FDA U.S. FOOD & DRUG ADMINISTRATION

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Production and Service Controls Process: Part 3

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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 MDSAP Audit Process
  - MDSAP: Management Process
  - MDSAP: Measurement, Analysis and Improvement Process
  - MDSAP: Design and Development Process
  - MDSAP: Production and Service Controls Process: Parts 1 and 2

Learning Objectives

- Review the purpose of auditing the Production and Service Controls process
- Explain the audit tasks for Production and Service Controls process, **Part 3** to include:
  - Description and related Clauses and Regulations
  - Country-specific requirements and assessment of conformity
  - Links to other MDSAP processes

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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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Task 1-20

- Audit tasks 1-10 were discussed in MDSAP training module Production and Service Controls, Part 1
- Audit tasks 11-20 were discussed in MDSAP training module Production and Service Controls: Part 2
- Part 3 will commence with audit Task 21

Task 21

21. Verify that acceptance activities assure conformity with specifications and are documented. *Confirm the extent of acceptance activities are commensurate with the risk posed by the device.*

Clause and Regulation: [ISO 13485:2016: 4.2.1, 7.4.3, 7.5.8, 8.2.6; TG(MD)R Sch1 P1 2, Sch3 P1 Cl1.4(5)(d); RDC ANVISA 16/2013: 5.3.1, 5.3.2, 5.3.3, 5.3.4, 9.2; MHLW MO169: 6, 39, 47,58, 59; 21 CFR 820.80, 820.250(b)]

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Task 21

- Additional country-specific requirements: Brazil (ANVISA), United States (FDA)
- Assessing conformity:
  - Confirm that the organization has defined processes for receiving, in-process, and final acceptance activities
  - Review a sample of batch records and confirm that acceptance activities
    - have been documented
    - Show specified requirements have been met
  - Confirm that the organization has taken the appropriate action to determine suitability of the acceptance activities

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 21.

Task 21

- *Links:*
  - *Purchasing*
    - Consider reviewing the purchasing controls and requirements for suppliers of products that undergo minimal acceptance activities at the device manufacturer
    - Consider selecting suppliers that supplied product that did not meet specified requirements
  - Design and Development

Task 22

22. Verify that the identification, control, and disposition of nonconforming products is adequate, based on the risk the nonconformity poses to the device meeting its specified requirements.

Clause and Regulation: [ISO 13485:2016: 7.5.8, 8.3; TG(MD)R Sch1 P1 2, Sch3 P1 Cl1.4(5)(b); RDC ANVISA 16/2013: 6.5.1, 6.5.2; MHLW MO169: 47 (Old: 47, 50, 60); 21 CFR 820.60, 820.90(a), 820.86, 820.100(a)]

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Task 22

- Additional country-specific requirements: None

- Assessing conformity:
  - Confirm that the organization has defined and implemented procedures for identification, control, segregation, evaluation, and disposition of nonconforming product
  - Ensure that the organization has established an interface/interaction between processes for identification of nonconforming product and corrective action

  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 22

Task 22

- *Links:*
  - *Measurement, Analysis and Improvement*
    - Be mindful of where the acceptance of nonconforming product has led to finished devices not meeting specified requirements
    - Consider reviewing the handling and evaluation of nonconforming products that were determined to be the underlying cause of quality problems

Task 22

- *Links:*
  - *Measurement, Analysis and Improvement*
    - Ensure the analysis of data regarding nonconforming product is considered as an input to the Measurement, Analysis and Improvement process
    - Ensure that corrective or preventive actions have been implemented when necessary

Task 23

23. If a product needs to be reworked, confirm the manufacturer has made a determination of any adverse effect of the rework upon the product. Verify the rework process has been performed according to an approved procedure, that the results of the rework have been documented, and that the reworked product has been re-verified to demonstrate conformity to requirements.

Clause and Regulation: [ISO 13485:2016: 8.3.4; RDC ANVISA 16/2013: 6.5.3; MHLW MO169: 60-4 (Old: 60); 21 CFR 820.90(b)]

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Task 23

- Additional country-specific requirements: None

- Assessing conformity:
  - Be mindful of where the underlying cause of quality problems are traced to devices that have been reworked
  - Consider reviewing process 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 23

Task 24

24. Verify that procedures are established and maintained for preserving the conformity of product and constituent parts of a product during internal processing, storage, and transport to the intended destination. This preservation encompasses identification, handling, packaging, storage, and protection, including those products with limited shelf-life or requiring special storage conditions.

Clause and Regulation: [ISO 13485:2016: 7.5.8, 7.5.11; TG(MD)R Sch1 P1 5; RDC ANVISA 16/2013: 5.2.1, 6.1.1, 6.2.1; CMDR 14; MHLW MO169: 47, 52; 21 CFR 820.130, 820.140, 820.150, 820.160(a)]

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Task 24

- Additional country-specific requirements: None

- Assessing conformity:
  - Confirm that the needed control measures are implemented

  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 24

Task 25

25. Confirm that the medical device organization performs a review of customer requirements, including the purchase order requirements, prior to the organization's commitment to supply a product to a customer. Verify that the medical device organization maintains documentation required by regulatory authorities regarding maintenance of distribution records.

Clause and Regulation: [ISO 13485:2016: 4.2.1, 5.2, 7.2.2, 7.5.9; RDC ANVISA 16/2013: 6.3; MHLW MO169: 6, 11, 28, 48, 49; 21 CFR 820.160(a)]

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Task 25

- Additional country-specific requirements: Brazil (ANVISA), Canada (HC), United States (FDA)

- 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 25

Task 26

26. If installation activities are required, confirm records of installation and verification activities are maintained.

Clause and Regulation: [ISO 13485:2016: 7.5.3; RDC ANVISA 16/2013: 8.1; MHLW MO169: 42; 21 CFR 820.170]

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Task 26

- Additional country-specific requirements: None

- Assessing conformity:
  - Confirm necessary installation procedures are in place

  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 26

Task 27

27. Determine if servicing activities are conducted and documented in accordance with defined and implemented instructions and procedures. Confirm service records are used as a source of quality data in the Measurement, Analysis and Improvement process.

Clause and Regulation: [ISO 13485:2016: 4.2.1, 7.5.4, 8.4; RDC ANVISA 16/2013: 8.2; MHLW MO169: 6, 43, 61; 21 CFR 820.200]

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Task 27

- Additional country-specific requirements: Brazil (ANVISA), United States (FDA)

- Assessing conformity:
  - Observe instances of where nonconformities occurred and/or complaints were received after the servicing
  - Confirm data regarding service reports is analyzed for possible corrective or preventive action

  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 27

Task 27

- *Links:*
  - *Measurement, Analysis and Improvement*
    - When reviewing the organization's service reports, the audit team should be mindful of service reports that appear to be product complaints
    - Ensure that service reports that appear to be complaints have been appropriately addressed
    - Confirm the organization is taking appropriate corrections and/or corrective actions

Task 28

28. ***When appropriate, verify that risk control and mitigation measures are applied to transport, installation and servicing, in accordance with the organization's risk management practices.***

Clause and Regulation: [ISO 13485:2016: 7.1, 7.5.1, 7.5.3, 7.5.4, 7.5.11; TG(MD)R Sch1 P1 2; RDC ANVISA 16/2013: 2.4; MHLW MO169: 26, 40, 42, 43, 52; 21 CFR 820.160(a), 820.170(a), 820.200(a)]

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Task 28

- Additional country-specific requirements: None

- Assessing conformity:
  - Confirm that the necessary processes have been implemented to ensure the risk control measures are in place

  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 28

Task 29

29. Determine, based on the assessment of the production and service process overall, whether management provides the necessary commitment to the production and service process to ensure devices meet specified requirements and quality objectives.

Clause and Regulation: [ISO 13485:2016: 5.1, 5.2; RDC ANVISA 16/2013: 2.2.1; MHLW MO169: 10, 11]

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Task 29

- 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 29.

Summary

- Accomplishment of the outcomes for auditing the Production and Service Controls process is accomplished through the completion of all 29 audit tasks.

Conclusion

- This concludes the training for MDSAP process: Production and Service Controls


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