Medical Device Single Audit Program

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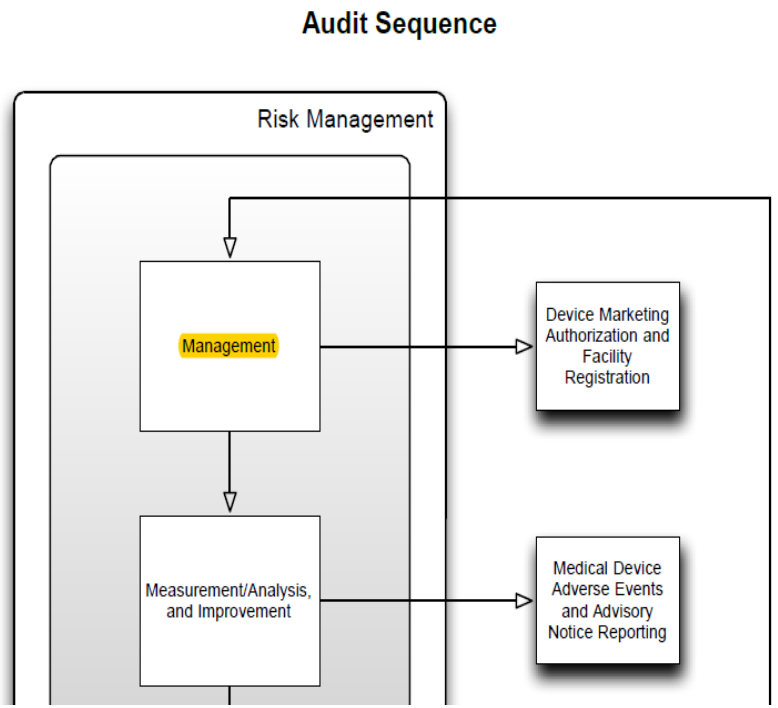
Audit Sequence, Chapter 1 - Management

- The Management process is the first process to be audited per the MDSAP audit sequence



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- The requirements for the Management process are defined in the clauses of ISO 13485 and Country regulations:
  - ISO 13485:2016: Clauses 4.1.1, 4.1.2, 4.1.3, 4.2.2, 4.1.4, 4.1.5, 4.2.1, 4.2.4, 4.2.5, 5.1, 5.3, 5.4.1, 5.4.2, 5.5.1, 5.5.2, 5.5.3, 5.6, 6.1, 6.2, 7.1, 7.2.1, 7.2.3,

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- The requirements for the Management process are defined in the clauses of ISO 13485 and Country regulations:
  - TG (MD)R Sch3 P1 1.4, Sch1 P1 2
  - CMDR / SOR-98-282
  - RDC ANVISA 16/2013: 2.1, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.3, 2.4, 2.5, 5.6, 3.1
  - MHLW MO169: 5, 6, 7, 8, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 25.4, 26
  - 21 CFR 820.20, 820.25, 820.50. 820.30, 820.40, 820.180, 820.5

- At times there are additional country-specific requirements

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- The intent of the **Management process** is to provide adequate resources for
  - device design
  - Manufacturing
  - quality assurance
  - Distribution
  - Installation
  - servicing activities

- to assure the QMS is
  - functioning properly and effectively
  - to monitor the QMS
  - make necessary adjustments.

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- The purpose of auditing this process:
  - Verify top management ensures an adequate and effective QMS has been implemented and maintained.

- Links to other Processes:
  - Measurement, Analysis and Improvement (MA&I)
  - Design and Development (D&D)
  - Purchasing (P)
  - Production and Service Controls (P&SC)
  - Device Marketing Authorization and Facility Registration (DMA&FR)

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- Basics from 13485:2016
  - QMS General requirements
    - Documentation and Records requirements
  - Management Responsibility
    - Quality policy
    - Planning
    - Responsibility and authority
    - Management review

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- Basics from 13485:2016
  - Resource Management
    - Provision of resources
    - Human resources
  - Product Realization
    - Planning of product realization
    - Customer related processes

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- There are 11 highlighted areas 'tasks' that are evaluated in detail.

  Major topics include:

  - Quality system procedures, instructions and records 

    - Quality policy, Quality Objectives
  - QMS Planning
  - Management responsibilities and authority
    - Management review Links (MA&I)
    - Commitment to risk management Links (D&D)
    - Controls to ensure appropriate market authorization Links (DMA&FR)

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- Major topics (continued):
  - Resources
  - Training, Competency 

(P&SC) 

  - Outsourcing 

(P) 

Sources

- ISO 13485:2016
- The Australian Therapeutic Goods (Medical Devices) Regulations (TG(MD)R Sch 3)
- Brazil Good Manufacturing Practices (RDC ANVISA 16/2013)
- Japan Ordinance of Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostics Reagents (MHLW Ministerial Ordinance No. 169)
- The Quality System Regulations (21 CFR Part 820)
- Canadian Medical Device Regulations (SOR/98-282)
- MDSAP Audit Model (AU P0002.004)

Questions?