WEBINAR

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

Jon Speer
Founder at Greenlight Guru

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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.

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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

LACK OF CROSS FUNCTIONALITY

5 PROBLEMS WITH CAPA PROCESSES

REACTIVE INSTEAD OF PROACTIVE

OVERUSE VS. UNDERUSE

WEAK ROOT CAUSE DETERMINATION

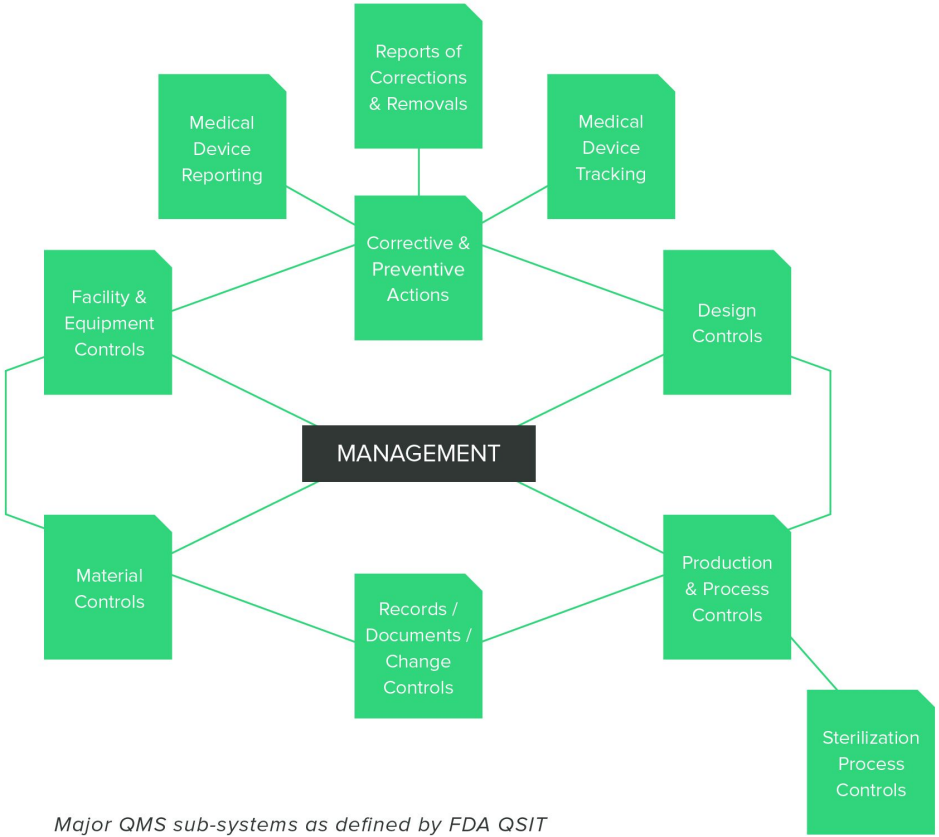
POORLY DEFINED QUALITY PROCESSES

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

SUPPLIER MANAGEMENT

RELATIONSHIP BETWEEN CAPA AND OTHER QMS PROCESSES

AUDIT MANAGEMENT

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

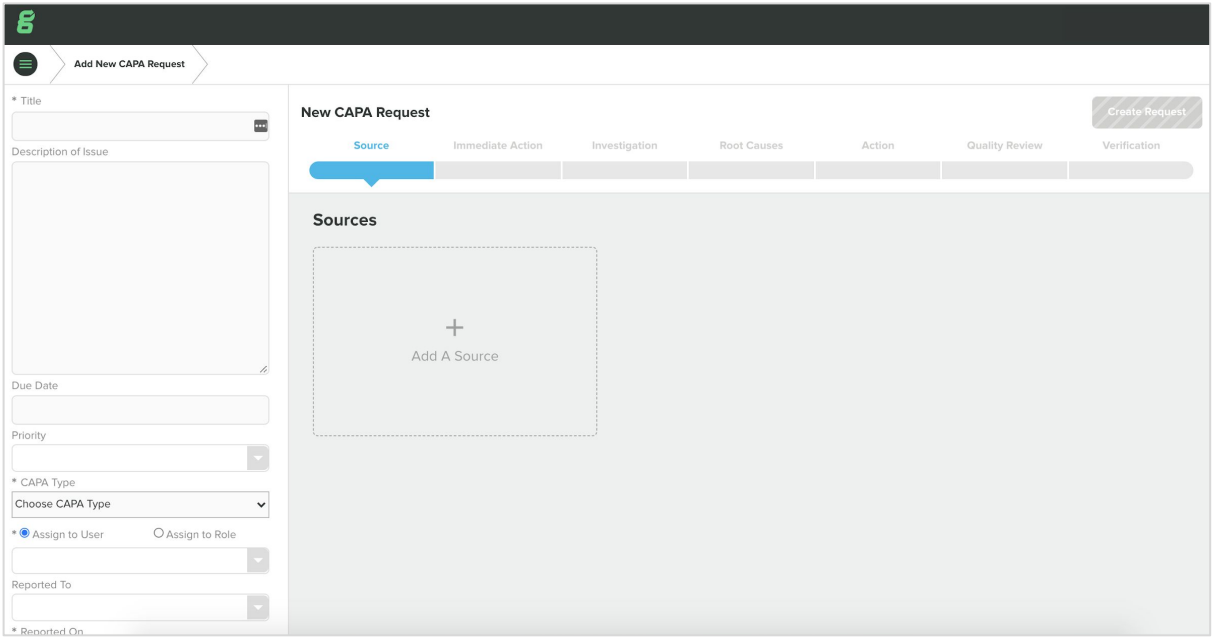
CAPA PROCESS – STEP-BY-STEP

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.

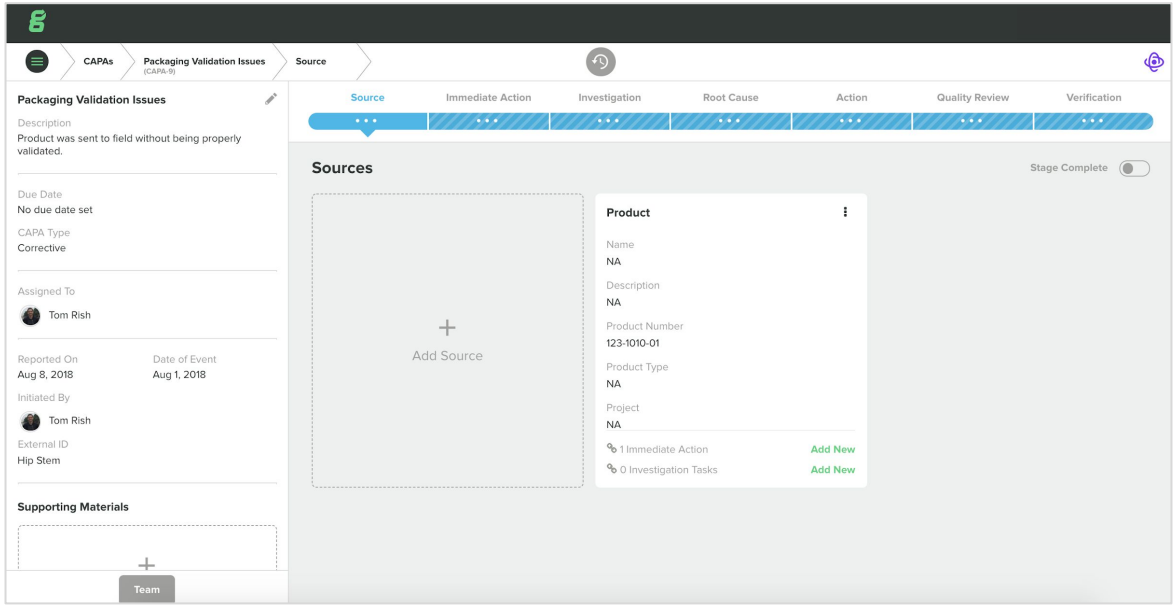
4. If accepted, issue and initiate CAPA.

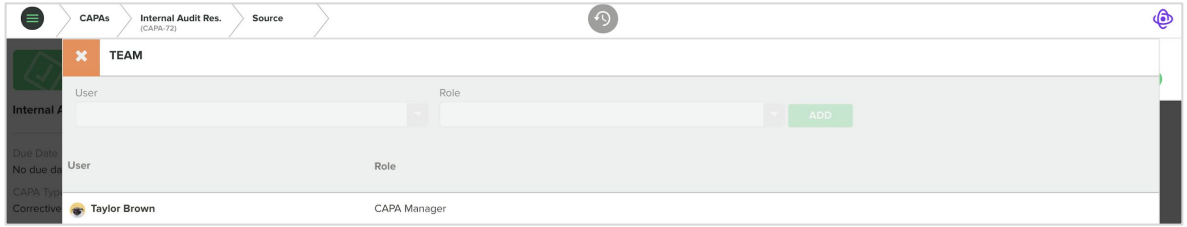


CAPA PROCESS – STEP-BY-STEP

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

6. Determine CAPA cross-functional team





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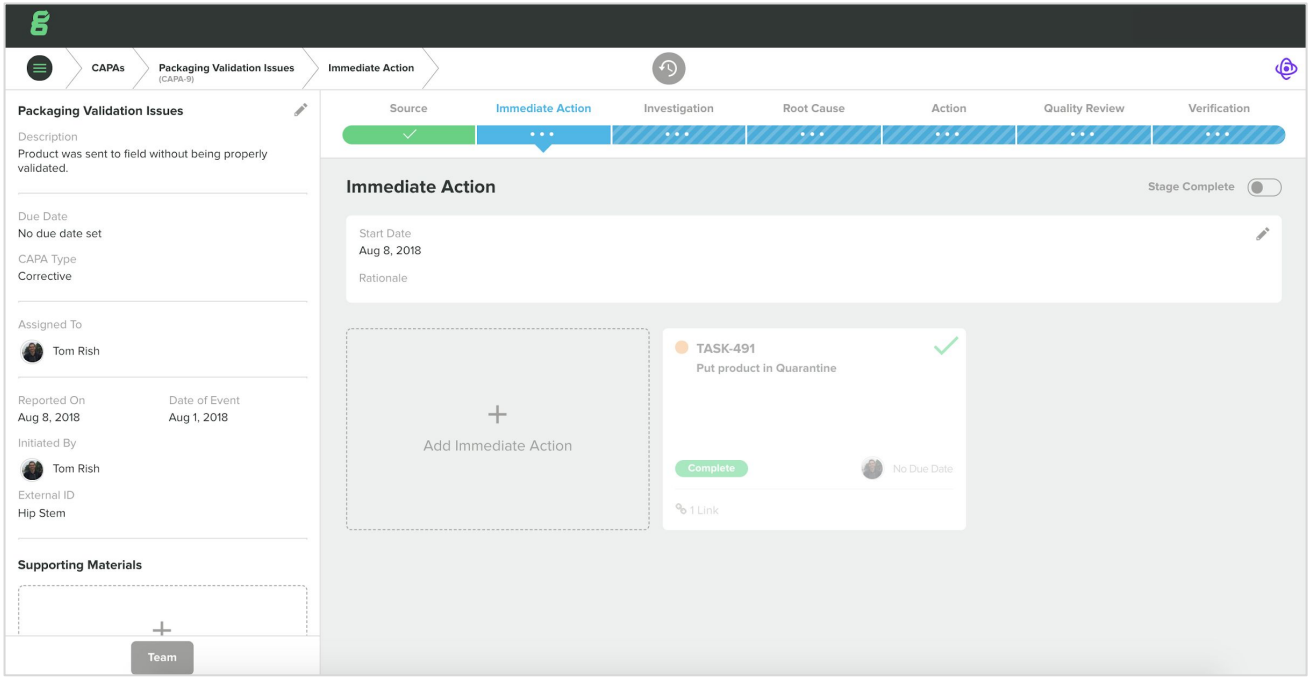
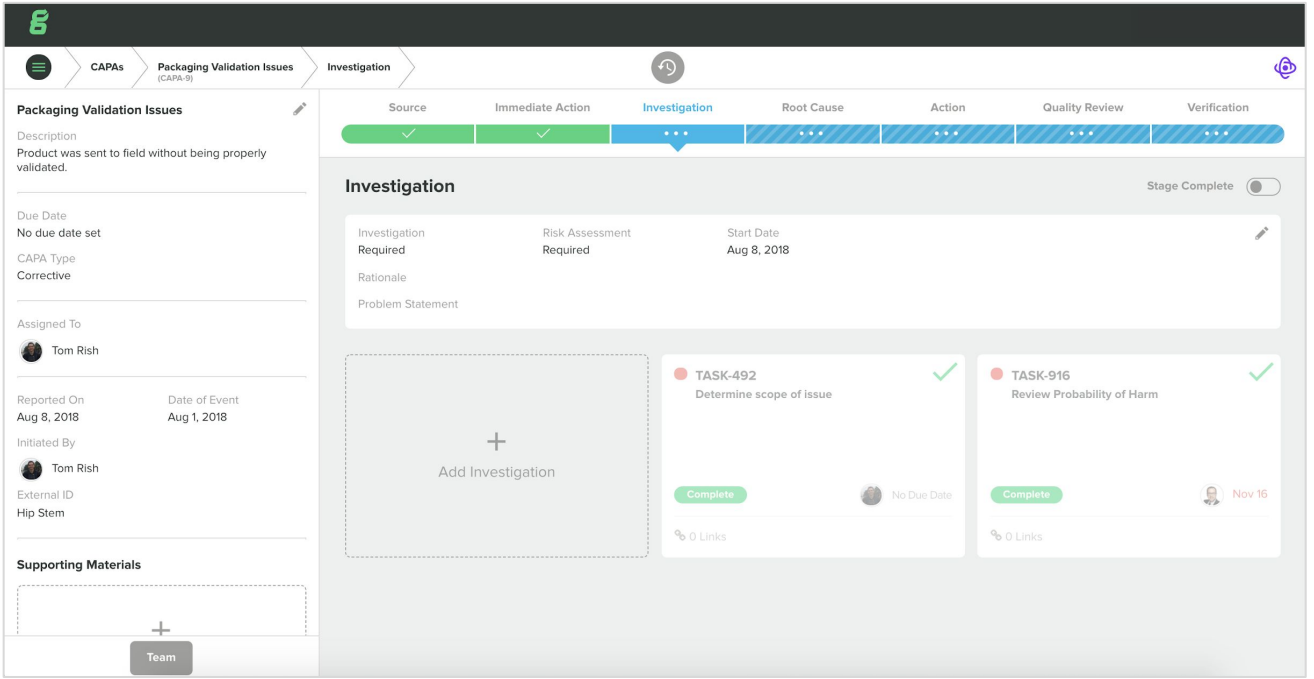
CAPA PROCESS – STEP-BY-STEP

7. Identify any immediate actions and corrections required.



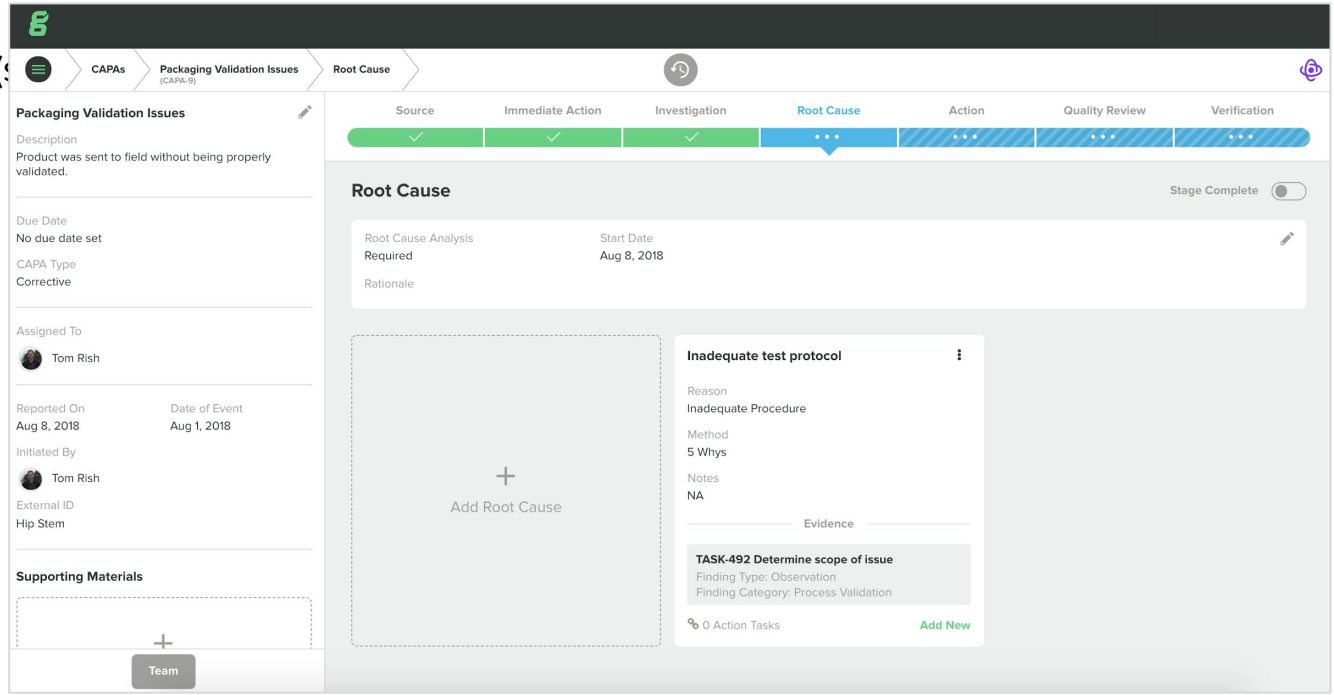
CAPA PROCESS – STEP-BY-STEP

8. Investigate and capture findings.



CAPA PROCESS – STEP-BY-STEP

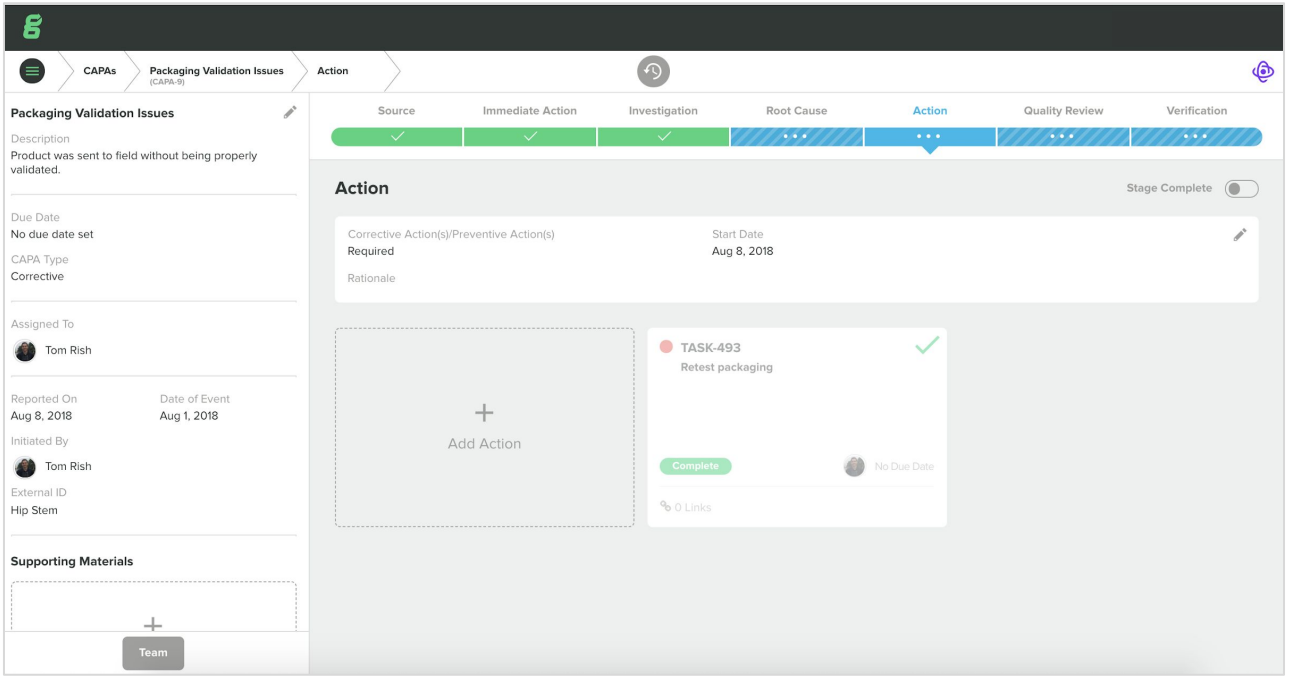
9. Determine root cause(s



CAPA PROCESS – STEP-BY-STEP

10. Specify corrective and/or preventive action plan.

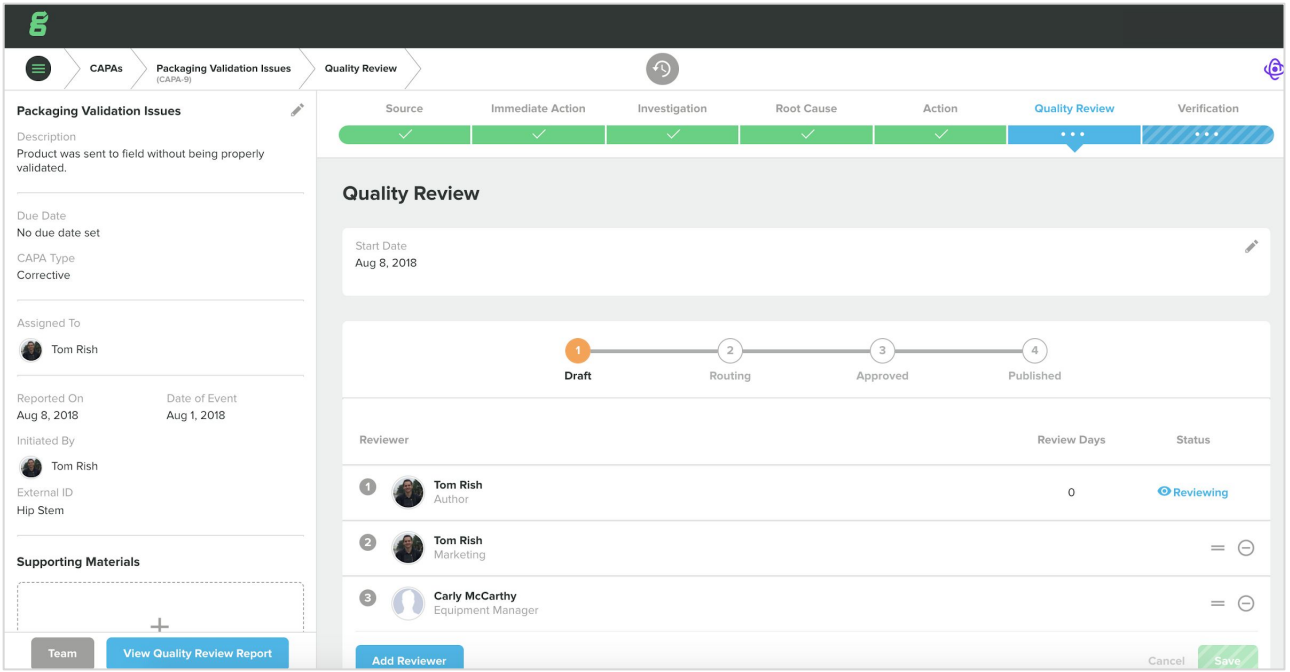
11. Complete action plan.



CAPA PROCESS – STEP-BY-STEP

12. Review CAPA for completeness.

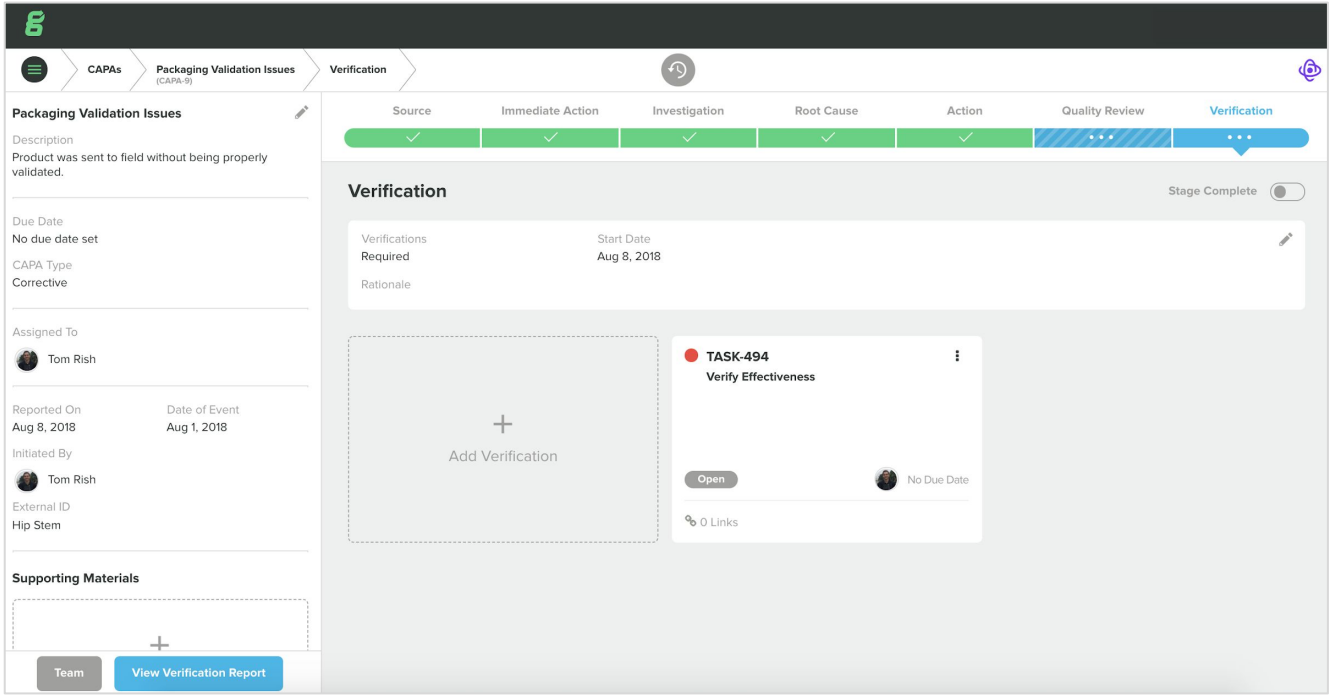
13. Approve CAPA actions



CAPA PROCESS – STEP-BY-STEP

14. Specify steps for effectiveness verification.

15. Verify effectiveness of CAPA.



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15. Verify effectiveness of CAPA.

QUESTIONS?

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