Management Controls

Tonya A. Wilbon
Deputy Director, Acting
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration
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

- Design Controls
- Corrective and Preventive Actions
- Management
- Material Controls
- Production and Process Controls
- Records, Documents, and Change Controls
- Equipment and Facility Controls
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

www.fda.gov
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

www.fda.gov
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

www.fda.gov
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

www.fda.gov
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