Comparison of the Quality System Regulation and ISO 13485: Corrective and Preventive Action

FDA Small Business
Regulatory Education for Industry (REdI)
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Why Should We Care?

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HHS/FDA **RIN:** 0910-AH99 **Publication ID:** Spring 2018

Title: •Harmonizing and Modernizing Regulation of Medical Device Quality Systems

Abstract:

FDA intends to harmonize and modernize the Quality System regulation for medical devices. The revisions will supplant the existing requirements with the specifications of an international consensus standard for medical device manufacture, ISO 13485:2016. The revisions are intended to reduce compliance and recordkeeping burdens on device manufacturers by harmonizing domestic and international requirements. The revisions will also modernize the regulation.

Agency: Department of Health and Human Services(HHS)
RIN Status: First time published in the Unified Agenda
Major: No
EO 13771 Designation: Other
CFR Citation: 21 CFR 820
Legal Authority: 21 U.S.C. 351 21 U.S.C. 352 21 U.S.C. 360 21 U.S.C. 360c 21 U.S.C. 360d 21 U.S.C. 360e 21 U.S.C. 360h 21 U.S.C. 360i 21 U.S.C. 360j 21 U.S.C. 360l 21 U.S.C. 371 21 U.S.C. 374 21 U.S.C. 381 21 U.S.C. 383 42 U.S.C. 216 and 262 42 U.S.C. 263a 42 U.S.C. 264
Legal Deadline: None

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule Stage
Unfunded Mandates: No

Timetable:

Action	Date	FR Cite
NPRM	04/00/2019	

Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: No
Included in the Regulatory Plan: No
RIN Data Printed in the FR: No

Government Levels Affected: Undetermined
Federalism: No

No Additional Questions Please!

Learning Objectives

- Introduce 21 CFR 820 and ISO 13485:2016
- Provide background on the regulation and standard
- Compare requirements in regulation and standard
  - as they relate to Corrective Action and Preventive Action

Poll

Do you have a quality system that complies with the Quality System Regulation (21 CFR Part 820)?

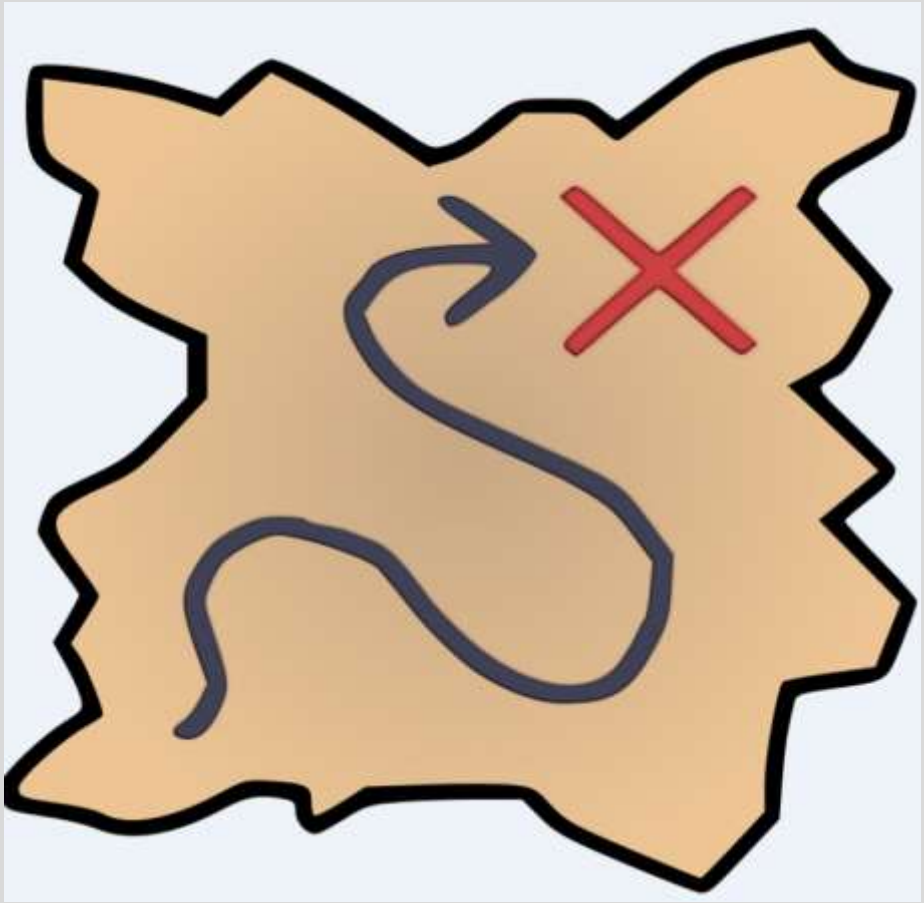
1. Yes
2. No
3. I don't know
4. I plead the fifth. There's an FDA investigator in the room

Poll

Do you have a quality management system that conforms to the International Medical Devices Standard ISO 13485:2016?

1. **Yes**
2. **No**
3. **I don't know**
4. **I plead the fifth. There's an ISO 13485 lead auditor in the room**

How Did We Get Here - Background



Background:

21 CFR 820

The Quality System Regulation

- 1978 Good Manufacturing Practice
- cGMP
- 1990 Safe Medical Device Amendments
- 1996 Quality System Regulation
- 2012 Amendments
- Today

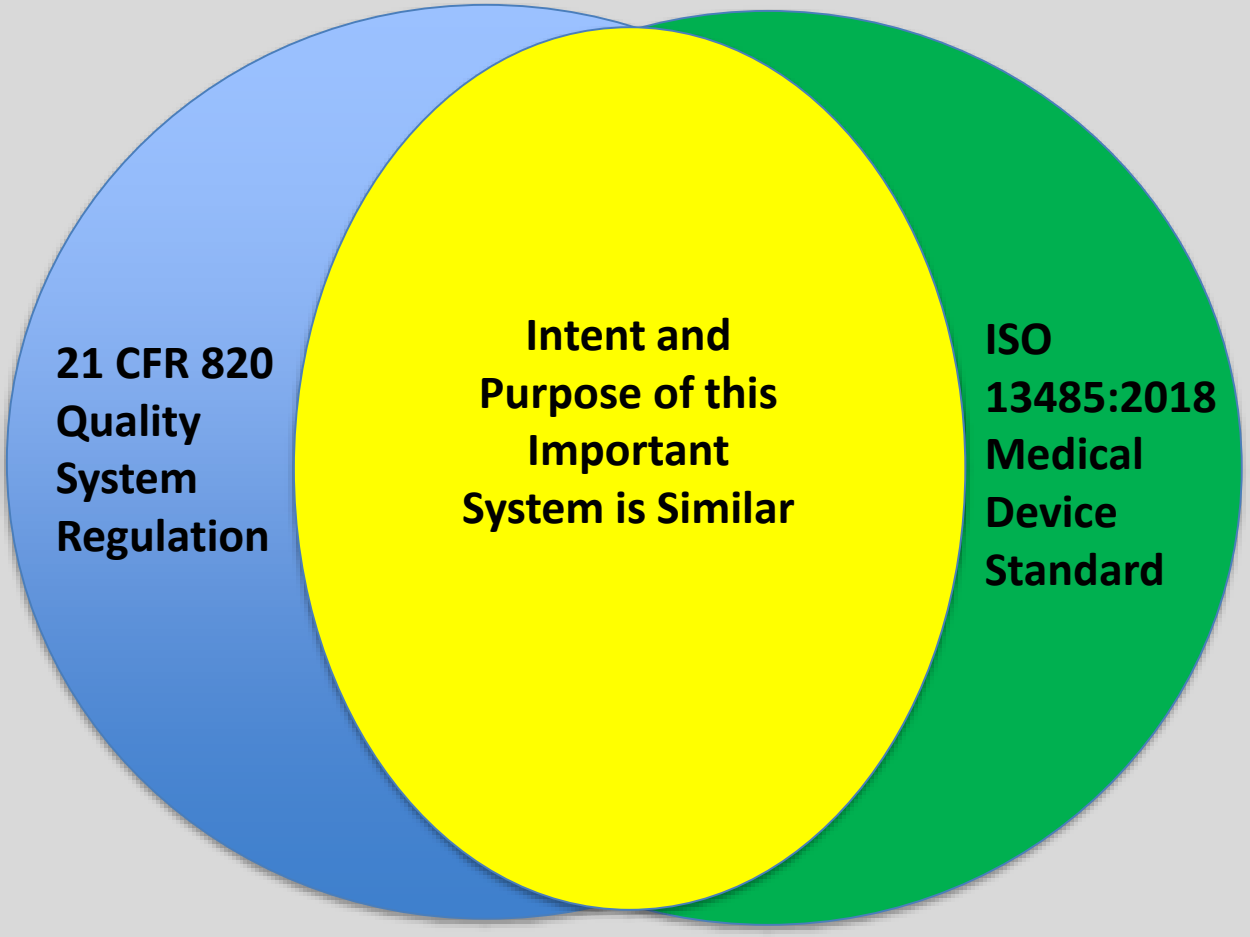
Background

ISO 13485

Medical Devices – Quality Management Systems

- GHTF 1992 (Harmonization)
- ISO 9001:1994
- ISO 13485:1996
- ISO 13485:2003
- IMDRF 2011 (Convergence)
- MDSAP 2012
- ISO 13485:2016
- Today

Regulation and Standard CAPA Comparison



Comparison: Intent

The purpose of the requirements in both are to:

1. Collect and analyze information and data
2. Identify nonconformities and potential nonconformities
3. Determine their cause(s), evaluate need to take action and identify action
4. Verify identified action is effective and does not have adverse effects
5. Implement action and review effectiveness

Definitions

All definitions are from ISO 9000:2015, Quality management systems – Fundamentals and vocabulary

3.12.3 Correction

Action to eliminate a detected *nonconformity* (3.6.9)

- Note 1 to entry: A correction can be made in advance of, in conjunction with or after a *corrective action* (3.12.2)
- Note 2 to entry: A correction can be, for example, *rework* (3.12.8) or *regrade* (3.12.4)

Definitions

3.12.2 Corrective Action

Action to eliminate the cause of a *nonconformity* (3.6.9) and to prevent recurrence

- Note 1 to entry: There can be more than one cause for a nonconformity
- Note 2 to entry: Corrective action is taken to prevent recurrence whereas *preventive action* (3.12.1) is taken to prevent occurrence

Definitions

3.12.1 Preventive Action

Action to eliminate the cause of a potential *nonconformity* (3.6.9) or other potential undesirable situation

- Note 1 to entry: There can be more than one cause for a potential nonconformity
- Note 2 to entry: Preventive action is taken to prevent occurrence whereas *corrective action* (3.12.2) is taken to prevent recurrence

Comparison: Layout

Regulation 21 CFR 820

Subpart J – Corrective and Preventive Action

820.100

(a) Procedures,

data analysis, investigation, identification of actions, v&v, implementation, communication, management review

(b) Records

Standard ISO 13485

8.4 Analysis of data

8.5 Improvement

8.5.2 Corrective Action

8.5.3 Preventive Action

Comparison: Similarities

Both require that you:

- have procedures to address corrective and preventive actions
- document those procedures and the results from those activities
- use appropriate statistical techniques

Comparison: Similarities

Both require you to:

1. Collect and analyze information and data
2. Identify nonconformities and potential nonconformities
3. Investigate and determine cause (root) of nonconformity
4. Determine if and what action(s) is required to prevent occurrence or reoccurrence

Comparison: Similarities

Both require you to:

5. Verify* action(s) does not have any adverse effects
6. Verify* action(s) is effective
7. Implement those action(s)
8. Update all documentation and ensure those changes are implemented

*21 CFR 820 also includes validation. Note order of activity

Specifics in Regulation 21 CFR 820

Specifically calls out requirement to:

- communicate CAPA information to those directly responsible for assuring the quality of such product – 820.100 (a)(6)
- submit relevant information on CAPA for management review – 820.100 (a)(7)

Specifics in Regulation 21 CFR 820

- Calls out both verifying or validating corrective and preventive action
  - to ensure that such action is effective and
  - does not adversely affect the finished device – 820.100(a)(4)

Specifics in Standard ISO 13485

Specifically requires that:

- organization uses the subsystem to look at overall effectiveness of and make changes to improve the QMS as necessary – 8.5.1 General
- necessary corrective actions are taken without “undue delay” – 8.5.2 Corrective Action

Specifics in Standard ISO 13485

- Requires that you consider regulatory requirements when verifying both actions

- Requires that both corrective actions and preventive actions are appropriate for the effects of nonconformities encountered or potential problems

8.5.2 Corrective action

8.5.3 Preventive action

Additional Resources

- AAMI Quality Systems White Paper Comparison of 21 CFR 820 to ISO 13485:2016 - 2018.pdf
- NSF US FDA QS Regulation verse ISO 13485:2016 QMS Requirements.pdf

Summary

- Introduced 21 CFR 820 and ISO 13485:2016
- Reviewed a short history of the regulation and standard
- Compared requirements in regulation and standard
  - as they relate to Corrective Action and Preventive Action

Questions?

Your Call to Action

- Keep current on potential regulatory changes being proposed
- Understand these changes as they relate to your quality management system, especially corrective actions and preventive actions
- Use this knowledge to ensure your devices are safe, effective and meet both user needs and regulatory requirements

Thank You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