Corrective and Preventive Action: Case Study

FDA Small Business
Regulatory Education for Industry (REdI)
Boston, MA
May 30, 2019

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U.S. Food and Drug Administration

DEATH

by

CAPA

Poll

Select the most appropriate response that reflects your company's use of its Corrective and Preventive Action (CAPA) subsystem:

1. Overuse the CAPA subsystem
2. Underuse the CAPA subsystem
3. Use the CAPA subsystem appropriately
4. Do not use a CAPA subsystem
5. Unsure

Learning Objectives

- Review CAPA reminders
- Identify tips to help decide when to open a CAPA
- Illustrate how to implement CAPA using a case study

CAPA Reminders

CAPA: Reminders

- Purpose
  - Address systemic quality issues
- Regulatory requirements
  - Title 21 Code of Federal Regulations 820.100

CAPA Tips

CAPA: Tips

Open a CAPA when:

- Incident caused injury or death
- Multiple occurrences of similar/same event
- Procedures indicate it cannot be addressed in another process/way
- Risk assessment determined issue to be critical

CAPA Case Study

CAPA: Case Study

Background:

- Ivy Innovations, Incorporated manufactures Class II antimicrobial susceptibility test (AST) devices

CAPA: Case Study

Background:

- Ivy Innovations performed final acceptance activities for 4 different lots of AST devices
  - for gram positive organisms
- Acceptance criteria for each lot:
  - 98% of the sample should be completely sealed

CAPA: Case Study

Nonconformity/nonconforming product:

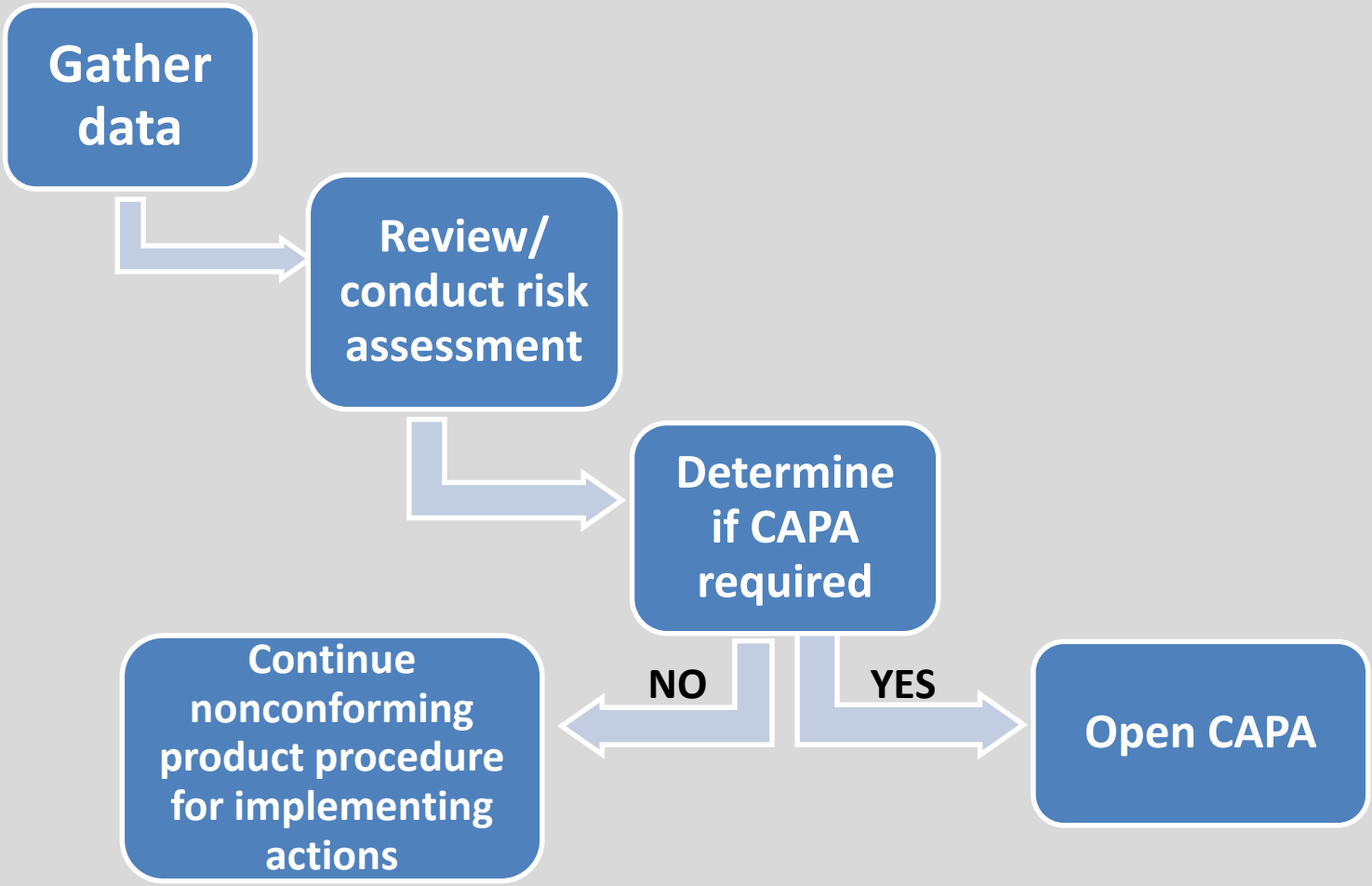
- AST devices did not meet final acceptance criteria
- Finished device inspection revealed partially opened pouches in all lots
- # Partially sealed pouches for the 4 lots sampled:
  - 16 out of 100 devices (**84% completely sealed**)
  - 19 out of 100 devices (**81% completely sealed**)
  - 8 out of 100 devices (**92% completely sealed**)
  - 11 out of 100 devices (**89% completely sealed**)

CAPA: Case Study

CAPA

Nonconforming product procedure

CAPA: Open or Not?



Should we open a CAPA?

Name: Ivy Innovations, Incorporated		**Document #:** NCR093087 **Issued:** July 2015 **Rev. No.:** Rev1.0 **Effective Date:** July 18, 2015
Title: Nonconformance Report (NCR) Form		
Approved by: QSM	**Date Approved:** 7/4/2015	

NON-CONFORMANCE REPORT (NCR) FORM

NCR #: 32

Initiated by: Alyssa Pitts Date: 2/14/2019

Affected Products/Lots/batch: Pink Pearl Antimicrobial Susceptibility Tests, Lots #141908; #071908; #091908; and #871908

Description of Nonconformity (Attach supporting documents):

Final acceptance activities for 4 different lots of the Pink Pearl antimicrobial susceptibility test (AST) devices for gram positive organisms were completed. The Pink Pearl AST devices did not meet final acceptance criteria and the finished device inspection revealed partially opened pouches in all lots sampled during testing. The acceptance criteria was 98% completely sealed pouches of all the devices sampled in each lot. The number of partially sealed pouches for the 4 lots sampled were:

- 16 out of 100 devices (84% completely sealed)
- 19 out of 100 devices (81% completely sealed)
- 8 out of 100 devices (92% completely sealed)
- 11 out of 100 devices (89% completely sealed).

Initial Risk assessment documents were reviewed to determine if this failure was initially identified and evaluated and determined to be considered critical to the process/product. Risk assessment indicated sealed pouches were critical to the AST devices.

Containment Action/Correction: All remaining product of the 4 lots were labeled as nonconforming and placed in area designated for nonconforming product.
Risk management documents were reviewed to determine if this failure was initially identified and if considered critical to process.

Document CAPA Decision

Name: Ivy Innovations, Incorporated		**Document #:** NCR093087 **Issued:** July 2015
Title: Nonconformance Report (NCR) Form		**Rev. No.:** Rev1.0 **Effective Date:** July 18, 2015

[X] Open CAPA **CAPA# 83** [X] Investigate

Actions taken (Correction/ Corrective):

All lots segregated and responsible personnel notified; See CAPA #83

Investigation Required: [X] Yes [ ] No, If No, why?

Approved: [X]

Responsible Manager: Tonya Wilbon, Date: 02/21/2019

CLOSE OUT: Date: _____

CAPA Administrator/QMS: _____

CAPA Administrator Signature & Date: _____

Open CAPA: Case Study

AST device:

- Multiple occurrences of similar/same event
  - Multiple devices in multiple lots with partially sealed devices
- Risk assessment determined issue to be critical
  - Could lead to delayed/incorrect treatment

CAPA: Case Study

Open CAPA

CAPA Form A

Name: Ivy Innovations, Incorporated		**Document #:** CAPA141908
Title: Corrective Action and Problem Report (CAPA)		**Issued:** September 2015 **Rev. No.:** Rev1.4
Approved by: QSM/VP of QA	**Date Approved:** 9/27/2015	**Effective Date:** September 30, 2015

CORRECTIVE ACTION AND PREVENTIVE ACTION (CAPA)

CAPR #: 83

Initiated by: Athena Robinson Date: 2/22/2019

Affected Products/Devices: Pink Pearl Antimicrobial Susceptibility Tests, Lots #141908; #071908; #091908; and #871908

Description of Nonconformity:

Final acceptance activities for 4 different lots of the Pink Pearl antimicrobial susceptibility test (AST) devices for gram positive organisms were completed. The Pink Pearl AST devices did not meet final acceptance criteria and the finished device inspection revealed partially opened pouches in all lots sampled during testing. The acceptance criteria was 98% completely sealed pouches of all the devices sampled in each lot. The number of partially sealed pouches for the 4 lots sampled were:

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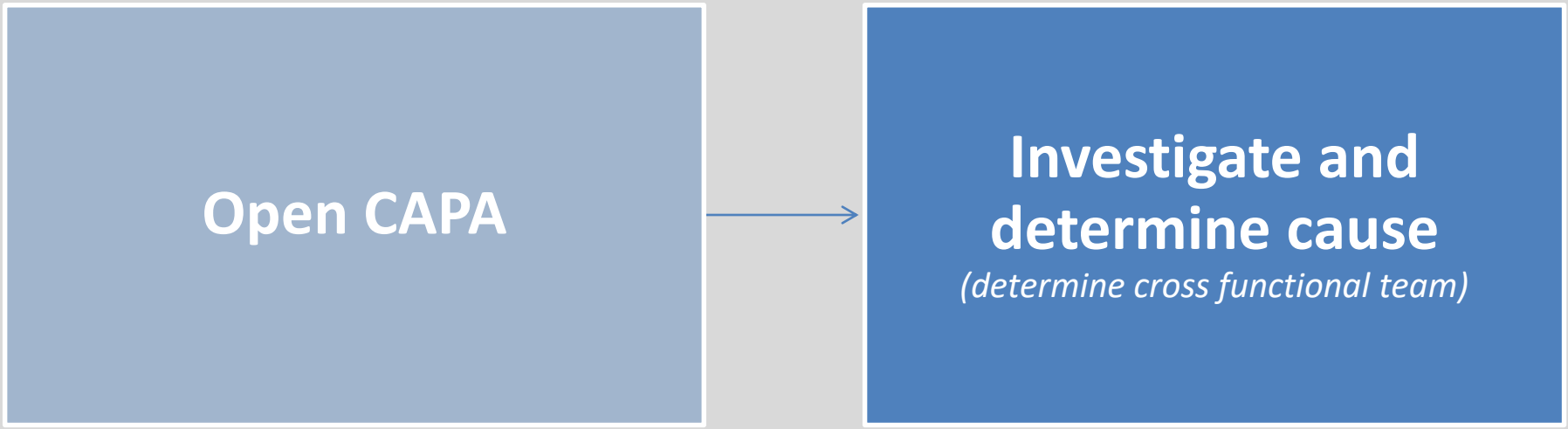
Investigation/Root Cause:

CAPA: Case Study



CAPA: Investigation

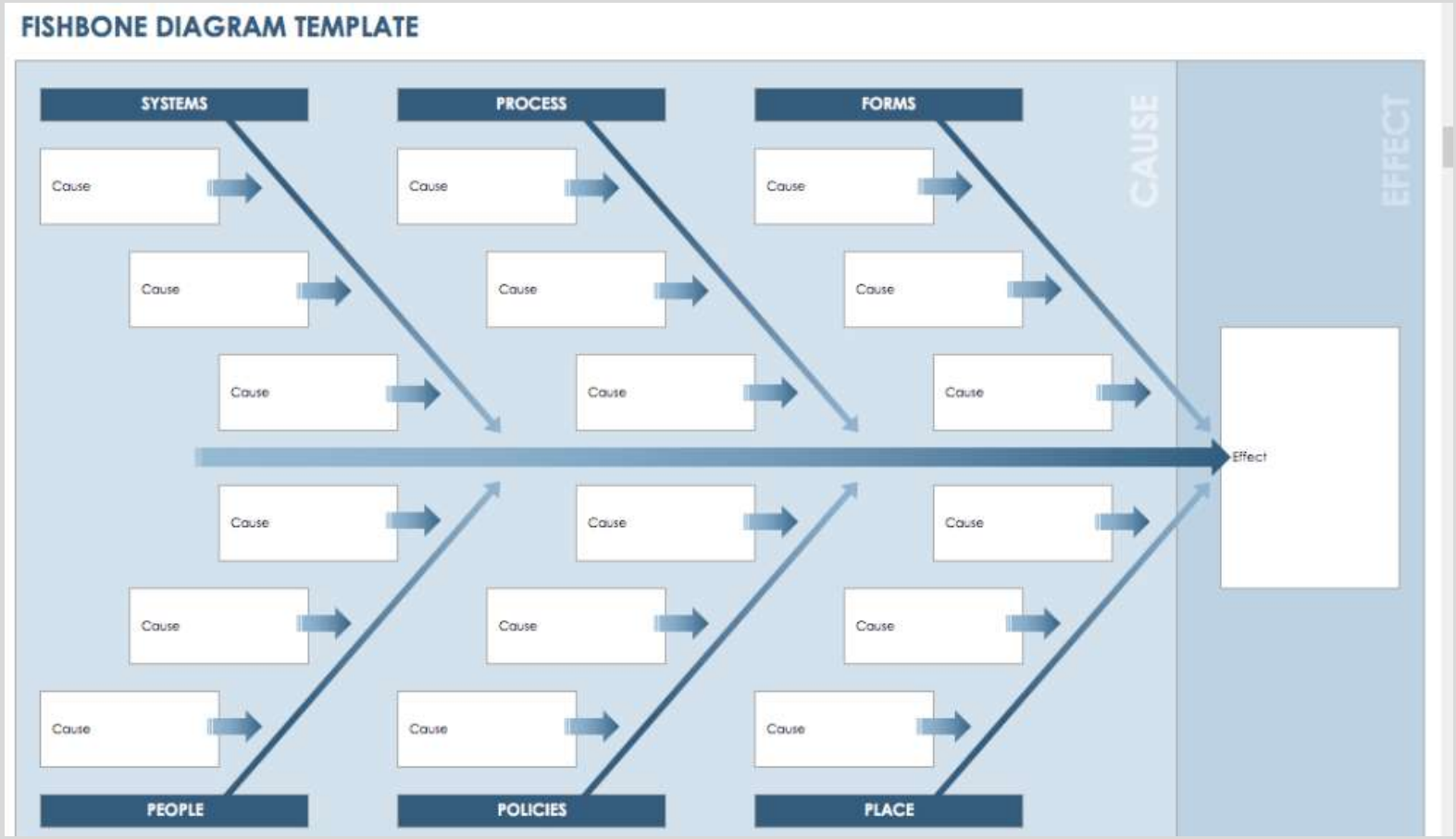
- Determine cause of nonconformity
  - 5 Whys
  - Fishbone (Ishikawa) diagram
  - Failure Mode and Effects Analysis (FMEA)
  - Fault Tree Analysis (FTA)

CAPA: Investigation

Name: Ivy Innovations, Incorporated		**Document #:** CAPA #83 **Rev. No.:**Rev1.4 **Effective Date:** September 2018

Investigation: 5 Whys Method		
Why 1	Why were AST packages partially sealed?	**Answer:** The adhesive did not hold the seals together.
Why 2	Why did the adhesive not hold the seal together.	**Answer:** The temperature was not hot enough to ensure optimal seal strength.
Why 3	Why was the temperature not hot enough?	**Answer:** The temperature gauge was not set appropriately.
Why 4	Why was the temperature gauge not set appropriately?	**Answer:** The engineer did not confirm the temperature of the sealing machine before starting.
Why 5	Why did the engineer not confirm the temperature of the sealing machine prior to sealing?	**Answer:** The engineer indicate he was not aware he had to confirm the temperature each time.

CAPA: Investigation



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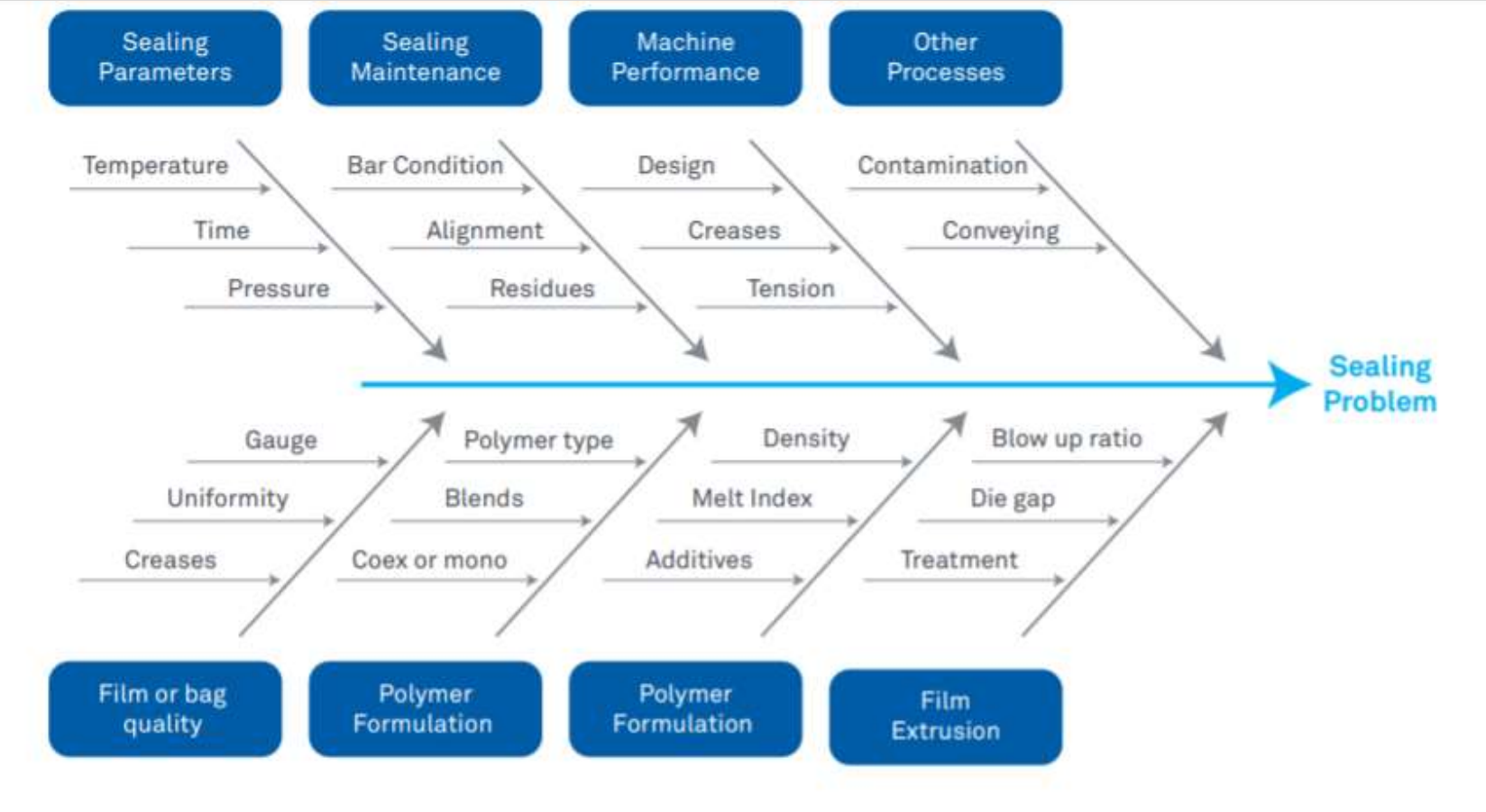
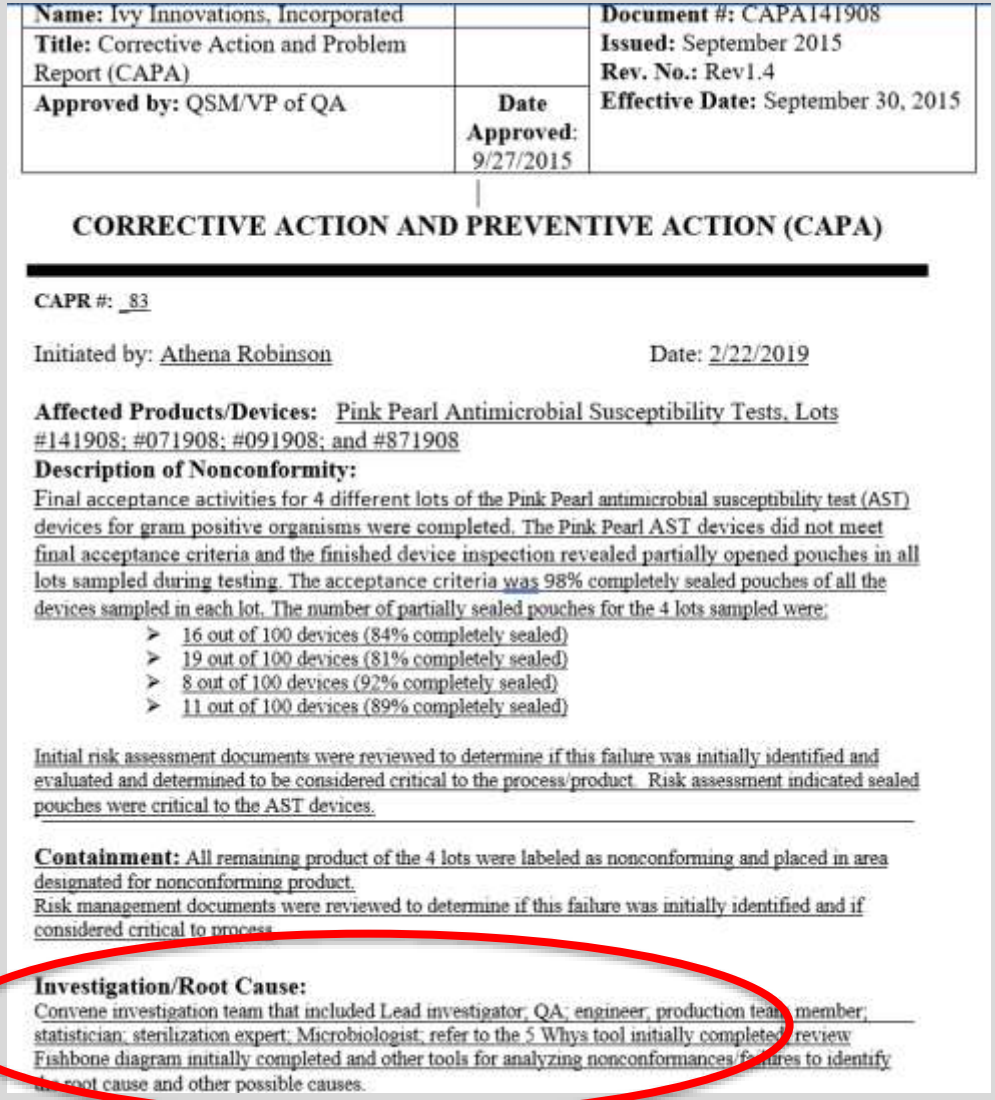


CAPA: Investigation



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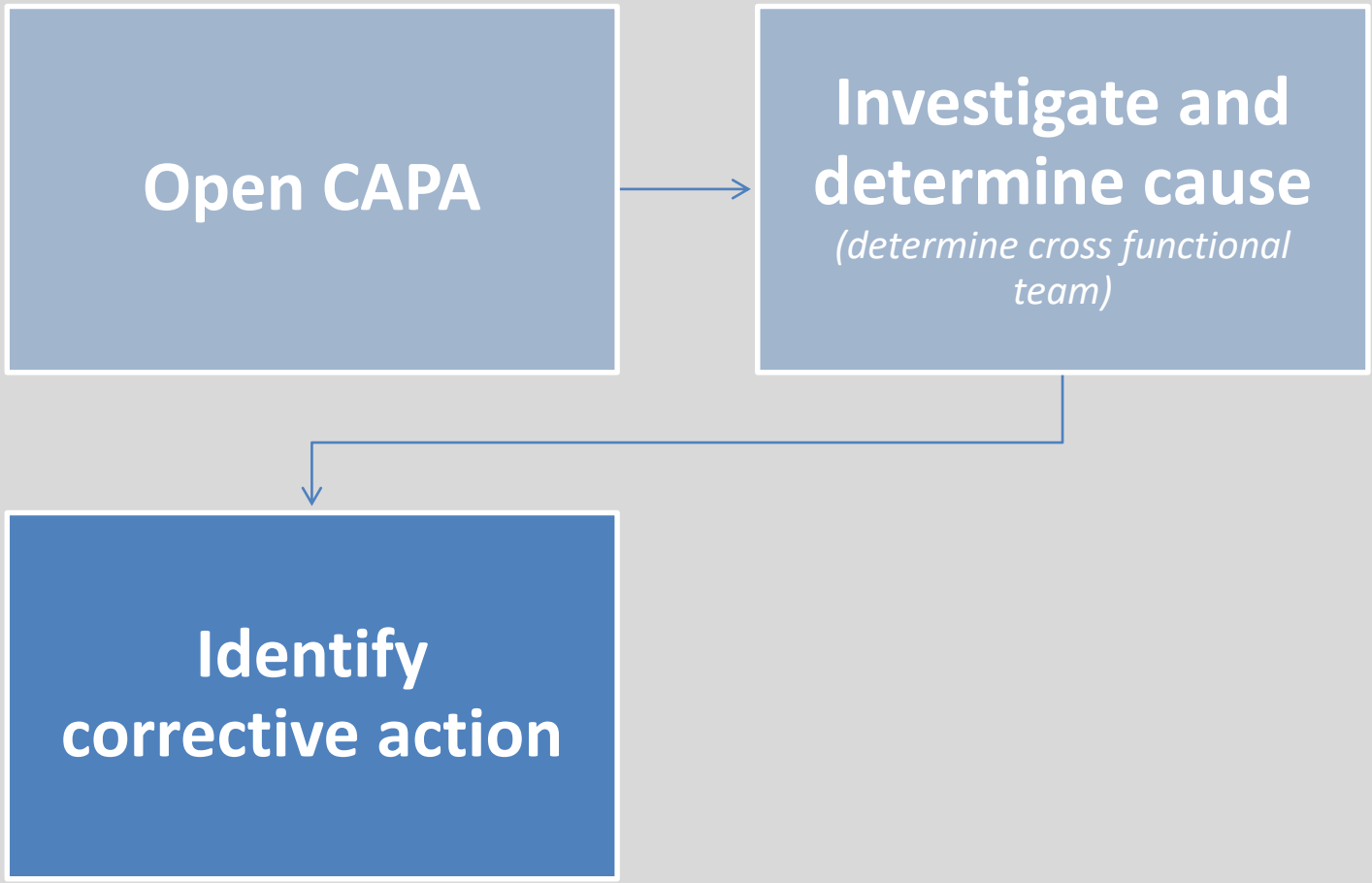
Containment: All remaining product of the 4 lots were labeled as nonconforming and placed in area designated for nonconforming product.

Risk management documents were reviewed to determine if this failure was initially identified and if considered critical to process.

Investigation/Root Cause:

Convene investigation team that included Lead investigator; QA; engineer; production team member; statistician; sterilization expert; Microbiologist; refer to the 5 Whys tool initially completed; review Fishbone diagram initially completed and other tools for analyzing nonconformances/failures to identify the root cause and other possible causes.

CAPA: Case Study



CAPA: Case Study

- Identify corrective action
  - Use information from 5 Whys
  - Use information from Fishbone diagram

CAPA: Case Study

Name: Ivy Innovations, Incorporated		**Document #:** CAPA #83 **Rev. No.:**Rev1.4 **Effective Date:** September 2018

Description of Problem/Nonconformity: Final acceptance activities for 4 different lots of the Pink Pearl antimicrobial susceptibility test (AST) devices for gram positive organisms. The Pink Pearl AST devices did not meet final acceptance criteria and the finished device inspection revealed partially opened pouches in all lots. The acceptance criteria was 98% completely sealed pouches of all the devices sampled in each lot. The number of partially sealed pouches for the 4 lots sampled were:

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The 4 lots affected were: Lot #141908; #071908; #091908; and #871908.

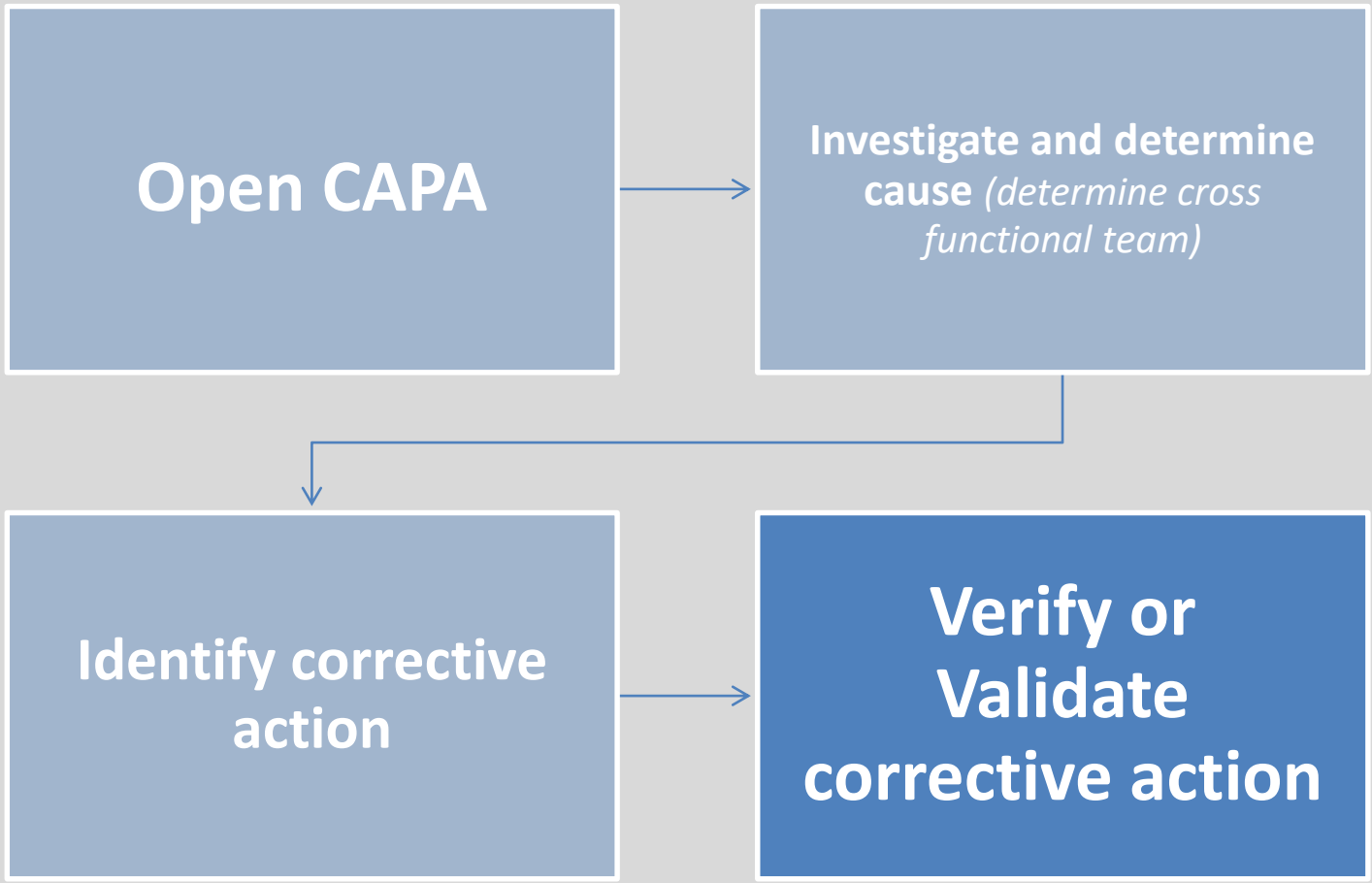
Containment Action/Correction: All remaining product of the 4 lots were labeled as nonconforming and placed in area designated for nonconforming product.
Risk management documents were reviewed to determine if this failure was initially identified and if considered critical to process.

Investigation: 5 Whys Method

Why 1	Why were AST packages partially sealed?	**Answer:** The adhesive did not hold the seals together.
Why 2	Why did the adhesive not hold the seal together.	**Answer:** The temperature was not hot enough to ensure optimal seal strength.
Why 3	Why was the temperature not hot enough?	**Answer:** The temperature gauge was not set appropriately.
Why 4	Why was the temperature gauge not set appropriately?	**Answer:** The engineer did not confirm the temperature of the sealing machine before starting.
Why 5	Why did the engineer not confirm the temperature of the sealing machine prior to sealing?	**Answer:** The engineer indicated he was not aware he had to confirm the temperature each time.

Root Cause	Employee not trained on and not implementing the procedure	**Corrective Action:** Develop check list for employee to follow (if it does not already exist); revise SOP to reflect use of checklist; retrain all staff

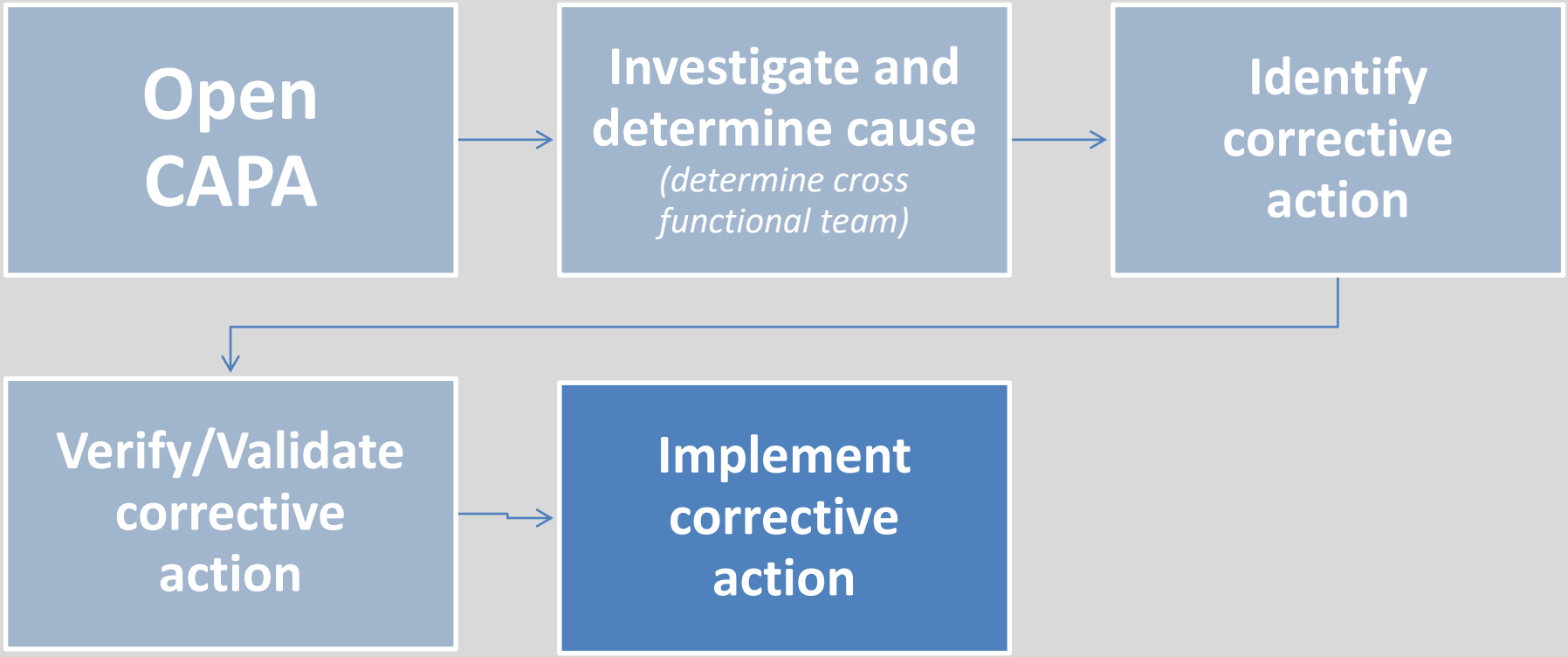
CAPA: Case Study



CAPA: Verify Corrective Action

- Verify corrective action is effective
  - Verify that package seals are complete when trained employees use SOP with checklist
- Verify corrective action does not adversely affect AST device

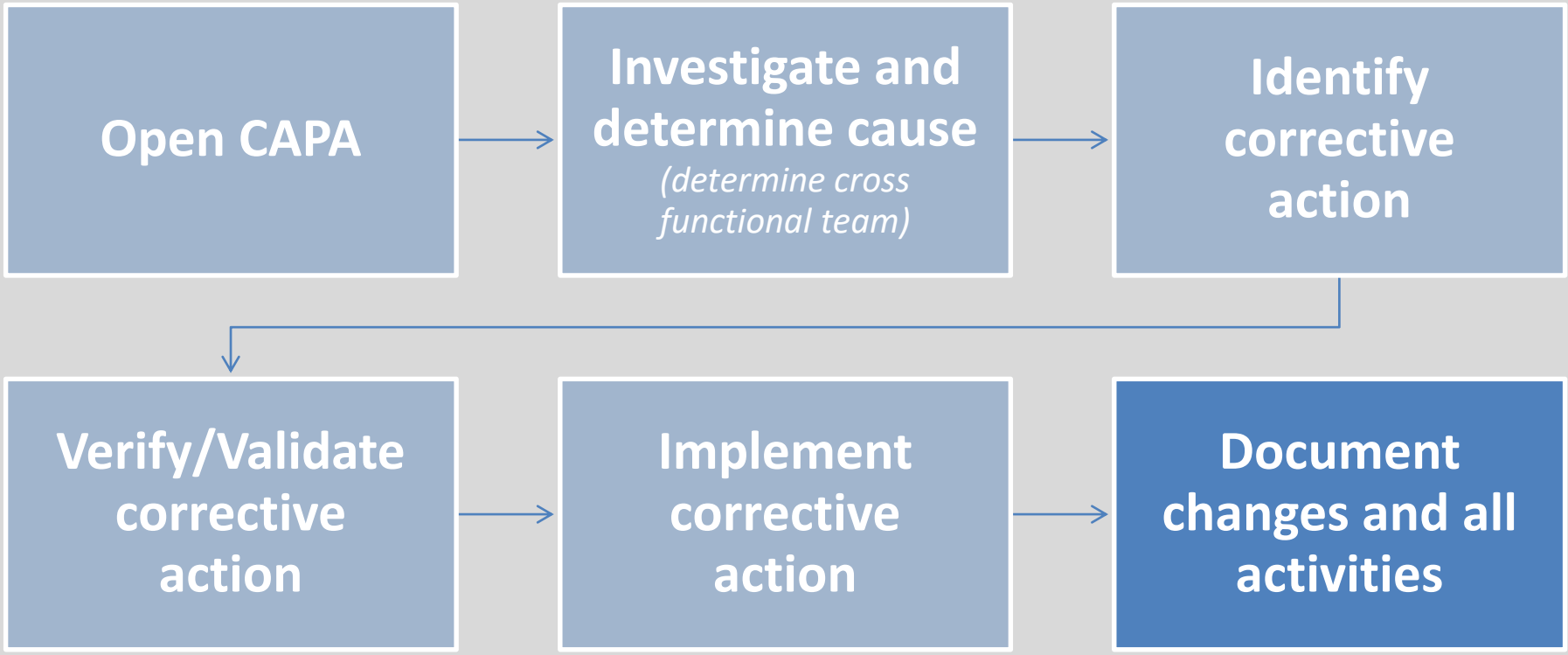
CAPA: Case Study



CAPA: Implement Corrective Action

- Corrective action implementation:
  - Checklist created
  - SOP revised to include checklist
  - Employees trained
- Document/record all activities completed

CAPA: Case Study



CAPA: Document Activities

- Document all activities on CAPA form

Investigation/Root Cause:

Convene investigation team that included Lead investigator; QA; engineer; production team member; statistician; sterilization expert; Microbiologist; refer to the 5 Whys tool initially completed, review Fishbone diagram initially completed and other tools for analyzing nonconformances/failures to identify the root cause and other possible causes

Root cause was identified as employee failed to check the temperature of the sealer to ensure it was set at the correct temperature for sealing the pouches for the Pink Pearls AST device.

Actions taken (Correction, Corrective Action):

Created checklist for activities to be completed including checking the temperature of the sealer; revise SOP to include the checklist for checking the temperature; train employees on new checklist

Disseminated changes to all employees responsible for the Pink Pearls AST device; Provided summary for management review meeting; documented all activities on the CAPA form

1

CAPA: Document Activities

Approved: [X]

Responsible Manager: Whitney Lewis Date: 03/30/2019

CAPA Administrator: Curtis Marie Rogers Date: 03/31/2019

Verification/Implementation/Effectiveness Check:

Verify trained employee was able to operate the sealer machine using the revised SOP; verified that the AST packages were completely sealed on a statistically valid number of samples.

Completed: [X] Investigator: Alyssa Pitts Date: 4/2/2019

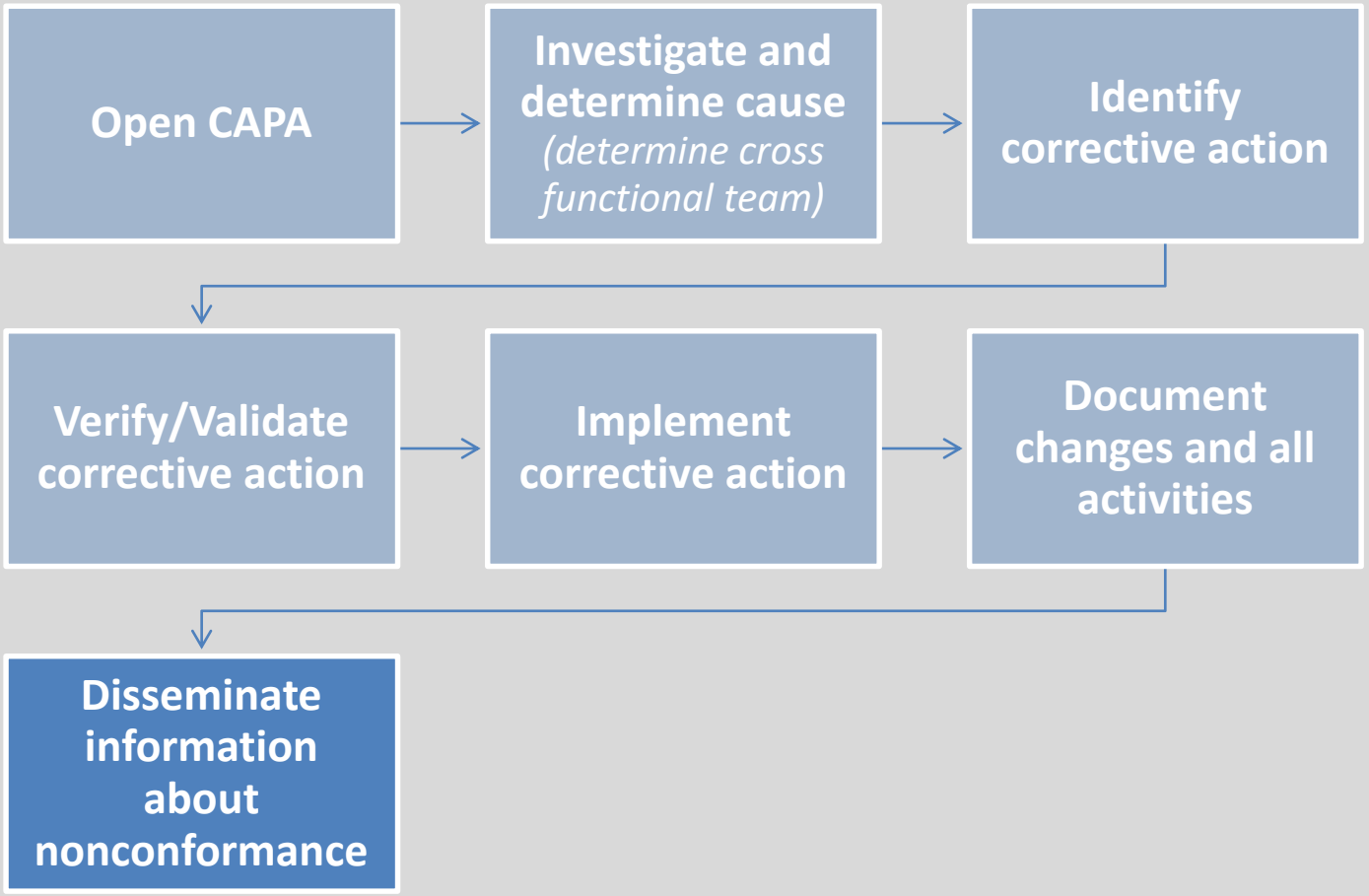
Approved: [X] Responsible Manager: Tonya Wilbon CAPA Administrator Curtis Rogers Date: 04/06/19

CLOSE OUT: Date: 04/10/19 QSEB notified: [X]

CAPA Administrator/QMS Curtis Marie Rogers

CAPA Administrator Signature & Date: *Curtis Marie Rogers* 04/10/19

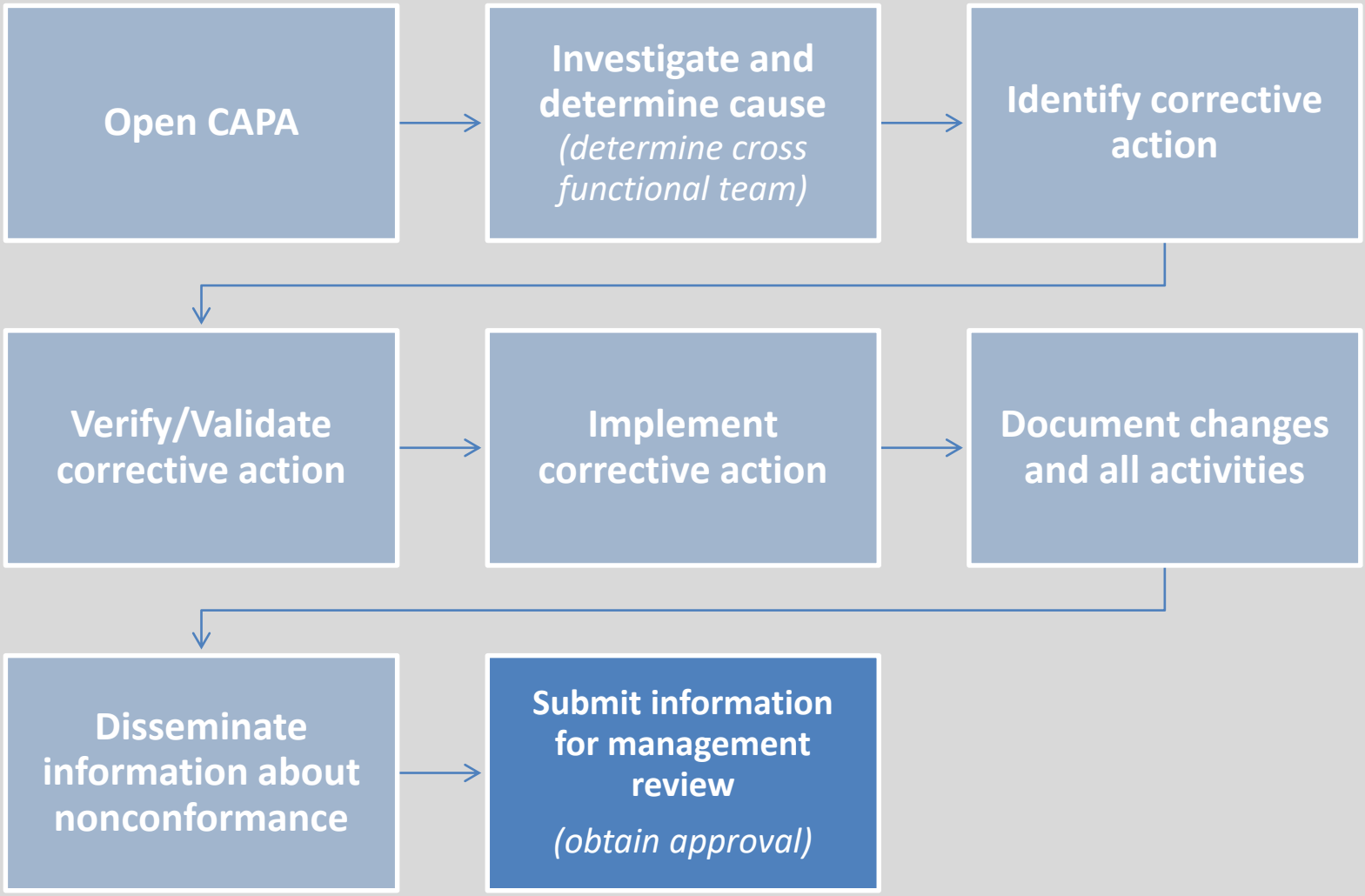
CAPA: Case Study



CAPA: Disseminate Information

- Notify all individuals responsible for Pink Pearls AST device
  - Notify by email
  - In person Staff meeting
  - Conference call
  - Formal training
- Must document notification

CAPA: Case Study



CAPA: Management Review

- Document submitting information for management review
  - Management review meetings

CAPA: Management Review

Actions taken (Correction, Corrective Action):
Created checklist for activities to be completed including checking the temperature of the sealer; revise SOP to include the checklist for checking the temperature; train employees on new checklist Disseminated changes to all employees responsible for the Pink Pearls AST device; Provided summary for management review meeting; documented all activities on the CAPA form

Investigator: Athena Robinson **Date:** 3/22/2019

Approved: X

Responsible Manager: Whitney Lewis Date: 03/30/2019

CAPA Administrator: Curtis Marie Rogers Date: 03/31/2019

Verification/Implementation/Effectiveness Check:
Verify trained employee was able to operate the sealer machine using the revised SOP; verified that the AST packages were completely sealed on a statistically valid number of samples.

Completed: X Investigator: Alyssa Pitts Date: 4/2/2019

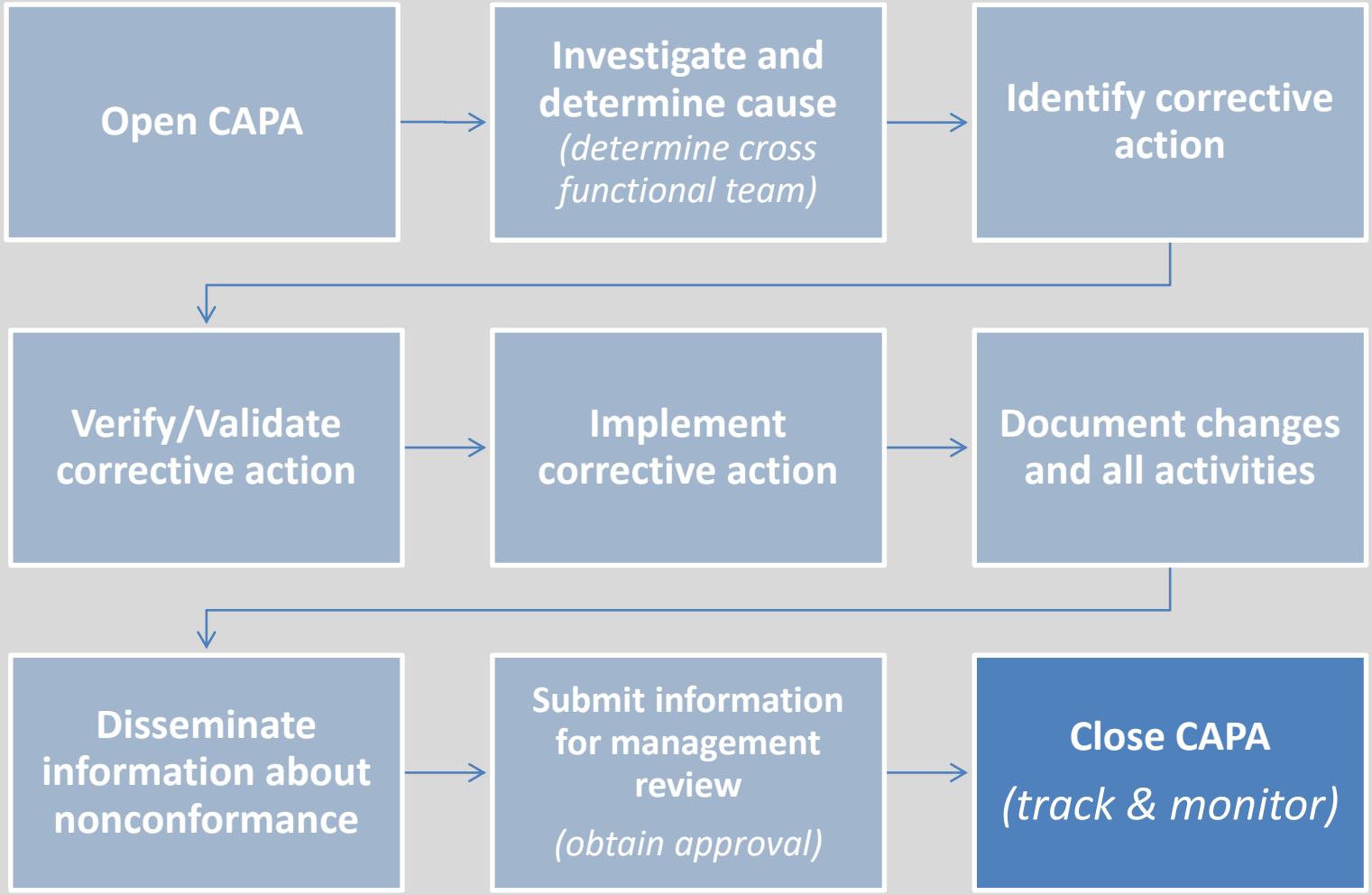
Approved: X Responsible Manager: Tonya Wilbon CAPA Administrator Curtis Rogers Date: 04/06/19

CLOSE OUT: Date: 04/10/19 QSEB notified: X

CAPA Administrator/QMS Curtis Marie Rogers

CAPA Administrator Signature & Date: *Curtis Marie Rogers* 04/10/19

CAPA: Case Study



CAPA: Close

- Obtain appropriate approvals
  - Include date
  - Signature of approving official

CAPA: Close

Verification/Implementation/Effectiveness Check:
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Approved: [X] Responsible Manager: Tonya Wilbon CAPA Administrator Curtis Rogers Date: 04/06/19

CLOSE OUT: Date: 04/10/19 QSEB notified: [X]

CAPA Administrator/QMS Curtis Marie Rogers

CAPA Administrator Signature & Date: *Curtis Marie Rogers* 04/10/19

Summary

- CAPA is an important element of the quality management system
- When CAPA is used appropriately,
  - Companies can deal effectively with product and quality problems
  - Companies can prevent or minimize device failures
- Not every nonconformance or complaint requires opening a CAPA

Resources

- Corrective and Preventive Action: 21 CFR 820.100
- Guide to Inspections of Quality Systems
- Global Harmonization Task Force document: Quality Management System- Medical Devices- Guidance on corrective and preventive action and related QMS processes

Questions

Your Call to Action

- Review tips to help decide when to open a CAPA early in process
- Feed CAPA information back into quality management system
- Document all activities completed


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