

# **Managing Medical Device Nonconforming Product with Quality**

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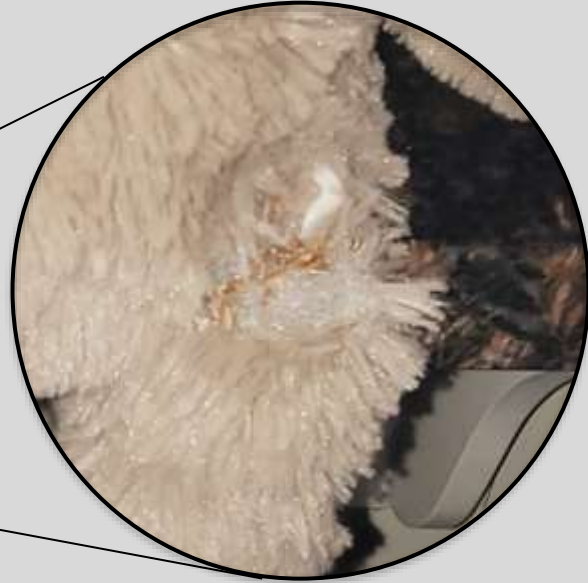
Division of Industry and Consumer Education

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

## Nonconforming Product



# 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	<a href="http://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820">www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820</a>
7,8	CDRH Learn - Nonconforming product	<a href="http://www.fda.gov/training-and-continuing-education/cdrh-learn">www.fda.gov/training-and-continuing-education/cdrh-learn</a>
12-19	AAMI Quality Systems White Paper	<a href="http://www.aami.org/docs/default-source/uploadedfiles/filedownloads/whitepaper/qs-white-paper-21cfr820-13485.pdf">www.aami.org/docs/default-source/uploadedfiles/filedownloads/whitepaper/qs-white-paper-21cfr820-13485.pdf</a>

# 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

