Management Controls

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Learning Objectives

- Provide background about management controls
- Explain purpose of the management controls subsystem
- Review the Quality System Regulation requirements for management controls

Background

The 7 Subsystems of a Quality System

Background

- Major subsystem
- Key quality indicator of your quality system
- Basic foundation of an effective quality management system

Background

- Management is ultimately responsible for the **entire** Quality System

Background: Definition

Quality System

Organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

21 CFR § 820.3(v)

Purpose of Management Controls

Purpose

1. **Provides adequate resources for operations**
   - Qualified people
   - Equipment (including manufacturing equipment)
   - Adequate facilities

Purpose

2. **Ensures an adequate and effective quality system has been established**

- Controlled manufacturing processes
- Controlled documentation
- Calibrated, inspected, and tested equipment

Purpose

3. **Monitors the quality system and make necessary adjustments**

- Management Representative ensures quality system is monitored
- Adjustments are based on periodic management reviews

Requirements of Management Controls

Quality System Regulation

Management Controls Subsystem:

- 21 CFR 820.20: Management responsibility
- 21 CFR 820.22: Quality audit
- 21 CFR 820.25: Personnel

Management Responsibility

1. **Establish a quality policy and objectives**

- Quality policy is established by management with executive responsibility
- Addresses quality
- Quality policy must be understood and implemented by all employees

Manager with Executive Responsibility

- Senior employee
- Able to establish and change quality policy and quality system
- Definition consistent with ISO 9001

Management Responsibility

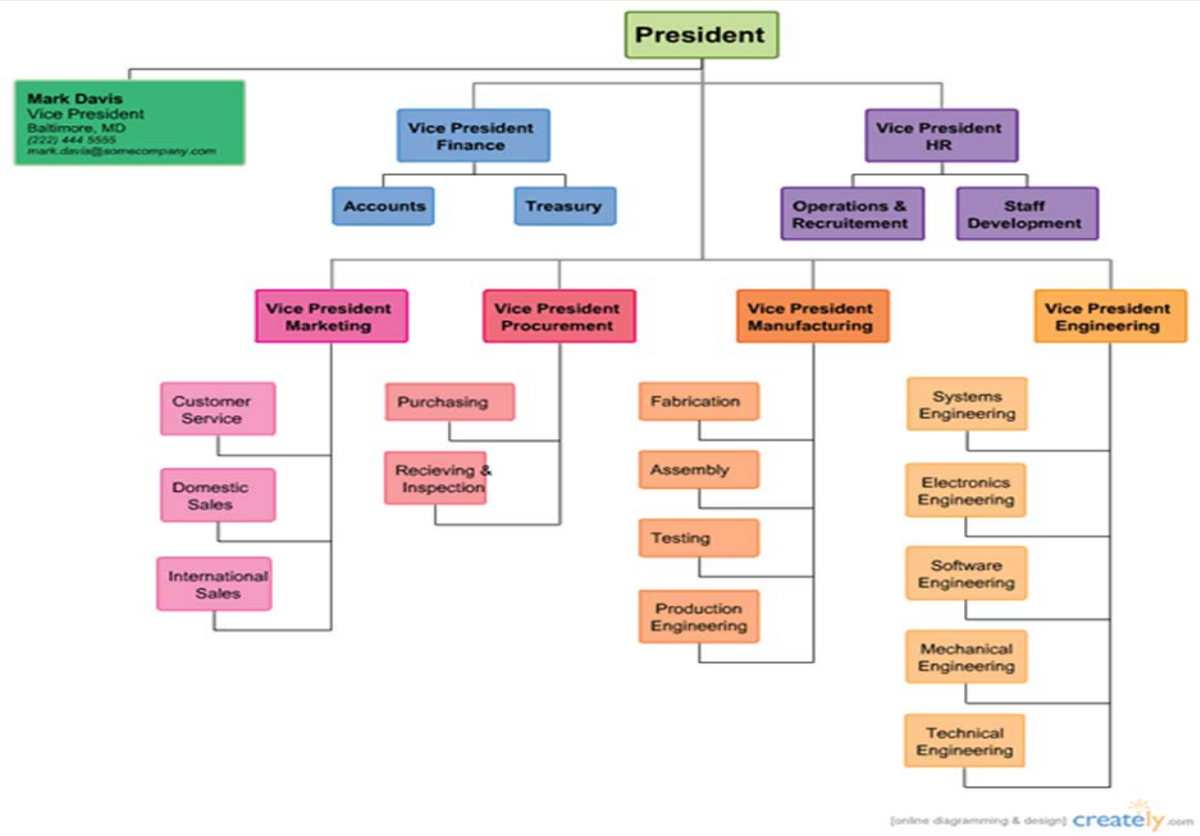
2. **Establish and maintain organizational structure**

- Must be adequate for time and employees
- Must control all functions affecting device quality
  - Technical functions
  - Administrative functions
  - Human factors

Organizational Structure

- Consider device type, organizational goals, and customer needs
- May vary based on:
  - Class (i.e., Class I, II, or III) of medical device
  - Size of manufacturer

Sample Organization Chart



Organization

Establish appropriate responsibility and authority

- Independent to every function affecting quality
- Individuals must be able to perform assigned tasks
- Teams are not limited to single specialty; may be inter-disciplinary

Organization

Provide adequate resources

- Assure quality objective can be achieved
- Must be available
- Assign trained personnel

Examples of Inadequate Resources

- Not meeting deliverables/timelines
- High volume of non-conforming product awaiting disposition
- Lengthy time to resolve investigations
- Lengthy time to implement corrective actions

Organization

Appoint a management representative

- One member of management (not multiple)
- Appointment must be documented
- Ensures quality system is established and maintained
- Reports to Executive Management on performance of quality system

Management Responsibility

3. Conduct management reviews

- By management with executive responsibility
- With sufficient frequency
- Measure firm's quality system
- Use internal audit outcomes to consider updates to quality system

Management Reviews

- Must be documented
- Must have management review instructions and procedures
- Not routinely reviewed by FDA

Management Responsibility

4. Establish a quality plan

- Define quality practices, resources, and activities
- Plan to document quality system activities
  - may be an independent document
  - may reference Device Master Record, Quality System Record, and other quality system records already in place
- No specific format required

Management Responsibility

5. Establish quality system procedures

- Composed of both system level procedures and device specific procedures
- Outline of structure of documentation used in quality system only required where appropriate

Quality System Regulation

Management Controls Subsystem:

- 21 CFR 820.20: Management responsibility
- **21 CFR 820.22: Quality audit**
- 21 CFR 820.25: Personnel

Quality Audits

- **Conduct quality audit of entire quality system**
  - Quality System Inspection Technique is limited; is not comprehensive for internal audit
  - Assure quality system is in compliance
  - Determine effectiveness of quality system
  - Conducted by individual without direct responsibility
  - Conducted with sufficient frequency

Quality Audits

- Take corrective action when necessary
- Results reported to executive management and reviewed during management reviews
- Date and results of audits/re-audits documented

Quality Audits

- **Quality Audit procedures may include:**
  - Responsibilities for each part of the audit process
  - Schedule of audits
  - Auditor qualifications
  - When to re-audit
  - Scope and purpose of audit
  - Checklist
  - Documentation format

Quality System Regulation

Management Controls Subsystem:

- 21 CFR 820.20: Management responsibility
- 21 CFR 820.22: Quality audit
- **21 CFR 820.25: Personnel**

Personnel

- **Have sufficient personnel with necessary education, background, training and experience**
  - Ensure all quality system activities are performed
  - Identify training needs
  - Ensure all personnel are trained

Personnel

- Determine personnel qualifications:
  - Review resume
  - Interview employees
  - Contact references

Personnel

- Personnel are trained and made aware of device defects
- Trained personnel prevent non-conforming product from being released to market

Personnel

- Document training
- Staff conducting verification and validation activities must be informed of device defects

Summary

- Management Controls is one of the basic foundations of the quality management system.
- Management Controls provides adequate resources, monitor, and make adjustments to the quality system.
- Management controls involve audit of entire quality system.

Summary

- Requirements are codified under:
  - 21 CFR 820.20
  - 21 CFR 820.22
  - 21 CFR 820.25

- Management is ultimately responsible for the entire quality management system.

Call to Action

- The role of management is to ensure evaluation of the suitability and effectiveness of the entire quality management system.

Industry Education Resources

Three Resources

1. **CDRH Learn – Multi-Media Industry Education**
   - over 115 modules
   - videos, audio recordings, power point presentations, software-based “how to” modules
   - mobile-friendly: access CDRH Learn on your portable devices

   http://www.fda.gov/Training/CDRHLearn

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/DeviceAdvice

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: www.fda.gov/DICE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