

WEBINAR

# HOW TO IMPLEMENT AND MAINTAIN A MODERN CAPA SYSTEM WHILE AVOIDING COMMON PITFALLS



**Jon Speer**

*Founder at Greenlight Guru*

# MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME

75

years  
industry  
experience

275k

podcast  
listeners

#1

blog and  
podcast in  
the industry

90k

look to us for the  
latest in medical  
device quality

## FEATURED IN

THE VERGE



Forbes

QUALITYDIGEST



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Intelligence



MedicalDesign  
& OUTSOURCING

TNW  
THE NEXT WEB

Entrepreneur

MPO  
MEDICAL PRODUCT OUTSOURCING



"One stop shop for MDQMS"



"My QMS is world class"



"Greenlight Guru Software is the handrail for  
Medical Device Development and  
Documentation"



# ABOUT THE PRESENTER

**Jon Speer**

*Founder at Greenlight Guru*



- **22+** years in medical device industry
- Product development engineer, quality manager, regulatory specialist
- **40+** products to market
- Expert at QMS implementations
- Dozens of ISO audits & FDA inspections

***Greenlight Guru produces beautifully simple quality, design control and risk management software exclusively for medical device manufacturers.***

[jon.speer@greenlight.guru](mailto:jon.speer@greenlight.guru)

+1 317 960 4280

***greenlight guru***

# Topics We'll Cover Today

- Regulatory Focus on CAPA
- Overview of CAPA
- 5 Problems with CAPA Processes
- Relationship between CAPA & other QMS Processes
- Impact of Risk Management on CAPA
- How to shift from Reactive to Proactive
- CAPA Process – Step by Step
- Q&A

# REGULATORY FOCUS ON CAPA

# CAPA REMAINS TOP ISSUE DURING FDA INSPECTIONS

FDA 483 OBSERVATIONS — TOP 5 OBSERVATIONS (2018)	
SHORT DESCRIPTION	FREQUENCY
Lack of or inadequate procedures (CAPAs)	354
Lack of or inadequate complaint procedures	229
Purchasing controls, Lack of or inadequate procedures to ensure that all purchased product conforms to specifications	142
Lack of Written MDR Procedures	139
Lack of or inadequate process validation	138



<https://www.fdanews.com/ext/resources/files/Conference2/FIS19Presentations/Damron-FDA-483-and-Warning-Letter-Trends.pdf>  
<https://datadashboard.fda.gov/ora/cd/inspections.htm>

# OVERVIEW OF CAPA

# OVERVIEW OF CAPA

## FDA 21 CFR Part 820.100

(a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

- (1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;
- (2) Investigating the cause of nonconformities relating to product, processes, and the quality system;
- (3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;
- (4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;
- (5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
- (6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and
- (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

(b) All activities required under this section, and their results, shall be documented.



# OVERVIEW OF CAPA

## ISO 13485:2016

### 8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered.

The organization shall document a procedure to define requirements for:

- a) reviewing nonconformities (including complaints);
- b) determining the causes of nonconformities;
- c) evaluating the need for action to ensure that nonconformities do not recur;
- d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
- e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
- f) reviewing the effectiveness of corrective action taken.

Records of the results of any investigation and of action taken shall be maintained (see 4.2.5).

# OVERVIEW OF CAPA

## ISO 13485:2016

### 8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems.

The organization shall document a procedure to describe requirements for:

- a) determining potential nonconformities and their causes;
- b) evaluating the need for action to prevent occurrence of nonconformities;
- c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
- d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
- e) reviewing the effectiveness of the preventive action taken, as appropriate.

Records of the results of any investigations and of action taken shall be maintained (see 4.2.5).

# OVERVIEW OF CAPA

## REGULATION (EU) 2017/745

- Corrective and preventive actions are monitored via post-market surveillance.
  - Your post-market surveillance system must be able to identify the need for any CAPAs.
- Distributors and importers are required to maintain a quality management system.
- CAPAs are required inputs for your periodic safety update report. Ensure QMS is updated with appropriate procedures and all processes are traceable.
- Every nonconformance affecting product should prompt a risk-based evaluation for field safety corrective action

# OVERVIEW OF CAPA



## FINAL DOCUMENT

### Global Harmonization Task Force

**Title:** Quality management system –Medical Devices – Guidance on corrective action and preventive action and related QMS processes

**Authoring Group:** Study Group 3

**Date:** 4 November 2010

*The acronym 'CAPA' will not be used in this [guidance] document because the concept of corrective action and preventive action has been incorrectly interpreted to assume that a preventive action is required for every corrective action.*

*This document will discuss the escalation process from different 'reactive' sources which will be corrective in nature and other 'proactive' sources which will be preventive in nature. The manufacturer is required to account for both types of data sources whether they are of a corrective or preventive nature.*

# OVERVIEW OF CAPA



*The purpose of the corrective and preventive action subsystem is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence.*

*Verifying or validating corrective and preventive actions, communicating corrective and preventive action activities to responsible people, providing relevant information for management review, and documenting these activities are essential in dealing effectively with product and quality problems, preventing their recurrence, and preventing or minimizing device failures.*

*One of the most important quality system elements is the corrective and preventive action subsystem.*

# 5 PROBLEMS WITH CAPA PROCESSES

## 5 PROBLEMS WITH CAPA PROCESSES

# LACK OF CROSS FUNCTIONALITY

## 5 PROBLEMS WITH CAPA PROCESSES

**REACTIVE INSTEAD OF PROACTIVE**



# 5 PROBLEMS WITH CAPA PROCESSES

## OVERUSE VS. UNDERUSE

## 5 PROBLEMS WITH CAPA PROCESSES

# WEAK ROOT CAUSE DETERMINATION

## 5 PROBLEMS WITH CAPA PROCESSES

# POORLY DEFINED QUALITY PROCESSES

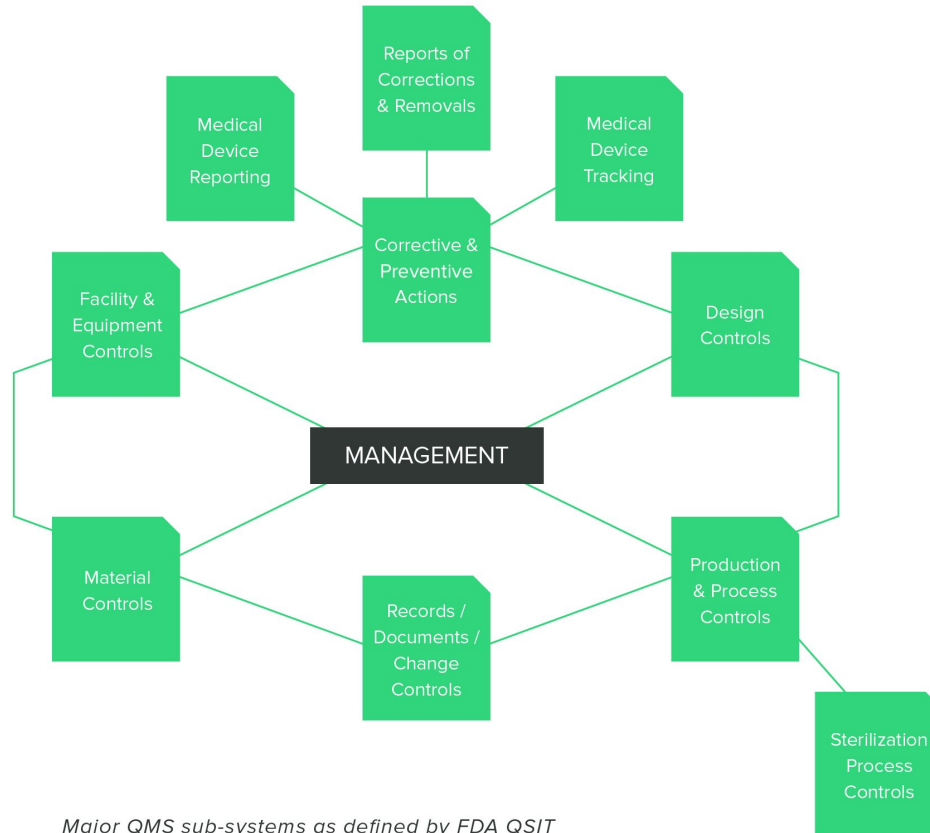
## 5 PROBLEMS WITH CAPA PROCESSES

**POLL:**

**WHICH OF THESE 5 CAPA PROBLEMS DOES  
YOUR COMPANY STRUGGLE WITH THE MOST?**

# RELATIONSHIP BETWEEN CAPA AND OTHER QMS PROCESSES

# RELATIONSHIP BETWEEN CAPA & OTHER QMS PROCESSES



*Major QMS sub-systems as defined by FDA QSIT*

# RELATIONSHIP BETWEEN CAPA AND OTHER QMS PROCESSES

## CUSTOMER FEEDBACK + COMPLAINTS

# RELATIONSHIP BETWEEN CAPA AND OTHER QMS PROCESSES

## NONCONFORMING PRODUCT



# RELATIONSHIP BETWEEN CAPA AND OTHER QMS PROCESSES

**PRODUCTION + PROCESS CONTROLS**

# RELATIONSHIP BETWEEN CAPA AND OTHER QMS PROCESSES

## SUPPLIER MANAGEMENT

# RELATIONSHIP BETWEEN CAPA AND OTHER QMS PROCESSES

## AUDIT MANAGEMENT

# RELATIONSHIP BETWEEN CAPA AND OTHER QMS PROCESSES

## DESIGN CONTROLS

# RELATIONSHIP BETWEEN CAPA AND OTHER QMS PROCESSES

## MANAGEMENT REVIEW

# RELATIONSHIP BETWEEN CAPA AND OTHER QMS PROCESSES

## RISK MANAGEMENT

# IMPACT OF RISK MANAGEMENT **ON CAPA**

# IMPACT OF RISK MANAGEMENT ON CAPA

## CAPA for systemic issues

### Addressing CAPA has a direct impact on Risks

- Design-related issues
- Process-related issues
- Supplier-related issues



# IMPACT OF RISK MANAGEMENT ON CAPA

- Risk-based QMS (CAPA is the key)
- Risk-based decision making process
- Priority + urgency
- Holistic approach
- Root cause determination
- Verify effectiveness

**A healthy CAPA process should be 100% risk-based!**

**SHIFTING FROM REACTIVE TO PROACTIVE**

# SHIFTING FROM REACTIVE TO PROACTIVE

- Tendency is to be reactive (“corrective”) to situations rather than proactive (“preventive”)
- Effective QMS should identify opportunities to reduce and prevent issues from occurring
- Emphasis has previously been too focused on compliance-only

# SHIFTING FROM REACTIVE TO PROACTIVE

MAKE THE SHIFT TO ...

**TRUE QUALITY**

# CAPA PROCESS **STEP-BY-STEP**

# CAPA PROCESS – STEP-BY-STEP

1. Create CAPA request and submit for review. Identify sources of CAPA worthy issue.
2. Review CAPA request. Determine whether or not issue requires CAPA investigation.
3. Accept or reject CAPA request.
4. If accepted, issue and initiate CAPA.

The screenshot displays the 'Add New CAPA Request' interface in the Greenlight Guru system. On the left, a form for creating a new request includes fields for Title, Description of Issue, Due Date, Priority, CAPA Type (with a dropdown menu), and assignment options (Assign to User or Assign to Role). Below these are fields for Reported To and Reported On. The main area on the right is titled 'New CAPA Request' and features a progress bar with stages: Source, Immediate Action, Investigation, Root Causes, Action, Quality Review, and Verification. The 'Source' stage is currently active and highlighted in blue. Below the progress bar, there is a section labeled 'Sources' with a large dashed box containing a plus sign and the text 'Add A Source'. A 'Create Request' button is located in the top right corner of the main area.

# CAPA PROCESS – STEP-BY-STEP

5. Finalize CAPA sources  
(i.e. products, processes)

6. Determine CAPA  
cross-functional team

The screenshot shows the 'Source' step of the CAPA process. The left sidebar contains details for 'Packaging Validation Issues':

- Description: Product was sent to field without being properly validated.
- Due Date: No due date set
- CAPA Type: Corrective
- Assigned To: Tom Rish
- Reported On: Aug 8, 2018
- Date of Event: Aug 1, 2018
- Initiated By: Tom Rish
- External ID: Hip Stem

The main area is titled 'Sources' and features a large dashed box with a plus sign and the text 'Add Source'. To the right, a 'Product' dropdown menu is open, showing the following details:

- Name: NA
- Description: NA
- Product Number: 123-1010-01
- Product Type: NA
- Project: NA
- 1 Immediate Action (Add New)
- 0 Investigation Tasks (Add New)

At the bottom of the sidebar, there is a 'Supporting Materials' section with a dashed box and a plus sign, and a 'Team' button.

The screenshot shows the 'Team' step of the CAPA process. The left sidebar contains details for 'Internal Audit Res. (CAPA-72)':

- Due Date: No due date set
- CAPA Type: Corrective

The main area is titled 'TEAM' and features a table with columns for 'User' and 'Role'. The table is currently empty, and there is an 'ADD' button at the bottom right.

# CAPA PROCESS – STEP-BY-STEP

7. Identify any immediate actions and corrections required.

The screenshot displays the Greenlight Guru CAPA (Corrective and Preventive Action) process interface. The top navigation bar shows the 'CAPAs' section, with 'Packaging Validation Issues (CAPA-9)' selected. The 'Immediate Action' step is highlighted in the process flow. The left sidebar contains details for the CAPA, including a description, due date, CAPA type, assigned to, reported on, date of event, initiated by, external ID, and supporting materials. The main area shows the 'Immediate Action' step with a 'Start Date' of 'Aug 8, 2018' and a 'Rationale' field. A task card for 'TASK-491 Put product in Quarantine' is visible, marked as 'Complete' with a green checkmark. A 'Stage Complete' toggle is also present.

**Packaging Validation Issues**

Description  
Product was sent to field without being properly validated.

Due Date  
No due date set

CAPA Type  
Corrective

Assigned To  
Tom Rish

Reported On  
Aug 8, 2018

Date of Event  
Aug 1, 2018

Initiated By  
Tom Rish

External ID  
Hip Stem

Supporting Materials

**Immediate Action**

Source  
✓

Investigation  
...

Root Cause  
...

Action  
...

Quality Review  
...

Verification  
...

Stage Complete ☐

Start Date  
Aug 8, 2018

Rationale

+  
Add Immediate Action

TASK-491  
Put product in Quarantine

Complete

No Due Date

1 Link



# CAPA PROCESS – STEP-BY-STEP

## 8. Investigate and capture findings.

The screenshot displays the Greenlight Guru CAPA (Corrective and Preventive Action) process interface, specifically the 'Investigation' step. The interface is divided into a left sidebar and a main content area.

**Left Sidebar (CAPA Details):**

- Section: Packaging Validation Issues**
  - Description:** Product was sent to field without being properly validated.
  - Due Date:** No due date set
  - CAPA Type:** Corrective
  - Assigned To:** Tom Rish
  - Reported On:** Aug 8, 2018
  - Date of Event:** Aug 1, 2018
  - Initiated By:** Tom Rish
  - External ID:** Hip Stem
- Supporting Materials:** A dashed box with a '+' icon and a 'Team' button below it.

**Main Content Area (Investigation):**

- Navigation Bar:** Source, Immediate Action, Investigation (active), Root Cause, Action, Quality Review, Verification.
- Investigation Section:**
  - Investigation Required:** Required
  - Risk Assessment Required:** Required
  - Start Date:** Aug 8, 2018
  - Problem Statement:** (Empty field)
- Task Cards:**
  - TASK-492:** Determine scope of issue. Status: Complete. No Due Date.
  - TASK-916:** Review Probability of Harm. Status: Complete. Due Date: Nov 16.
- Buttons:** '+ Add Investigation' and '0 Links'.

# CAPA PROCESS – STEP-BY-STEP

## 9. Determine root cause(s)

The screenshot displays the Greenlight Guru CAPA (Corrective and Preventive Action) process interface. The top navigation bar shows the current step is 'Root Cause', with previous steps 'CAPAs' and 'Packaging Validation Issues' also visible. The left sidebar contains details for the 'Packaging Validation Issues' CAPA, including its description, due date, type, assigned personnel, and event details. The main workspace is divided into a 'Root Cause' section with a large area to add root causes and a right-hand panel showing details for an 'Inadequate test protocol' finding, including its reason, method, and associated tasks.

**Packaging Validation Issues**

Description  
Product was sent to field without being properly validated.

Due Date  
No due date set

CAPA Type  
Corrective

Assigned To  
Tom Rish

Reported On  
Aug 8, 2018

Date of Event  
Aug 1, 2018

Initiated By  
Tom Rish

External ID  
Hip Stem

**Supporting Materials**

Team

**Root Cause**

Root Cause Analysis  
Required

Start Date  
Aug 8, 2018

Rationale

**Inadequate test protocol**

Reason  
Inadequate Procedure

Method  
5 Whys

Notes  
NA

Evidence

**TASK-492 Determine scope of issue**  
Finding Type: Observation  
Finding Category: Process Validation

0 Action Tasks

Add New

# CAPA PROCESS – STEP-BY-STEP

10. Specify corrective and/or preventive action plan.
11. Complete action plan.

The screenshot displays the Greenlight Guru CAPA (Corrective and Preventive Action) process interface. The top navigation bar shows the following steps: CAPAs, Packaging Validation Issues, and Action. The 'Action' step is currently selected and highlighted in blue. Below the navigation bar, the 'Packaging Validation Issues' section is visible, containing fields for Description, Due Date, CAPA Type, Assigned To, Reported On, Date of Event, Initiated By, External ID, and Hip Stem. The 'Action' section is the main focus, showing a table with columns for Source, Immediate Action, Investigation, Root Cause, Action, Quality Review, and Verification. The 'Action' column is currently active, displaying a list of actions. One action, 'TASK-493 Retest packaging', is shown with a green checkmark and a 'Complete' button. A 'Stage Complete' toggle is also visible. The bottom of the interface features a 'Supporting Materials' section with a 'Team' button.

**Packaging Validation Issues**

Description  
Product was sent to field without being properly validated.

Due Date  
No due date set

CAPA Type  
Corrective

Assigned To  
Tom Rish

Reported On  
Aug 8, 2018

Date of Event  
Aug 1, 2018

Initiated By  
Tom Rish

External ID  
Hip Stem

**Supporting Materials**

**Action**

Stage Complete ☐

Source	Immediate Action	Investigation	Root Cause	Action	Quality Review	Verification
✓	✓	✓	...	...	...	...

**Action**

Corrective Action(s)/Preventive Action(s)  
Required

Start Date  
Aug 8, 2018

Rationale

**Task Card:** TASK-493 Retest packaging (Complete)

**Buttons:** Add Action, Complete, No Due Date, 0 Links

# CAPA PROCESS – STEP-BY-STEP

12. Review CAPA for completeness.

13. Approve CAPA actions

The screenshot displays the Greenlight Guru CAPA (Corrective and Preventive Action) process interface. The top navigation bar shows the progression from CAPAs to Packaging Validation Issues (CAPA-9) and then to the Quality Review step, which is currently active. A progress bar at the top indicates the status of various stages: Source, Immediate Action, Investigation, Root Cause, Action, Quality Review (active), and Verification.

**Packaging Validation Issues**

Description  
Product was sent to field without being properly validated.

Due Date  
No due date set

CAPA Type  
Corrective

Assigned To  
Tom Rish

Reported On  
Aug 8, 2018

Date of Event  
Aug 1, 2018

Initiated By  
Tom Rish

External ID  
Hip Stem

**Supporting Materials**

Team View Quality Review Report

**Quality Review**

Start Date  
Aug 8, 2018

Workflow Progress: 1 Draft, 2 Routing, 3 Approved, 4 Published

Reviewer	Review Days	Status
1 Tom Rish Author	0	Reviewing
2 Tom Rish Marketing		= -
3 Carly McCarthy Equipment Manager		= -

Add Reviewer

Cancel Save

# CAPA PROCESS – STEP-BY-STEP

14. Specify steps for effectiveness verification.
15. Verify effectiveness of CAPA.

The screenshot displays the Greenlight Guru software interface for the CAPA (Corrective and Preventive Action) process. The top navigation bar shows the current step is 'Verification' under the 'Packaging Validation Issues' category. The left sidebar contains details for the CAPA, including a description, due date, type, assigned person, and reported date. The main area shows a progress bar with steps: Source, Immediate Action, Investigation, Root Cause, Action, Quality Review, and Verification. The 'Verification' step is currently active, showing a 'Stage Complete' toggle and a list of verifications. A task card for 'TASK-494 Verify Effectiveness' is visible, with an 'Open' button and a 'No Due Date' status.

**Packaging Validation Issues**

Description  
Product was sent to field without being properly validated.

Due Date  
No due date set

CAPA Type  
Corrective

Assigned To  
Tom Rish

Reported On  
Aug 8, 2018

Date of Event  
Aug 1, 2018

Initiated By  
Tom Rish

External ID  
Hip Stem

**Supporting Materials**

Team View Verification Report

**Verification**

Stage Complete ☐

Verifications  
Required

Start Date  
Aug 8, 2018

Rationale

+ Add Verification

**TASK-494**  
Verify Effectiveness

Open

No Due Date

0 Links

# CAPA PROCESS – STEP-BY-STEP

1. Create CAPA request and submit for review. Identify sources of CAPA worthy issue.
2. Review CAPA request. Determine whether or not issue requires CAPA investigation.
3. Accept or reject CAPA request.
4. If accepted, issue and initiate CAPA.
5. Finalize CAPA sources (i.e. products, processes).
6. Determine CAPA cross-functional team.
7. Identify any immediate actions and corrections required.
8. Investigate and capture findings.
9. Determine root cause(s).
10. Specify corrective and/or preventive action plan.
11. Complete action plan.
12. Review CAPA for completeness.
13. Approve CAPA actions.
14. Specify steps for effectiveness verification.
15. Verify effectiveness of CAPA.

**QUESTIONS?**



**Jon Speer**

jon.speer@greenlight.guru

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