U.S. FOOD & DRUG ADMINISTRATION

Managing Medical Device Nonconforming Product with Quality

FDA Small Business Regulatory Education for Industry (REdI) Annual Conference

June 7, 2023

Ruth Bediakoh
Consumer Safety Officer
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Cute But Defective

Learning Objectives

- Discuss background information
- Review key definitions
- Identify requirements within the Quality System Regulation and ISO 13485:2016
- Discuss strategies for managing nonconforming product

Background Information

Background

- Nonconforming product:
  - Cited 104 times on Form FDA 483 in FY22
  - Can occur at anytime during the product lifecycle
  - Can pose significant risk to consumers
  - Are due to multiple causes

Key Definitions

What is Nonconformity?

- **21 CFR 820.3(q)**
  - Nonconformity means the nonfulfillment of a specified requirement
- **ISO 9000:2015 clause 3.6.9**
  - Nonconformity is non-fulfilment of a requirement

What is a Product?

- **21 CFR 820.3(r)**
  - Components, manufacturing materials, in- process devices, finished devices, and returned devices
- **ISO 13485:2016 clause 3.15**
  - Result of a process (service, software, hardware, processed materials)

Examples of Nonconforming Product

- Components/materials that fail receiving acceptance activities
- Product stored at warehouse exposed to heat, moisture, or other environmental factors that affect performance
- Product that fail in-process acceptance activities

Example of Nonconforming Product

Requirements

Requirements

21 CFR 820.90	ISO 13485:2016
820.90(a)	Clause 8.3.1
820.90(b)(1)	Clause 8.3.2
820.90(b)(2)	Clause 8.3.4

Requirements

21 CFR 820.90(a): Each manufacturer shall…
Establish, maintain, and document procedures for the identification, documentation, evaluation, segregation, and disposition
Evaluate and determine the need for an investigation and notify persons or organizations responsible
Document evaluation and any investigation

Requirements

ISO 13485:2016 Clause 8.3.1: The organization shall…
Ensure nonconforming product is identified and controlled
Define controls and persons responsible for the identification, documentation, segregation, evaluation and disposition
Determine the need for an investigation and notification of any external party responsible
Record and maintain nature of nonconformity and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions

Knowledge Check

Which of the following is a nonconforming product?

1. Product that does not meet applicable quality requirements
2. Received component that does not conform to the order submitted
3. Labeling without required warning on natural rubber medical gloves
4. All of the above

Requirements

21 CFR 820.90(b)(1): Each manufacturer shall…
Establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product
Document the review and disposition of nonconforming product
Document the justification for use and signatures of individual authorizing the use

Requirements

ISO 13485:2016 Clause 8.3.2: The organization shall…
Take action to eliminate the detected nonconformity
Take action to preclude its original intended use or application
Authorize its use, release or acceptance under concession
• Accepted under concession if justification is provided, approval is obtained, and meets applicable regulatory requirements
• Maintain records of the acceptance by concession and the identity of the person authorizing the concession

Requirements

21 CFR 820.90(b)(2): Each manufacturer shall…
Establish and maintain procedures for rework
Document rework and reevaluation activities in the DHR

Requirements

ISO 13485:2016 Clause 8.3.4: The organization shall…
Follow documented procedures for rework
Verify the product after rework
Ensure rework meets the required standards and regulatory requirements
Maintain records of all rework performed

Strategies for Managing Nonconforming Product

Managing Nonconforming Product: Strategies

- Identify and document electronically or manually
  - Barcode system
  - Color coded tags

Managing Nonconforming Product: Strategies

- Evaluate the nonconformance
  - To determine if an investigation is needed
  - Document any justification
  - Notify responsible parties

Managing Nonconforming Product: Strategies

- Separate nonconforming product
  - Designated bins
  - Designated area
- Investigate
  - When required
  - Document results and outcome

Managing Nonconforming Product: Strategies

- Decide on disposition
  - Use as is
  - Rework
  - Scrap
  - Return to supplier
- Document, review, and approve disposition
  - In the Device History Record (DHR)

Knowledge Check

Nonconforming product should always be investigated

1. True
2. False

Resources

Slide Number	Cited Resource	URL
7,8	Quality System Regulation	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820
7,8	CDRH Learn - Nonconforming product	www.fda.gov/training-and-continuing-education/cdrh-learn
12-19	AAMI Quality Systems White Paper	www.aami.org/docs/default-source/uploadedfiles/filedownloads/whitepaper/qs-white-paper-21cfr820-13485.pdf

Summary

- Nonconforming product can happen anytime during the life cycle of the product
- Manage nonconforming product per the Quality System Regulation
- Identify and document all activities and records

Questions