CAPA At A Glance

FDA Small Business Regulatory Education for Industry (REdI)

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CAPA

Australia: Therapeutic Goods Administration (TGA)

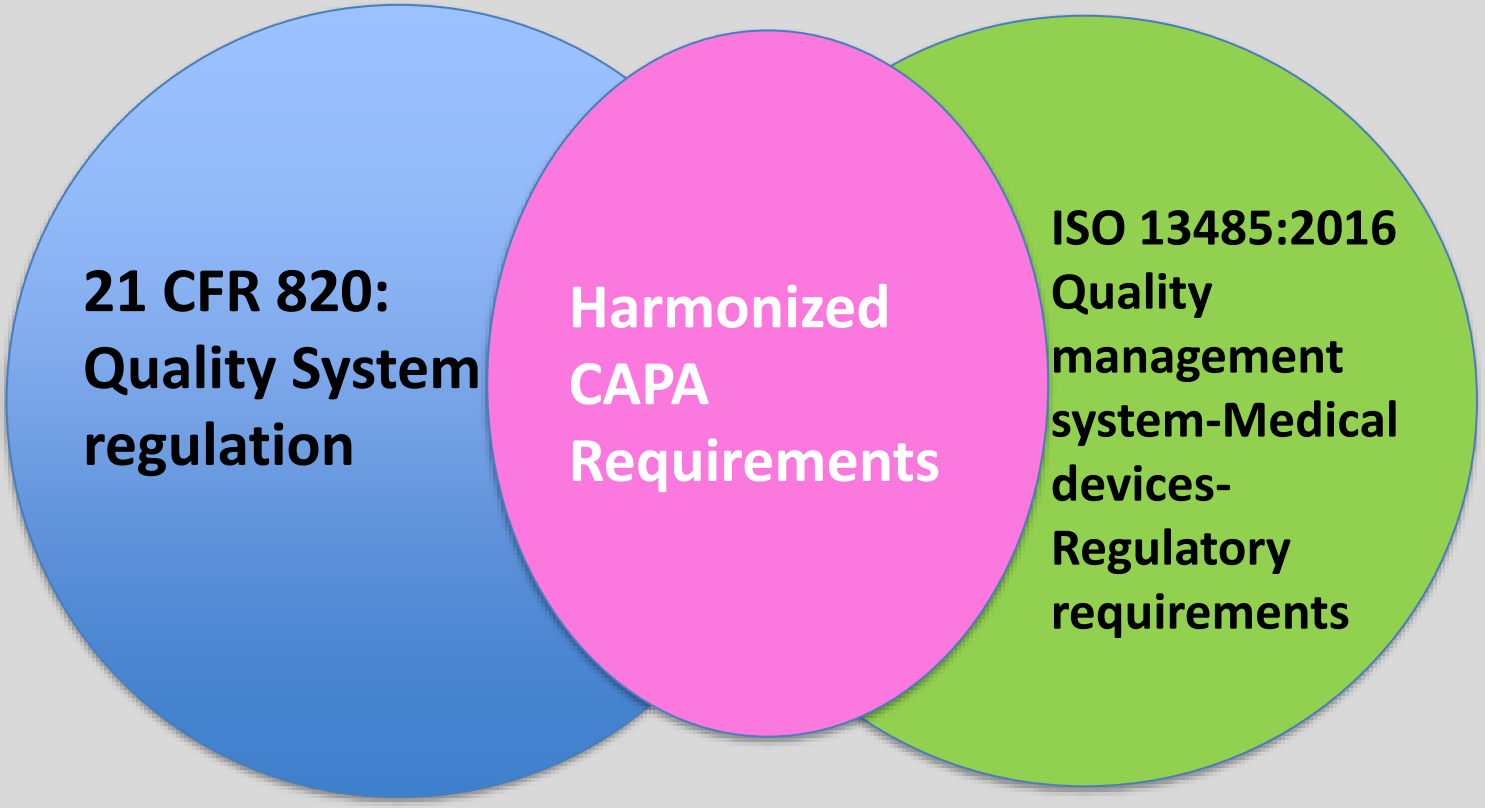
Food and Drug Administration (FDA)

Health Canada (HC)

Brazil: Agencia Nacional de Vigilancia Sanitaria (ANVISA)

Japan (MHLW/ PMDA)

CAPA


21 CFR 820: Quality System regulation
Harmonized CAPA Requirements
ISO 13485:2016 Quality management system-Medical devices-Regulatory requirements

Learning Objectives

- Review basic CAPA information
- State the QS regulation and ISO 13485: 2016 requirements for CAPA
- Identify the similarities and differences in QS regulation and ISO 13485: 2016 requirements for CAPA
- Review a CAPA example

CAPA Basics

CAPA Basics

- Acronym for Corrective and Preventive Action
- One of the 4 major subsystems of a quality system
- Corrective action is taken to prevent recurrence of nonconformity
- Preventive action is taken to prevent occurrence of nonconformity

CAPA Basics

CAPA Subsystem implemented to:

- Collect and analyze information
- Identify and investigate nonconformities (product and quality problems)
- Determine the cause of nonconformities
- Take appropriate and effective action
- Verify effectiveness of action taken

CAPA Requirements

- **Title 21 Code of Federal Regulations, Part 820: Quality System Regulation (21 CFR 820)**
  - 21 CFR 820.100 (Corrective and Preventive Action)
- **ANSI/AAMI/ISO 13485:2016: Medical devices-Quality management systems- Requirements for regulatory purposes (ISO 13485:2016)**
  - Clause 8.4 (Analysis of data)
  - Clause 8.5 (Improvement)

QS regulation and ISO 13485: 2016 CAPA Requirements

CAPA Requirements

21 CFR 820		ISO 13485: 2016	
Corrective and Preventive Action	820.100 - 820.100(a) - 820.100(a)(1)-(a)(7) - 820.100 (b)	Analysis of data	Clause 8.4
		Improvement - General - Corrective action - Preventive action	Clause 8.5 - Clause 8.5.1 -Clause 8.5.2 - Clause 8.5.3

CAPA Requirements

21 CFR 820.100
• Collect information and analyze information • Use appropriate statistical methodology • Identify and investigate product and quality problems • Take appropriate and effective action • Document activities and results • Disseminate information to those directly involved

CAPA Requirements

ISO 13485: 2016, Clause 8.4
• Document procedures to determine, collect, and analyze appropriate data • Determine appropriate methods used, including statistical techniques • Analyze data generated from specified minimum input sources • Use analysis as input for improvement process • Maintain records of the results

CAPA Requirements

ISO 13485: 2016 , Clause 8.5
• Identify and implement any changes • Take action to eliminate the cause of existing nonconformities without undue delay • Determine action to eliminate the causes of potential nonconformities • Document procedures for corrective action and preventive action • Maintain records of results obtained

Knowledge Check

A corrective action is taken to prevent the recurrence of a nonconformity.

a) True

b) False

Knowledge Check

A CAPA subsystem is implemented for which of the following reasons:

a) Collect and analyze information

b) Identify and investigate nonconformities

c) Determine the cause of nonconformities

d) a, b, and c

Similarities and Differences with CAPA Requirements

QS regulation and ISO 13485: 2016 CAPA Requirements

Similarities

- Require procedures for corrective and preventive action
- Require documented procedures and documented results from corrective and preventive action activities
- Require use of appropriate statistical techniques

QS regulation and ISO 13485: 2016 CAPA Requirements

Similarities

Require procedures to include requirements for:

- Collecting and analyzing information and data
- Identifying existing and potential nonconformities
- Investigating and determining the causes of the nonconformity

QS regulation and ISO 13485: 2016 CAPA Requirements

Similarities

Require procedures to include requirements for:

- Determining the required actions to prevent the occurrence or recurrence of nonconformity
- Implementing the corrective or preventive actions
- Verifying that the actions are effective

QS regulation and ISO 13485: 2016 CAPA Requirements

Similarities

Require procedures to include requirements for:

- Reviewing the effectiveness of the corrective or preventive action
- Implementing and recording changes in methods and procedures

QS regulation and ISO 13485: 2016 CAPA Requirements

Differences	
21 CFR 820.100	ISO 13485:2016
• Requires analysis of data for identification of existing or potential causes of nonconforming product or other quality problems	• Requires analysis of data for use as input for improvement to QMS • Requires analysis to include input from specific data sources included in the standard

QS regulation and ISO 13485: 2016 CAPA Requirements

Differences	
21 CFR 820.100	ISO 13485:2016
• No specific requirement	• Requires identification and implementation of changes through use of resources specified in the standard
• Requires verification or validation of the corrective or preventive action	• Requires verification of action only

QS regulation and ISO 13485: 2016 CAPA Requirements

Differences	
21 CFR 820.100	ISO 13485:2016
• No specific requirement	• Requires corrective actions be taken without “undue delay”

QS regulation and ISO 13485: 2016 CAPA Requirements

Differences	
21 CFR 820.100	ISO 13485:2016
• Requires that information related to quality problems be disseminated	• No specific requirement
• Requires relevant information about quality problems and any actions taken be submitted for management review	• No Specific requirement

Knowledge Check

What is one difference between the FDA QS regulation and ISO 13485:2016 standard?

a) **QS regulation requires a procedure for corrective and preventive action**

b) **QS regulation require use of statistical techniques.**

c) **QS regulation requires that information related to quality problems be disseminated**

CAPA Example

CAPA Example

- An establishment markets an implantable medical device in Europe
- Procedures specify compliance with ISO 13485: 2016
- ISO 13485: 2016 certified
- Would like to market device in the United States

CAPA Example

- Identify steps the establishment should consider:
  - to ensure it meets requirements
  - for implementing corrective and preventive actions
  - to market in both Europe and United States

CAPA Example

- Perform Gap analysis
- Identify additional CAPA requirements of QS regulation not specified in ISO 13485:2016:
  - Analyze data to identify existing or potential causes of nonconforming product or other quality problems
  - Ensure corrective/preventive action is verified OR validated

CAPA Example

- Identify additional CAPA requirements of QS regulation not specified in ISO 13485:2016:
  - Disseminate information about quality problems to those directly responsible for assuring the quality of such product
  - Requirement to submit relevant information about quality problems and any actions taken for management review

CAPA Example

- Ensure establishment's relevant procedures include additional CAPA requirements of QS regulation that were identified
- Ensure additional CAPA requirements of QS regulation are documented and implemented
- Ensure any linked QS procedures are updated to reflect additional QS requirements
- Ensure document control procedures are implemented and completed as required and training completed

Summary

- Requirements for corrective and preventive actions are specified in both the QS regulation (21 CFR 820.100) and ISO 13485:2016 (Clauses 8.4 and 8.5)
- CAPA requirements in QS regulation and ISO 13485:2016 are harmonized
- There are no conflicting CAPA requirements, but there are similarities and differences between these requirements

Resources

Slide Number	Cited Resource	URL
6	Quality System regulation	21 CFR 820.100
	CDRH Learn Module: Corrective and Preventive Action	CDRH Learn | FDA
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	AAMI Technical Information Report 102 (TIR 102)	TIR102:2019 (U.S. FDA 21 CFR mapping to the applicable regulatory requirement references in ISO 13485:2016)

Questions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