FDA U.S. FOOD & DRUG ADMINISTRATION

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Design and Development Process

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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

Learning Objectives

- Explain the Design and Development process
- Describe the purpose of auditing the Design and Development process
- Discuss the expected outcomes from audit of the Design and Development process
- Explain the audit tasks to include:
  - Description and related Clauses and Regulations
  - Country-specific requirements and assessment of conformity
  - Links to other MDSAP processes

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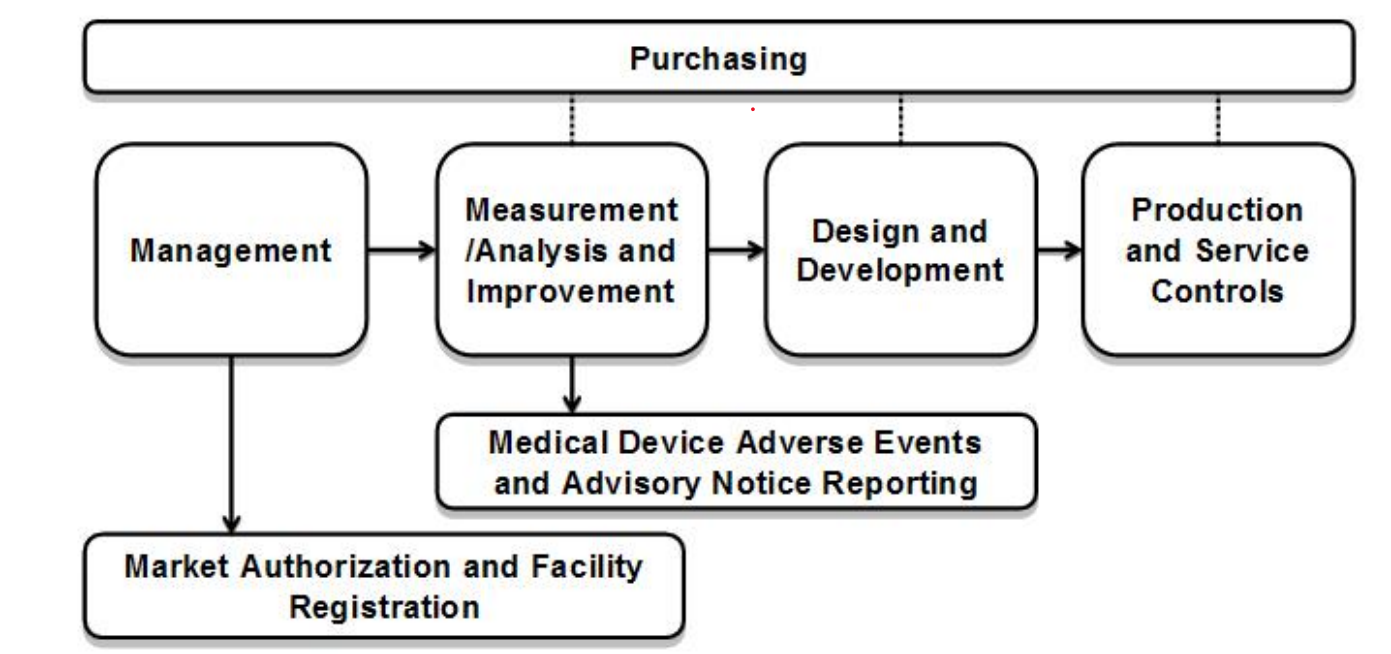
Design and Development process

- The Design and Development process:
  - Controls the design and development activities
  - Assure that devices meet user needs, intended uses, and specified requirements

- Attention to:
  - design and development planning
  - identifying design inputs, developing design outputs
  - verifying that design outputs meet design inputs
  - validating the design
  - controlling design changes
  - reviewing design results
  - transferring the design to production
  - compiling the appropriate records

will help an organization assure that resulting designs will meet user needs, intended uses, and requirements

MDSAP Audit Sequence



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Purpose of Auditing

- Design and Development process is audited to:
  - Verify that the organization establishes, documents, implements, and maintains controls
  - Ensure that medical devices meet user needs, intended uses and specified requirements

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Expected Outcomes

As a result of the audit of the Design and Development process, objective evidence will show whether the organization has:

A. Defined, documented and implemented procedures to ensure medical devices are designed according to specified requirements

B. Effectively planned the design and development of a device

C. Established mechanisms, including systematic review, for addressing incomplete, ambiguous or conflicting requirements

Expected Outcomes

As a result of the audit of the Design and Development process, objective evidence will show whether the organization has:

D. Determined the internally or externally imposed requirements for safety, function, and performance for the intended use, including regulatory requirements, risk management, and human factors requirements

E. Verified that design outputs satisfy design input requirements

F. Identified and mitigated, to the extent practical, the risks associated with the device, including the device software

Expected Outcomes

As a result of the audit of the Design and Development process, objective evidence will show whether the organization has:

G. Ensured that changes to device designs are controlled, that risks associated with design changes are identified and mitigated, to the extent practical, and that devices will continue to perform as intended

H. Performed design validation to ensure devices conform to user needs and intended use

I. Confirmed that designs are correctly transferred into production through methods and procedures

Learning Objectives

- Explain the Design and Development process
- Describe the purpose of auditing the Design and Development process
- Discuss the expected outcomes from audit of the Design and Development process
- **Explain the audit tasks to include:**
  - **Description and related Clauses and Regulations**
  - **Country-specific requirements and assessment of conformity**
  - **Links to other MDSAP processes**

Task 1

1. **Verify that those devices that are, by regulation, subject to design and development procedures have been identified. (See Annex 1)**

   Clause and Regulation: [ISO 13485:2016: 4.1.1, 4.2.1, 7.1, 7.3.10 ;TG(MD)R Regs Division 3.2; MHLW MO169: 5-1, 6, 26, 36-2 (Old: 5, 6, 26); 21 CFR 820.30(a)]

MDSAP Audit Approach

Task 1

- Additional country-specific requirements: Australia (TGA); Brazil (ANVISA); Canada (HC); and Japan (MHLW)
- Assessing conformity:
  - Verify that organization maintain a design change procedure
  - Verify that controls and records related to design trans to production have been determined
  - Verify that production line meets production 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 5: Design and Development, under task 1

Task 1

- *Links:*
  - *Purchasing*
    - If the organization outsources design and development activities, or any portion of the design and development, confirm that:
      - The organization treats the outsourced firm as a supplier;
      - Has appropriately qualified and maintains control over the supplier;
      - Communicates requirements to the supplier, including regulatory requirements
      - Has arrangements to verify that the design and development activities satisfy those requirements

Task 2

2. **Select a completed design and development project for review.**

   Priority criteria for selection:

   – complaints or known problems with a particular device
   – product risk
   – recent design changes, particularly design changes made to correct quality problems associated with the device design
   – combination product (if marketed to Australia)
   – age of design (prefer most recent)
   – designs that have not been recently audited

Clause and Regulation: None

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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 5: Design and Development, under task 2

Task 2

- *Links:*
  - *Measurement, Analysis and Improvements*
    - Be mindful of how the identified quality problems from the Measurement, Analysis and Improvement process are related to specific aspects of the design and development of the device

Task 3

3. **Verify the design and development process is planned and controlled. Review the design plan for the selected design and development project to understand the design and development activities; including the design and development stages, the review, verification, validation, and design transfer activities that are appropriate at each stage; and the assignment of responsibilities, authorities, and interfaces between different groups involved in design and development.**

   Clause and Regulation: [ISO 13485:2016: 4.2.1, 7.1, 7.3.2; TG(MD)R Sch3 P1 Cl 1.4(4)&(5)(c); RDC ANVISA 16/2013: 4.1.2, 4.1.11; MHLW MO169: 6, 26, 30; 21 CFR 820.30(b), 820.30(j)]

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Task 3

- Additional country-specific requirements: Australia (TGA); Canada (HC)

- Assessing conformity:
  - Review design plans such as flowcharts, Gantt charts, Program Evaluation Review Technique(PERT) charts
  - Expect to see interfacing between research and development, marketing, regulatory, manufacturing, and quality departments

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 5: Design and Development, under task 3

Task 4

4. **For the device design and development record(s) selected, verify that design and development procedures have been established and applied. Confirm the design and development procedures address the design and development stages, review, verification, validation, design transfer, and design changes.**

Clause and Regulation: [ISO 13485:2016: 4.2.1, 7.3.1, 7.3.10; TG(MD)R Sch3 P1 Cl 1.4(4)&(5)(c); RDC ANVISA 16/2013: 4.1.1; MHLW MO169: 6, 30, 36-2 (Old: 6, 30); 21 CFR 820.30(a), 820.30(j)]

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Task 4

- Additional country-specific requirements: United States (FDA)
- Assessing conformity:
  - Verify that Design and Development procedures address the regulatory requirements
  - Ensure that organization maintains defined and documented design change procedures

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 5: Design and Development, under task 4

Task 5

5. **Verify that design and development inputs were established, reviewed and approved; and that they address customer, functional, performance and safety requirements, intended use, applicable regulatory requirements, and other requirements including those arising from human factors issues, essential for design and development. *Verify that any risks and risk mitigation measures identified during the risk management process are used as an input in the design and development process.***

Clause and Regulation: [ISO 13485:2016: 4.2.1, 5.2, 7.2.1, 7.3.3; TG(MD)R Sch1 P1 2, Sch3 P1 Cl 1.4(2)&(5)(c); RDC ANVISA 16/2013: 2.4, 4.1.3, 4.1.11; CMDR 10-20, 21-23, 66, 67,68; MHLW MO169: 6, 11, 27, 31, 55-1 (Old: 6, 11, 27, 31, 55); 21 CFR820.30(c), 820.30(g)]

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Task 5

- Additional country-specific requirements: Australia (TGA); and United States (FDA)

- Assessing Conformity:
  - Review the sources used to develop the inputs
  - Determine that relevant aspects of the requirements for the device were covered

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 5: Design and Development, under task 5

Task 5

- *Links:*
  - *Device Marketing Authorization and Facility Registration*
    - Confirm the organization has considered regulatory requirements for registration, listing, notification and licensing
    - Confirm if organization has complied with these requirements prior to marketing the device

Task 6

6. **Confirm the design and development inputs are complete, unambiguous, and not in conflict with each other.**

Clause and Regulation: [ISO 13485:2016: 7.3.3; TG(MD)R Sch 3 Part 1.4(4), RDC ANVISA 16/2013: 4.1.3; MHLW MO169: 31; 21 CFR820.30(c)]

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Task 6

- Additional country-specific requirements: Australia (TGA)

- Assessing Conformity:
  - Verify that the organization performed a design review after the initial requirements were determined

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 5: Design and Development, under task 6

Task 7

7. **Review medical device specifications to confirm that design and development outputs are traceable to and satisfy design input requirements. Verify that the design and development outputs essential for the proper functioning of the medical device have been identified. Outputs include, but are not limited to, device specifications, specifications for the manufacturing process, specifications for the sterilization process (if applicable), the quality assurance testing, and device labeling and packaging.**

Clause and regulation: [ISO 13485:2016: 4.2.1, 4.2.3, 7.3.4; TG(MD)R Sch3 P1 Cl 1.4(5)(c); RDC ANVISA 16/2013: 4.1.5, 4.1.4, 4.1.11; MHLW MO169: 6, 7-2, 32 (Old: 6, 32); 21 CFR 820.30(d), 820.30(f)]

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Task 7

- Additional country-specific requirements: Australia (TGA)
- Assessing Conformity:
  - Review the process for determining how the essential outputs were identified
  - Verify that determination of essential outputs was done in accordance with design output procedures

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 5: Design and Development, under task 7

Task 7

- *Links:*
  - *Purchasing*
  - *Production and Service Controls*
    - Be mindful of production processes and supplied product that are essential to the proper functioning of the device
    - Consider reviewing production processes and supplied products that have been the highest risk or greatest effect on the essential design outputs

Task 8

8. ***Verify that risk management activities are defined and implemented for product and process design and development. Confirm that risk acceptability criteria are established and met throughout the design and development process.*** **Verify that any residual risk is evaluated and, where appropriate, communicated to the customer (e.g., labeling, service documents, advisory notices, etc).**

Clause and Regulation: [ISO 13485:2016: 4.2.1, 7.1, 7.3.3, 7.3.4; TG(MD)R Sch1 P1 2, Sch3 P1 Cl 1.4(5)(c)(iii); RDC ANVISA 16/2013: 2.4, 4.1.11, RDC ANVISA 56/2001; CMDR 10, 11, 15, 16; MHLW MO169: 6, 26, 31,32; 21 CFR 820.30(g)]

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Task 8

- Additional country-specific requirements: Brazil (ANVISA); and the United States (FDA)
- Assessing Conformity:
  - Verify that risk management is initiated early in the design and development process
  - Confirm risk management process involves the proactive and reactive response to quality data that indicates new or changing product 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 5: Design and Development, under task 8

Task 9

9. ***Confirm that design verification and/or design validation includes assurances that risk control measures are effective in controlling or reducing risk.***

   Clause and Regulation: [ISO 13485:2016: 7.1, 7.3.6, 7.3.7; TG(MD)R Sch1 P1 2, Sch3 P1 Cl 1.4(5)(c); RDC ANVISA 16/2013: 2.4, 4.1.4, 4.1.8, 4.1.11; CMDR 10,11, 15, 16; MHLW MO169: 26, 34, 35-1 (Old: 26, 34, 35); 21 CFR 820.30(f), 820.30(g)]

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Task 9

- Additional country-specific requirements: None

- Assessing Conformity:
  - Confirm that the identified risk control measures are actually effective in reducing or controlling risk

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 5: Design and Development, under task 9

Task 10

10. **Verify that design and development validation data show that the approved design meets the requirements for the specified application or intended use(s). *Verify that design validation testing is adjusted according to the risk of the product and element being validated.***

    Clause and Regulation: [ISO 13485:2016: 4.2.1, 7.3.7; TG(MD)R Sch1 P1 2; Sch3 P1 Cl1.4(5)(d); RDC ANVISA 16/2013: 2.4, 4.1.8, 4.1.11; CMDR 12, 18, 19; MHLW MO169: 6, 35-1 (6, 35); 21 CFR 820.30(g)]

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Task 10

- Additional country-specific requirements: Australia (TGA)

- Assessing Conformity:
  - Confirm that the design validation data show that the approved design met the predetermined user needs and intended uses

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 5: Design and Development, under task 10

Task 11

11. Verify that clinical evaluations and/or evaluation of the medical device safety and performance were performed as part of design validation if required by national or regional regulations.

Clause and Regulation: [ISO 13485:2016: 4.2.1, 7.3.7; TG(MD)R Reg 3.11, Sch3 P1 Cl 1.4(5)(c)(vii), Sch3 P8; RDC ANVISA 16/2013: 4.1.8, 4.1.11, RDC ANVISA 56/2001; CMDR 12, 18, 19; MHLW MO169: 6, 35-1 (Old: 6, 35); 21 CFR 820.30(g)]

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Task 11

- Additional country-specific requirements: Australia (TGA)

- Assessing Conformity:
  - Verify whether clinical evaluations have been performed as part of design validation
  - Verify whether acceptance criteria has 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 5: Design and Development, under task 11

Task 12

12. If the medical device contains software, verify that the software was subject to the design and development process. Confirm the software was included within the risk management process.

Clause and Regulation: [ISO 13485:2016: 7.3.2, 7.3.10; TG(MD)R Sch1 P1 2, Sch1 EP12.1; RDC ANVISA 16/2013: 2.4, 4.1.8, 4.1.11; CMDR 20; MHLW MO169: 30, 36-2 (Old: 30); 21 CFR 820.30(g)]

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Task 12

- Additional country-specific requirements: None

- Assessing Conformity:
  - Confirm that the software is part of the design and development plan for the device
  - Confirm that appropriate software verification activities were conducted
  - Review actual results of selected software tests

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 5: Design and Development, under task 12

Task 13

13. **Verify that design and development changes were controlled, verified (or where appropriate validated), and approved prior to implementation. Confirm any new risks associated with the design change have been identified and mitigated to the extent practical.**

Clause and Regulation: [ISO 13485:2016: 4.2.1, 4.2.3, 7.1, 7.3.9, 7.3.10; TG(MD)R Sch1 P1 2, Sch3 P1 Cl 1.4(5)(f), Sch3 P1Cl1.5(4); RDC ANVISA 16/2013: 2.4, 4.1.4, 4.1.8, 4.1.10, 4.1.11, Brazilian Law 6360/76 - Art. 13; CMDR 1, 34; MHLW MO169: 6, 7-2, 26, 36-1, 36-2, 55-1 (Old: 6, 26, 36); 21 CFR 820.30(i)]

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Task 13

- Additional country-specific requirements: Australia (TGA); Brazil (ANVISA); Canada (HC); Japan (MHLW), and the United States (FDA)

- Assessing Conformity:

  Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 5: Design and Development, under task 13

Task 13

- *Links:*
  - *Measurement, Analysis and Improvement process Device Marketing*
    - Confirm that design controls have been applied to the change, in accordance with the organization's procedures
    - Confirm design changes were effective
  - *Device Marketing Authorization and Facility Registration*
    - Confirm regulatory requirements for registration, listing, notification and licensing were considered

Task 14

14. **Verify that design reviews were conducted at suitable stages as required by the design and development plan. Confirm the participants in the reviews include representatives of functions concerned with the design and development stage being reviewed, as well as any specialist personnel needed.**

    Clause and Regulation: [ISO 13485:2016: 4.2.1, 7.3.2, 7.3.5; TG(MD)R Sch3 P1 C1.4(5)(c)(i); RDC ANVISA 16/2013: 4.1.6, 4.1.11; MHLW MO169: 6, 30, 33; 21 CFR 820.30(e)]

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Task 14

- Additional country-specific requirements: Unites States (FDA)

- Assessing Conformity:
  - Confirm that the review included an individual who did not have direct responsibility for the design stage being reviewed
  - Confirm that outstanding action items are being resolved or have been resolved

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 5: Design and Development, under task 14

Task 15

15. Verify that design changes have been reviewed for the effect on products previously made and delivered, and that records of review results are maintained.

Clause and Regulation: [ISO 13485:2016: 7.3.9; RDC ANVISA 16/2013: 4.1.10; MHLW MO169: 36-1 (Old: 36); 21 CFR 820.30(i)]

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Task 15

- Additional country-specific requirements: None
- Assessing Conformity:
  - Ensure the design change does not negatively impact products in distribution

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 5: Design and Development, under task 15

Task 16

16. **Determine if the design was correctly transferred to production.**

Clause and Regulation: [ISO 13485:2016: 4.2.1, 4.2.3, 7.3.8; RDC ANVISA 16/2013: 4.1.7, 4.1.9, 4.1.11, 4.2; MHLW MO169: 6, 7-2, 35-2 (Old: 6, 30); 21 CFR 830.30(h)]

MDSAP Audit Approach

Task 16

- Additional country-specific requirements: Brazil (ANVISA)
- Assessing Conformity:
  - Review how the design for the project was transferred into production specifications
  - Review significant elements of the manufacturing processes
  - Compare the significant elements with the approved design outputs

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 5: Design and Development, under task 16

Task 16

- *Links:*
  - *Production and Service Controls*
    - Verify production processes for the device have been defined, documented, and implemented
    - Confirm potential hazards that could be introduced or exacerbated by the production process have been identified, and production controls have been established
  - *Purchasing*
    - Confirm that the manufacturer has determined the type and extent of supplier controls

Task 17

17. **Determine, based on the assessment of the design and development process overall, whether management provides the necessary commitment to the design and development process.**

    Clause and Regulation: [ISO 13485:2016: 4.1.3, 5.1, 5.5.1; TG(MD)R Sch3 P1 Cl 1.4(5)(b)(ii); RDC ANVISA 16/2013: 2.2.1; MHLW MO169: 5, 10, 15]

MDSAP Audit Approach

Task 17

- 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 5: Design and Development, under task 17

Summary

- Design and Development process is intended to:
  - Control the design and development activities
  - Assure that devices meet user needs, intended uses, and specified requirements.

Conclusion

This concludes the training module for MDSAP process: Design and Development


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