

Management Controls

**FDA Small Business
Regulatory Education for Industry (REdI)
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Poll

D2S3-1

View Votes

EditEnd Poll

D2S3-1: What role of Management do you play at your firm?

<input type="radio"/> Management with executive responsibility.	<div></div>	0%	(0)
<input type="radio"/> My firm's management representative.	<div></div>	0%	(0)
<input type="radio"/> Part of management (not 1 or 2 above).	<div></div>	0%	(0)
<input type="radio"/> Not part of management/none of the above.	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☒ Broadcast Results

Learning Objectives

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

The 7 Subsystems of a Quality System



Background

Management Controls:

- Key quality indicator
- Major subsystem
- Basic foundation of a quality management system

Background continued

Management is ultimately responsible for the entire Quality System

Background continued

Quality System means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

[21 CFR § 820.3(v)]

Purpose

Management Controls Subsystem:

- Provides adequate resources for operations
 - ❖ Qualified people
 - ❖ Equipment (including manufacturing equipment)
 - ❖ Training facilities

Purpose continued

Management Controls Subsystem:

- Ensures an adequate and effective quality system has been established
 - ❖ Controlled manufacturing processes
 - ❖ Controlled documentation
 - ❖ Calibrated, inspected, and tested equipment

Purpose continued

Management Controls Subsystem:

- Monitors the quality system and make necessary adjustments
 - ❖ Through management representative
 - ❖ Through periodic reviews

Essential Elements

Quality System Regulation requirements:

- 21 CFR 820.20: [Management responsibility](#)
- 21 CFR 820.22: [Quality audit](#)
- 21 CFR 820.25: [Personnel](#)

Essential Elements Continued

QS Regulation Requirement:

- Establish a quality policy and objectives
 - ❖ Quality policy established by Management with executive responsibility
 - ❖ Addresses quality
 - ❖ Quality policy understood and implemented

Essential Elements Continued

Management with executive responsibility:

- Senior employee
- Establish and make changes to the quality policy and quality system
- Definition Consistent with ISO 9001

Sample Quality Policy

We at XYZ Company have a personal commitment to understand, meet and, when possible, exceed our Customer's Requirements through the continuous improvement of our processes. We are dedicated to delivering defect-free product on-time at the most competitive cost possible.

Quiz/Fact Check

D2S3-2

View Votes

Edit

End Poll

D2S3-2: What part of the previous quality policy is not required to be understood per 21 CFR 820.20?

<input type="radio"/> Continuous Improvement of processes	<div></div>	0%	(0)
<input type="radio"/> Delivering defect free product	<div></div>	0%	(0)
<input type="radio"/> Meet and exceed customer's expectation	<div></div>	0%	(0)
<input type="radio"/> Delivering product at most competitive cost	<div></div>	0%	(0)
<input type="radio"/> None of the above	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☐ Broadcast Results

Essential Elements continued

QS Regulation Requirement:

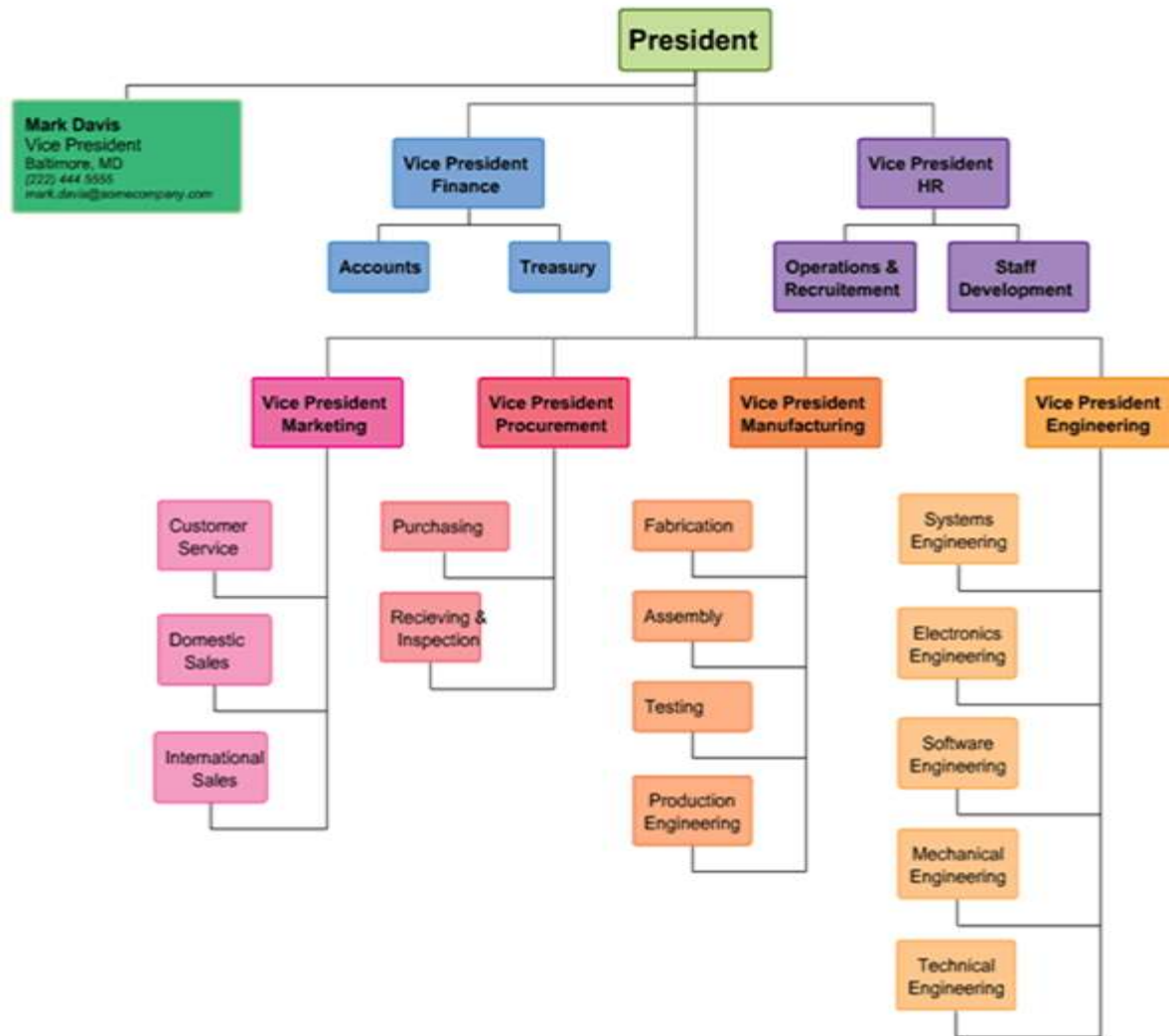
- Establish and maintain organizational structure
 - ❖ Must be adequate
 - ❖ Must control functions affecting the quality of the device
 - Technical functions
 - Administrative functions
 - Human Factors

Essential Elements continued

QS Regulation Requirement:

- Establish organizational structure continued.
 - ❖ Determined by type of device, organizational goals, and needs of customer

Sample Organization Chart



Essential Elements continued

QS Regulation Requirement:

- 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 nonconforming product awaiting disposition
- Time to resolve investigations
- Time to implementing CAs

Essential Elements continued

QS Regulation Requirement:

- Establish appropriate responsibility and authority
 - ❖ Independent to every function affecting quality
 - ❖ Not required to be a stand alone group

Essential Elements continued

QS Regulation Requirement:

- Appoint a management representative
 - ❖ Member of management
 - ❖ Appointment documented
 - ❖ Ensure quality system is established and maintained
 - ❖ Report on performance of quality system

Essential Elements continued

QS Regulation Requirement:

- Conduct management reviews
 - ❖ Conducted by management with executive responsibility
 - ❖ Conducted with sufficient frequency
 - ❖ Measure the firm's quality system
 - ❖ Consider updating quality system

Essential Elements continued

QS Regulation Requirement:

- Conduct management reviews continued.
 - ❖ Must be documented
 - ❖ Must have management review instructions/procedures
 - ❖ Not routinely reviewed by FDA

Poll

D2S3-3

View Votes

Edit

End Poll

D2S3-3: Do you have procedures in place that require in-person management reviews?

<input type="radio"/> Yes	<div></div>	0%	(0)
<input type="radio"/> No	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☒ Broadcast Results

Management Reviews May Include

Review Of:

- The organizational structure
- If device quality meets the company's quality objectives
- Information on product and process performance, customer feedback, etc.
- Internal audit results
- Complaints and Corrective Action (CAPA) and Preventive Actions

Essential Elements continued

QS Regulation Requirement:

- Establish a quality plan
 - ❖ Define quality practices, resources, and activities
 - ❖ May be independent document
 - ❖ May reference Device Master Record (DMR), Quality System Record (QSR) or other quality system element
 - ❖ No specific format required

Essential Elements continued

QS Regulation Requirement:

- 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

Essential Elements continued

QS Regulation Requirement:

- Conduct quality audits
 - ❖ Assure quality system is in compliance
 - ❖ Determine effectiveness of quality system
 - ❖ Conducted by individual who does not have direct responsibility
 - ❖ Conducted with sufficient frequency

Essential Elements continued

QS Regulation Requirement:

- Conduct quality audits continued.
 - ❖ Take corrective action when necessary
 - ❖ Report of results completed and reviewed by management
 - ❖ Date and results of audits/re-audits documented

Essential Elements continued

QS Regulation Requirement:

- Conduct quality audits continued.
 - ❖ Consist of a formal, planned check of all elements in quality system
 - ❖ Are not product/device audits
 - ❖ Can detect system defects
 - ❖ Recommended time to not exceed 12 month between quality audits

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

Essential Elements continued

QS Regulation Requirement:

- 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

- Identify Training needs:
 - ❖ Trace matrix
 - ❖ Job description
 - ❖ Testing
 - ❖ Continuing education requirements

Essential Elements continued

QS Regulation Requirement:

- Have sufficient personnel with necessary education, background, training and experience *cont.*
 - ❖ Document training
 - ❖ Make personnel aware of device defects
 - ❖ Make aware of device defects those performing verification/validation activities

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

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

QUESTIONS



Please complete the session survey:

surveymonkey.com/r/DEV-D2S3

Call to Action

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

