is audited to:
 - Verify that the manufacturer's processes are capable of ensuring that products will meet specifications
 - includes testing, infrastructure, facilities, equipment, and servicing

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Expected Outcomes

As a result of the audit of the Production and Service Controls process, objective evidence will show whether the organization has:

- A. Defined, documented and implemented procedures to ensure production and service processes are planned, developed, conducted, controlled, and monitored to ensure conformity to specified requirements
- B. Developed production and service process controls commensurate with the potential effect of the process on product risk

Expected Outcomes

As a result of the audit of the Production and Service Controls process, objective evidence will show whether the organization has:

- C. 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
- D. 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

Expected Outcomes

As a result of the audit of the Production and Service Controls process, objective evidence will show whether the organization has:

- E. Maintained records for each batch of medical devices that provides information for traceability and confirmation that the batch meets specified requirements
- F. 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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Task 1

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) 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.**

Clause and Regulation: [ISO 13485:2003: 7.1, 7.2.1, 7.5.1.1; TG(MD)R Sch 1 P1 2, Sch3 P1 Cl1.4(4), Sch3 P1 Cl1.4(5)(d)&(e); RDC ANVISA 16/2013: 2.2.1, 2.4, 4.1.2, 4.1.7, 5.1; 21 CFR 820.30(b), 820.20(a), 820.30(h), 820.70(a)]

Task 1

- Additional country-specific requirements: United States (FDA)
- Assessing conformity:
 - Be mindful of requirements:
 - For the product that relate to statutory and regulatory requirements
 - Necessary for the product to meet specified requirements and intended uses
 - For safe and efficacious use of the product
 - Confirm that the organization has defined quality objectives for the 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 6: Production and Service Controls, under task 1

Task 1

- Links:
 - Management
 - Confirm that the quality objectives related to the product were considered for inclusion in management review



Task 2

2. **Review production processes considering the following criteria. Select one or more production processes to audit.**

Clause and Regulation: None

[MDSAP Audit Approach](#)

Task 2

- **Priority criteria for selection:**
 - 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

Task 2

- Additional country-specific requirements: None
- Assessing conformity:

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 2

Task 3

3. For each selected process, determine if the production and service process is planned and conducted under controlled conditions that include the following:
 - the availability of information describing product characteristics
 - the availability of documented procedures, requirements, work instructions, and 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

Task 3

3. For each selected process, determine if the production and service process is planned and conducted under controlled conditions that include the following (*continued*):
 - the implementation of release, delivery and post delivery activities
 - the implementation of defined operations for labeling and packaging
 - the establishment of documented requirements for changes to methods and processes

Clause and Regulation: [ISO 13485:2016: 7.5.1, 8.2.5, 8.2.6; TG(MD)R Sch3 P1 Cl1.4(5)(d)&(e); RDC ANVISA 16/2013: 3.1.3, 4.2, 5.1, 5.2, 5.3, 5.4, 5.6; 5.6.1; 5.6.2; MHLW MO169: 40, 57, 58, 59; 21 CFR 820.70(a), 820.70(b), 820.75, 820.120, 820.130]

Task 3

- Additional country-specific requirements: None
- Assessing conformity:

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 3

Task 4

- 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.**

Clause and Regulation: [ISO 13485:2016: 4.2.1, 4.2.3, 6.4.2, 7.5.2; TG(MD)R Sch3 P1 Cl1.4(5)(d); RDC ANVISA 16/2013: 5.1.3.1, 5.1.3.4, 5.1.5.3; MHLW MO169: 6, 7-2, 25-2, 41 (Old: 6, 25, 41); 21 CFR 820.70(c), 820.70(d), 820.70(e), 820.70(h)]

Task 4

- Additional country-specific requirements: Brazil (ANVISA)
- Assessing conformity:
 - Confirm identification of cleanliness requirements for the finished device and proper controls
 - Confirm effective arrangements to control the manufacturing materials commensurate with risk were made

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 4

Task 5

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.**

Clause and Regulation: [ISO 13485:2016: 4.2.1, 6.3, 7.5.1; RDC ANVISA 16/2013: 5.1.2, 5.1.5; CMDR 14; MHLW MO169: 6, 24, 40; 21 CFR 820.70(g), 820.70(f)]

Task 5

- Additional country-specific requirements: Brazil (ANVISA)
- Assessing conformity:

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 5

Task 6

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**
 - **controlling contaminated or potentially contaminated product (including returned products) in order to prevent contamination of other product, the work environment, or personnel**

Clause and Regulation: [ISO 13485:2016: 4.2.1, 6.4; TG(MD)R Sch1 P2 7.2, 8; RDC ANVISA 16/2013: 5.1.3; MHLW MO169: 6, 25-1, 25-2 (Old: 6, 25); 21 CFR 820.70(c), 820.70(d), 820.70(e)]

Task 6

- Additional country-specific requirements: Brazil (ANVISA)
- Assessing conformity:

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 6.

Task 7

- 7. Determine if the selected process(es) and sub-process(es) have been reviewed, including any outsourced processes, to determine if validation of these processes is required.**

Clause and Regulation: [ISO 13485:2016:4.2.1, 4.1.6, 7.5.6; TG(MD)R Sch1 P2 8.2, 8.3; Sch3 P1 1.4(5)(d), RDC ANVISA16/2013: 5.5.2, 5.5.3; MHLW MO169: 6, 5-6, 45 (Old: 6, 45); 21 CFR 820.75(a)]

Task 7

- Additional country-specific requirements: Brazil (ANVISA); and the United States (FDA)
- Assessing conformity:
 - Confirm that the organization has identified processes which require validation

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 7

Task 7

- Links:
 - Purchasing
 - Review the controls the organization has instituted over suppliers that perform validated processes
 - Linkage can be particularly important for higher risk validated processes performed by suppliers



Task 8

- 8. Verify that the selected process(es) has 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 process(es) 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.**

Clause and Regulation: [ISO 13485:2016: 4.2.1, 7.5.6; TG(MD)R Sch1 P1 2(1), Sch3 P1 1.4(5)(d); RDC ANVISA 16/2013: 1.2.18, 5.5.1; MHLW MO169: 6, 45; 21 CFR 820.75(a), 820.75(c)]

Task 8

- Additional country-specific requirements: Australia (TGA)
- Assessing conformity:
 - Determine 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

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 8

Task 9

9. If product is supplied sterile: (See Annex 2).
- Verify the sterilization process is validated, periodically re-validated, and records of the validation are available
 - Verify that devices sold in a sterile state are manufactured and sterilized under appropriately controlled conditions
 - Determine if the sterilization process and results are documented and traceable to each batch of product

Clause and Regulation: [ISO 13485:2016: 4.2.1, 7.5.5, 7.5.6, 7.5.7; TG(MD)R Sch1 2(1) & 8.3, Sch3 P1 1.4(5)(d); RDC ANVISA 16/2013: 5.1.6, 5.5; CMDR 17; MHLW MO169: 6, 44, 45, 46; 21 CFR 820.75, 820.184(d)]

Task 9

- Additional country-specific requirements: Australia (TGA)
- Assessing conformity:
 - Ensure cleaning, packaging, and sterilization processes are validated
 - Ensure organization maintains appropriate controls over:
 - Routine monitoring and measurement 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

Detailed information 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

Task 10

- 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.**

Clause and Regulation: [ISO 13485:2016: 7.1, 7.5.1, 8.1, 8.2.6; TG(MD)R Sch1 P1 2, Sch3 P11.4(5)(b)&(e); RDC ANVISA 16/2013: 2.4, 5.1.1, 9.1; MHLW MO169: 26, 40, 54, 58, 59; 21 CFR 820.70(a), 820.250(a)]

Task 10

- Additional country-specific requirements: None
- Assessing conformity:
 - Confirm that the control measures are suitable for detecting process or product nonconformities

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 10

Summary

- The Production and Service Controls process is intended to manufacture products that meet specifications
- The organization must understand when deviations from device specifications could occur as a result of the production process or environment

Conclusion

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

