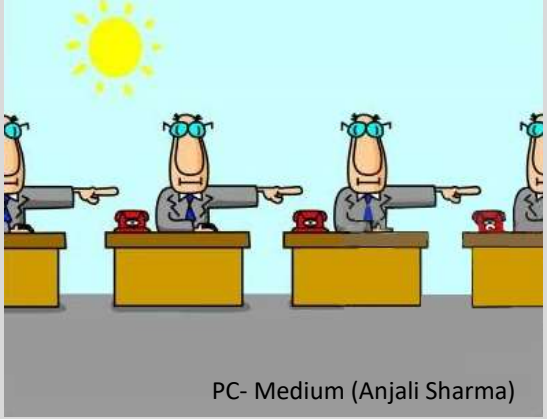
Management At A Glance

FDA Small Business Regulatory Education for Industry (REdI)

July 21, 2021

Vidya Gopal
Consumer Safety Officer
Postmarket and Consumer Branch
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Management At a Glance


PC- Medium (Anjali Sharma)


PC- Judith Orloff

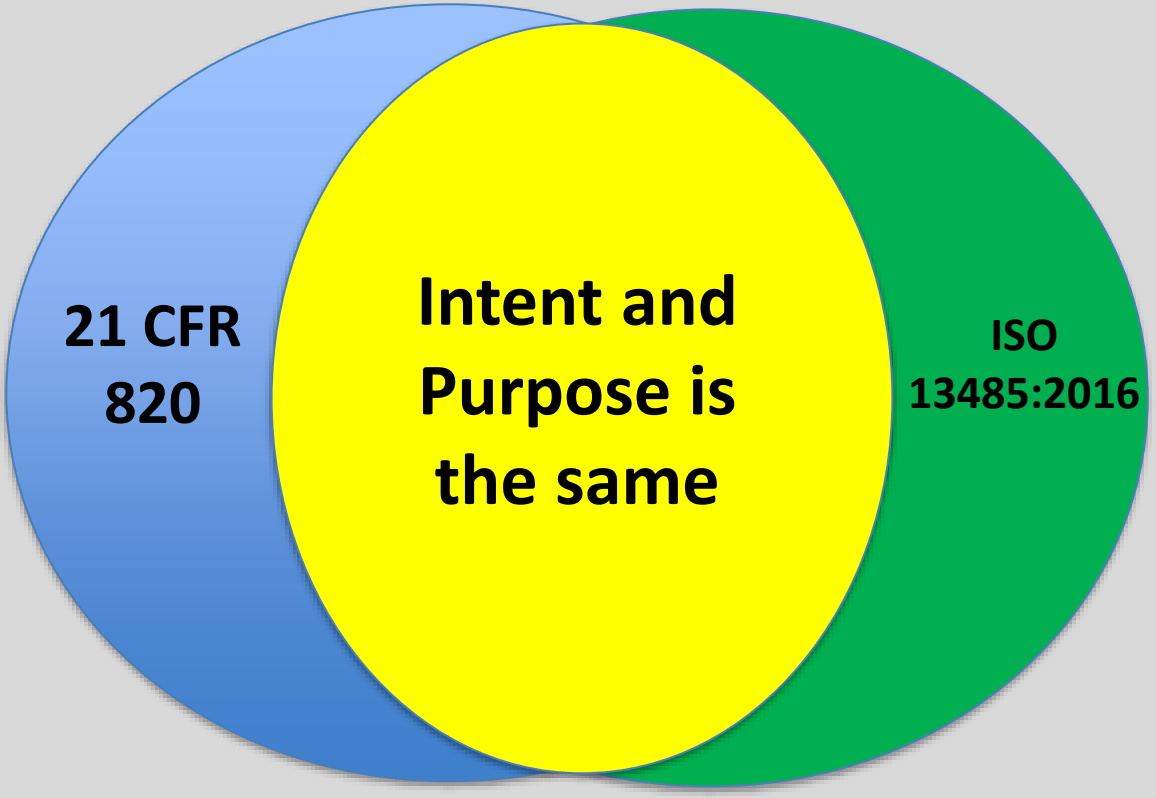
Management At a Glance

PC – Albright institute

Learning Objectives

- Discuss background information about Quality System (QS) regulation and ISO 13485: 2016
- State the QS regulation and ISO 13485: 2016 requirements for Management Controls
- Identify the differences and similarities in QS regulation and ISO 13485: 2016 for Management Controls
- Review an example of implementing Management Controls

Management At a Glance



Background

21 CFR 820

- 1978 Good Manufacturing Practice (GMP)
- current GMP
- 1990 Safe Medical Device Amendments
- 1996 Quality System Regulation
- 2012 Amendments
- Today

ISO 13485:2016

- GHTF 1992 (Harmonization)
- ISO 9001:1994
- ISO 13485:1996
- ISO 13485:2003
- IMDRF 2011 (Convergence)
- MDSAP 2012
- Today

Background

- FDA intends to modernize Quality System regulation

- Revisions intend to reduce compliance and recordkeeping burdens on device manufacturers
  - by harmonizing domestic and international requirements

FDA Update – Transition to ISO 13485:2016: www.fda.gov/media/123488/download

The 7 Subsystems of a Quality System

Management

21 CFR 820.20

Management responsibility

Management with executive responsibility is responsible for:

- Quality policy
- Appointing management representative
- Management review

ISO 13485

Clause 5.1 Management commitment

Top management is responsible for:

- Quality policy and objectives
- Management reviews
- Communicating importance of meeting requirements
- Availability of resources

Management

21 CFR 820.20	ISO 13485 5.2 Customer focus
N/A	Top management ensures that all requirements (customer and regulatory) are determined and met.

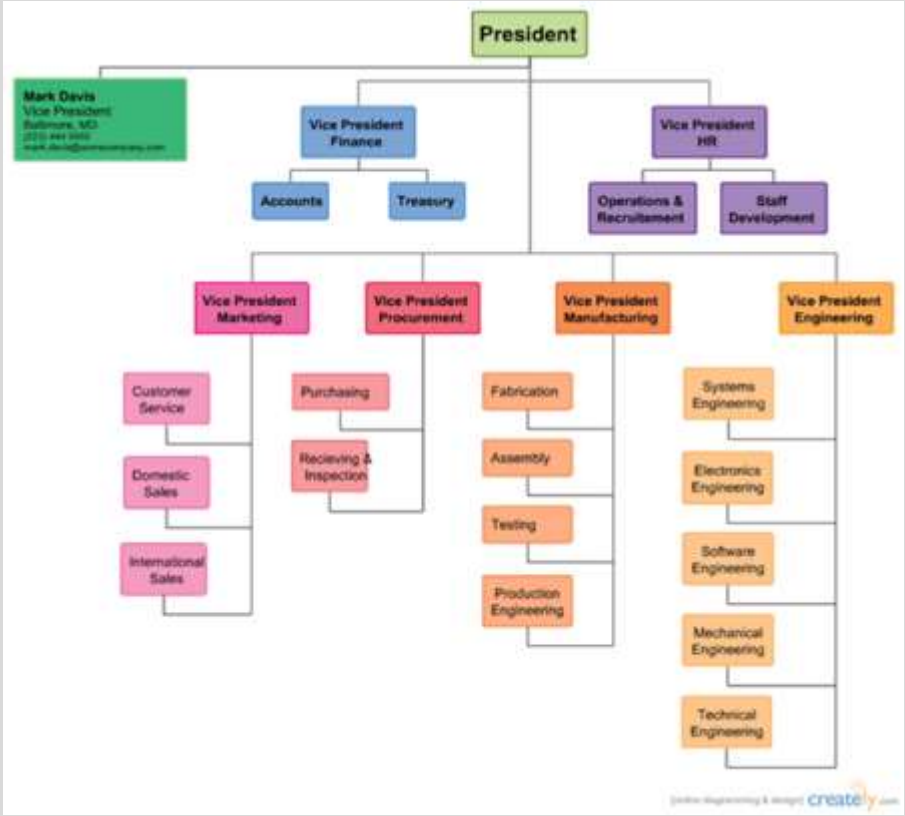
Quality Policy

21 CFR 820.20(a) Quality policy	ISO 13485 5.3 Quality policy
Both the regulation and standard require the quality policy be communicated and understood by the organization.	
	Specific criteria for review for continued suitability.

Organization

21 CFR 820.20(b) Organization	ISO 13485 5.5.1 Responsibility and authority
Establish an adequate organizational structure.	Document interrelation of all personnel that perform work that impact quality and ensure independence and authority necessary to perform that work.

Sample Organization Chart



Responsibility and Authority

21 CFR 820.20(b)(1) Responsibility and authority	ISO 13485 5.5.1 Responsibility and authority

- Requirements of Regulation and Standard are similar.
- Management must establish appropriate responsibility and authority

Resources

21 CFR 820.20(b)(2)	ISO 13485
Resources	5.1 Management commitment 6.1 Provision of resources

- Requirements of Regulation and Standard are similar.
- Management must provide adequate resources.

Knowledge Check

Who is responsible for getting the resources?

1. Everybody
2. Nobody
3. Management

Management Representative

21 CFR 820.20(b)(3) Management representative	ISO 13485 5.5.2 Management representative
Both the regulation and standard require the management representative to report on “performance” of Quality System.	
	An additional requirement is for promotion of awareness of regulatory and QMS requirements throughout the organization.

Management Review

21 CFR 820.20(c)	ISO 13485
Management review	5.6 Management review

Both the regulation and the standard require the management representative to review the effectiveness of the quality system at defined intervals (management reviews).

Quality Planning

21 CFR 820.20(d) and (e)

Quality planning

- Establish a quality plan
- Establish Quality System procedures and instructions

ISO 13485

5.4.2 QMS planning

- Quality objectives are established
- Quality objectives must be measurable and linked to the policy
- Top management is responsible for quality planning
- Changes to the system are planned and implemented without negative impact

Communication

21 CFR 820	ISO 13485 5.5.3 Internal communication
This is not specifically stated in the Regulation.	Requires that top management ensures appropriate communication processes are established for communication of the effectiveness of the QMS.

Quality System Procedures

21 CFR 820.20(e) **Quality system procedures**	**ISO 13485** **4.2 Documentation requirements** **4.2.1 General** **4.2.2 Quality manual**
Both the regulation and standard state that you should establish procedures and instructions and an outline of the structure of the documentation used in the Quality System.	
Does not require a quality manual.	Requires a quality manual that includes: • scope of the QMS • justifications of exclusions or non-application • QMS processes interactions • structure of the QMS documents

Example of Management Controls

Management reviews include:

- CAPA reports and trends
  - number of CAPA's opened
  - number of CAPA's closed
  - status of still-open CAPAs,
  - resources needed to close them
  - trends
- NCR/NMR reports and trends
- Information on product and process performance, customer feedback, including complaints and trends
- Organizational structure
- If device quality meets company's quality objectives
- Internal audit results

CAPA = Corrective and Preventive Action; NCR = Non-Conformance Report; NMR = Non-conforming Material Report

Interesting Case

- FDA investigators inspected a plant after receiving complaints
- They discovered a "gummy brown" substance on the syringe-filling machine and brown water flowing from taps, among other problems
- The plant was closed
- Federal prosecutors indicted the President (Management)

➢ An indictment on fraud, conspiracy and other charges alleges that his firm lied about performing sterility tests and produced prefilled syringes laced with bacteria

Interesting Case

- **OCI press releases and charges**

www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/criminal-investigations/press-releases

- **Press release**

www.chicagotribune.com/nation-world/chi-syringes-bd07-jun07-story.html

Top MANAGEMENT is responsible for safe and effective devices

Knowledge Check

Management is responsible for:

1. Providing adequate resources
2. Monitoring the QMS
3. Making Adjustments to the QMS
4. All of the above
5. None of the above

Summary

- Management Controls is one of the basic foundations of the quality management system
- Management provides adequate resources, monitor, and make adjustments to the quality management system
- Management is ultimately responsible for the entire quality management system
- Requirements are stated in 21 CFR 820.20 and ISO 13485:2016 Clause 5

Resources

Slide Number	Cited Resource	URL
6	Quality System regulation	21 CFR 820
6	ISO 13485: 2016	(For purchase)
7	AAMI Quality Systems White Paper Comparison of 21 CFR 820 to ISO 13485:2016-2018	https://www.aami.org/docs/default-source/uploadedfiles/filedownloads/whitepaper/qs-white-paper-21cfr820-13485.pdf
7	US FDA Quality System Regulation Versus ISO 13485: 2016 Quality Management System Requirements	US FDA System Regulation vs. ISO 13485:2016 Quality Management System Requirements (d2evkimvhatqav.cloudfront.net)
	CDRH Learn (management controls)	https://www.fda.gov/training-and-continuing-education/cdrh-learn

Questions


FDA
U.S. FOOD & DRUG
ADMINISTRATION