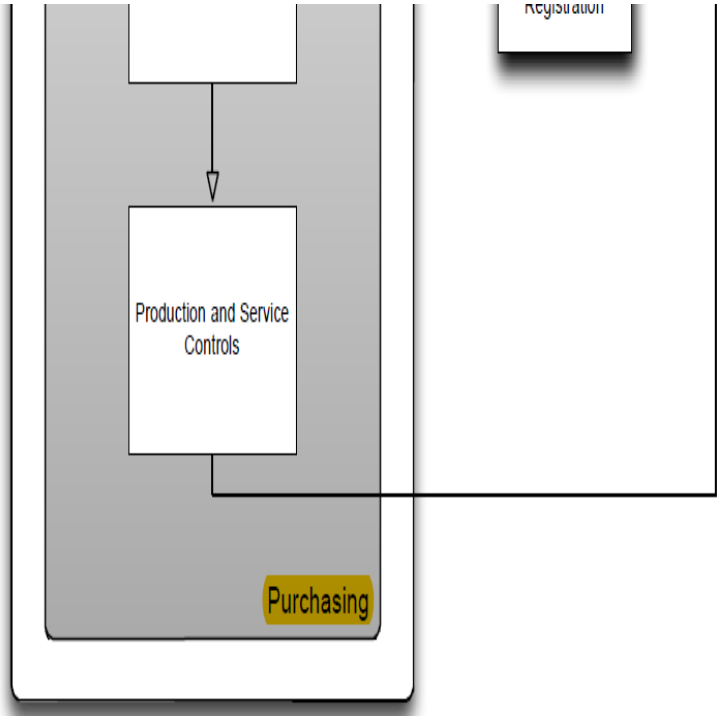
Medical Device Single Audit Program

Pamela Burdette-Miller
MDSAP Scheme Manager
NSAI Inc.

Audit Sequence, Chapter 7 - Purchasing

- The Purchasing process can be audited at various points during the audit.



Chapter 7 –Purchasing

- The requirements for the Purchasing process are defined in the clauses of ISO 13485 and Country regulations:
  - ISO 13485:2016: Clauses 4.1.2, 4.1.3, 4.1.5, 4.2.1, 5.2, 7.1, 7.4.1, 7.4.2, 7.4.3, 7.5.9, 8.4

Chapter 7 – Purchasing

- The requirements for the Management process are defined in the clauses of ISO 13485 and Country regulations:
  - TG(MD)R Sch1 P2, Sch3 P1
  - CMDR / SOR-98-282
  - RDC ANVISA 16/2013: 2.2.1, 2.3.3, 2.4, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 3.35, 3.1, 5.3.2, 5.3.3 6.4, 7.1.1.1
  - MHLW MO169: 5, 6, 11, 26, 37, 38, 39, 48, 49, 61
  - 21 CFR 820.20, 820.50, 820.65, 820.80, 820.100, 820.160

- At times there are additional country-specific requirements

Chapter 7 – Purchasing

- The intent of the **Purchasing process** is to ensure that…..
  - Purchased
  - Subcontracted
  - Received products
  - Received services
  - …..conform to specified requirements

- The organization is expected to establish and maintain documented controls for planning and performing purchasing activities.

Chapter 7 –Purchasing

- Purchasing controls depends on the effect of the product or service on the…
  - Quality
  - Safety
  - Effectiveness

…..finished device

Chapter 7 - Purchasing

- The purpose of auditing this process:
  - Verify that the organizations processes ensure that products (components, material, services providers, consultants, contractors) conform with the QMS and purchasing requirements. top management ensures an adequate and effective QMS has been implemented and maintained.

Chapter 7 - Purchasing

- Links to other Processes:
  - Management
  - Measurement, Analysis and Improvement (MA&I)
  - Design and Development (D&D)
  - Production and Service Controls (P&SC)

Chapter 7 - Purchasing

- Basics from 13485:2016
  - QMS General requirements
    - Documentation and Records requirements
  - Management responsibility
    - Customer focus
  - Planning of product realization

Chapter 7 - Purchasing

- Basics from 13485:2016
  - Purchasing
    - General purchasing process
    - Verification of purchased product
    - Supplier controls
    - Traceability
    - Analysis of data

Chapter 7 - Purchasing

- There are 11 highlighted areas 'tasks' (in addition to the basic requirements) that are reviewed in detail.

  Major topics include:

  - Planning
    - Affect of purchased product on the design output Links (D&D)
  - Supplier selection 

  - Control of Critical suppliers / Outsourced processes
    - Monitoring performance, evaluations and re-evaluation Links (P&SC, MA&I)
    - Records of Supplier evaluations Links (D&D, P&SC)

Chapter 7 - Purchasing

- Major topics (continued):
  - Communication of purchasing requirements and written agreements 

  - Risk control measures
  - Inspections / verification of purchased products (P&SC) Links 

  - Data from the evaluation of suppliers, verification activities and purchasing Links (MA&I)

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?