

Failure Investigation

“Treating the root cause, not the symptoms”

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Agenda

Importance of failure investigation. Why?

- Industry performance
- Failure Investigation steps
- Investigation Tools & Examples
- Good Investigation Practices
- Lessons learned

Why?

Let us paraphrase

21 CFR 820.90, Nonconforming product

21 CFR 820.100, Corrective and Preventive Action

21 CFR 820.198, Complaint Files

“LEGAL....YOU HAVE TO!”



Why?

21 CFR 820.90, Nonconforming product

*Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedure shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming products. The evaluation of nonconformance shall include a determination of **the need for an investigation** and notification of the persons or organizations responsible for the nonconformance. The evaluation and **any investigation shall be documented**'.*



Why?

21 CFR 820.100, Corrective and Preventive Action

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

(2) *Investigating the cause of non conformities relating to product, processes and the quality system’.*

21 CFR 820.198 (b), Complaint Files

Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate’.



Why?

21 CFR 820.198 (c), Complaint Files

*‘Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications **shall be** reviewed, evaluated and **investigated**’.*

21 CFR 820.198 (d), Complaint Files

*‘Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and **investigated** by a designated individual.....’.*



Why?

21 CFR 820.198 (e), Complaint Files

*'When an **investigation** is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. **The record of investigation shall include:***

- 1) *The name of the device*
- 2) *The date the complaint was received*
- 3) *Any device identification(s) and control number(s) used*
- 4) *The name, address and phone number of the complainant*
- 5) *The nature and details of the complaint*
- 6) ***The dates and the results of the investigation***
- 7) ***Any corrective action taken** and*
- 8) ***Any reply to the complainant**'.*



Why?

- Our Customers Expect
 - Safe, Reliable & Effective Products
- The FDA requires:
 - Implementation & compliance to procedures
 - Thorough investigations & testing commensurate with event & potential impact
 - Implementation & Effectiveness of all Corrective / Preventive Actions
 - Review & Disposition of investigations

Why?

- Good Business Practice
 - Process improvements
 - Elimination of recurring issues
 - Rework reduction
 - Scrap reduction

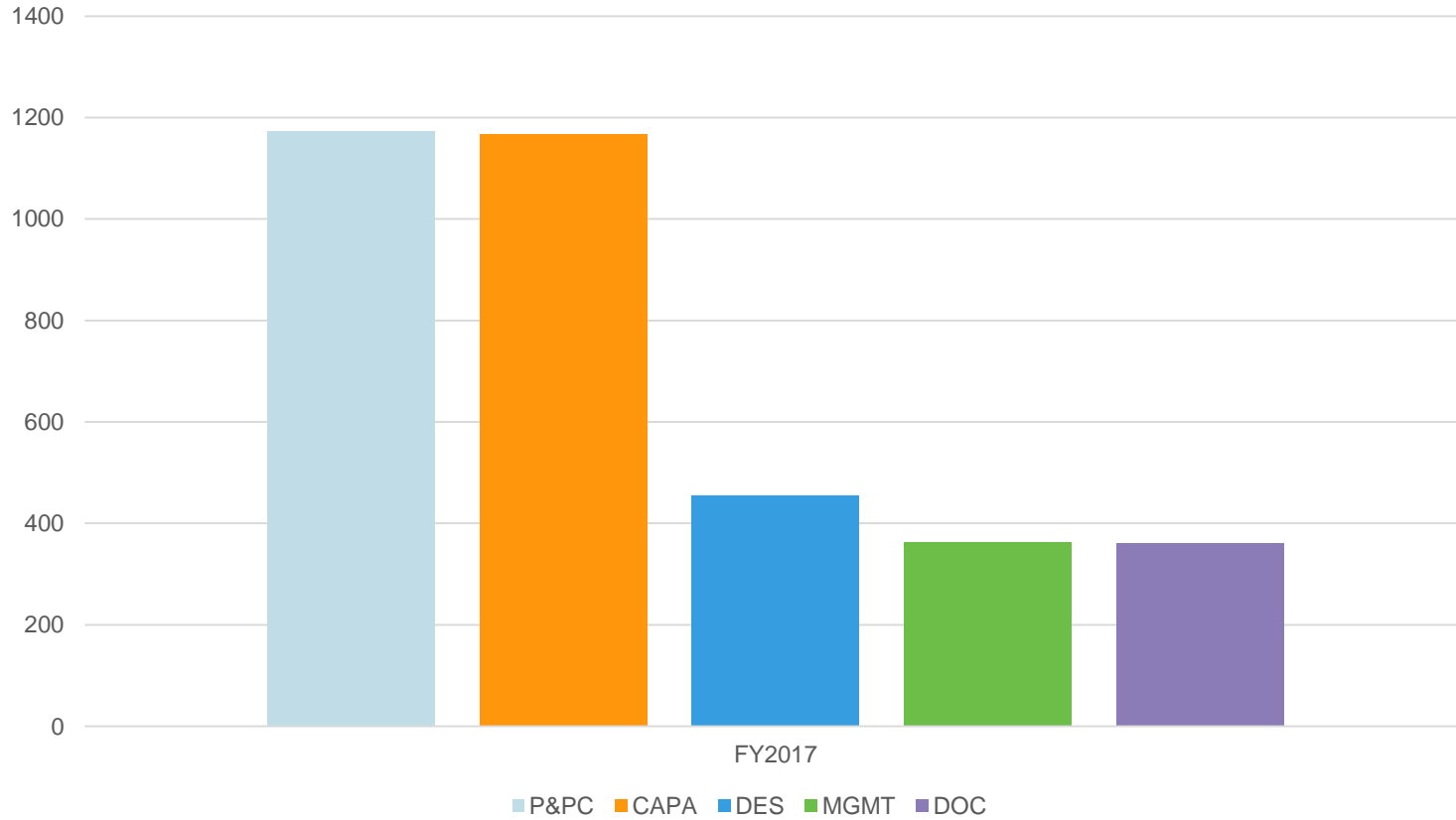
Why?

Patient Safety



FDA 2017 Top 5 483 Findings

Data from FY17 Annual FDA Medical Device Quality System



FDA Warning Letters with CAPA Cite

Data from FY17 Annual FDA Medical Device Quality System

Year	Number of WLs
FY2017	33
FY2016	75
FY2015	128
FY2014	107
FY2013	172
FY2012	163
FY2011	131
FY2010	79



How is Industry performing ?

FDA observations indicate:

1. Inadequate investigations
2. Lack of investigation
3. Failure to determine true root cause
4. Inadequate Corrective and Preventive Action
5. Lack of documentation



Industry trends

SO WHY IS THIS HAPPENING?

- Inaccurate problem statement
 - Symptoms are addressed but not the actual problem
 - The quick fix!
- Incomplete/Lack of a documented investigation
 - Root cause not established
- Inadequate/ incomplete effectiveness checks
- Timeliness



Failure Investigation

Key components

1. Problem Statement
 - How, what, when, where, why, who?
 - Determine the scope of problem (i.e., plant, division, facility, shift, machine, product code)
2. Containment, correction, communication, assess Risk
3. Identify root cause
4. Identify & implement Corrective & Preventive Actions
5. Horizontal deployment
6. Effectiveness verification



Failure Investigation

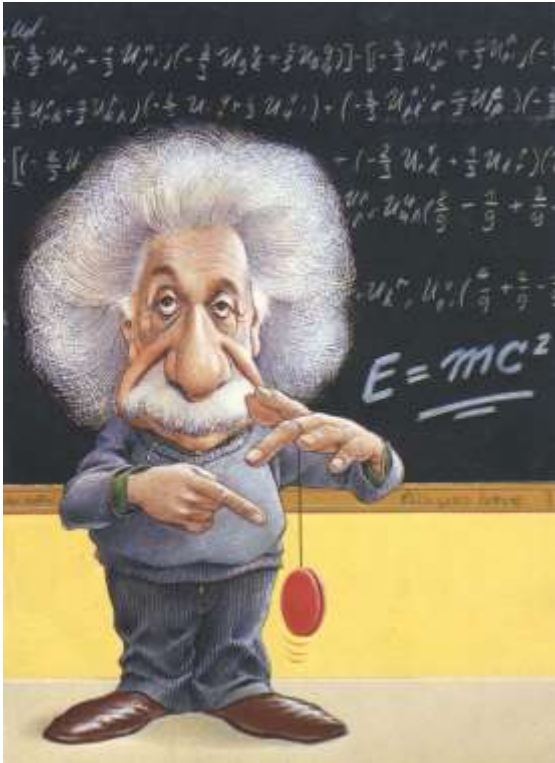
Ask

- **What** is known?
- **What** data/facts are needed?
- **What** tools should be used?
- **What** is the sense of urgency?
- **What** is the timeline for resolution?

Consider

- Any similar events reported or known?
- Complaints, Trend Reports
- Across Corporation – Globally
- Does the problem affect:
 - Other products?
 - Other processes?
 - Other facilities?
 - Other suppliers or manufacturers?

1. Identify problem statement



“The formulation of a problem is the most essential part of problem solving”

Albert Einstein

Problem Statement



What is a 'problem'?

When what happened is different than what should have happened

What is a problem statement?

Concise, yet complete definition of a problem.

Why is a problem statement important?

Necessary for the investigation

Clearly identifies & describes the problem you are trying to solve

Avoids guesswork

Defining the Problem Statement

Answers the following questions:

- What is the product or process involved?
- Where was the issue discovered?
- When was the issue discovered?
- Who discovered it?
- Why is it a problem?
- How was the issue discovered?

***Focuses on the difference
between actual and
expected***

**Includes measurable
and
objective evidence**



Example

Complaints have been received indicating an issue with Pulse Oximeters.

Complaint trends indicate that there is an issue with audio failures on Pulse Oximeters.

The complaint data from XXX to XXX demonstrates a trend in audio failures related to the main PCB board, PN 56983, of the X2312 Pulse Oximeters.

2. Assess Risk

1. Patient RISK Assessment
2. Health Hazard Evaluation (HHE) to evaluate field (post market) product performance; evaluate hazards and score health hazards based on **likelihood of occurrence**, **probability of injury**, and **severity of injury**.
3. Consult with Medical Practitioner
4. Decide on **Product CONTAINMENT**

3. Root cause analysis

The identifiable factor(s), based on objective evidence, which has (have) been determined to be responsible for the nonconformity, trend, or aberrant or unexpected result.

3. Root cause analysis continued

Root cause traps

1. Equipment failure

“It just broke”

2. Human error

Procedure is inaccurate, training is current, the employee made a mistake



3. Root cause analysis continued

3. Take a Broad Investigation Perspective
 - Any similar events reported or known?
4. Complaints / NCMRs / Repairs / Trend reports
5. Evaluate IMPACT on:
 - Other lots / product already distributed
 - Other products
 - Other processes
 - Other facilities
6. Quality System
7. Other suppliers or manufacturers



3. Root cause analysis continued

8. Investigation Tools & Examples

- FTA (Fault Tree Analysis)
- Failure Mode and Effects Analysis (FMEA)
- Cause & Effect and Fishbone technique
- 5 WHYS
- 8D Approach

Fault Tree Analysis

Undesired state of a system (top event) is analyzed using Boolean logic

Visually models logical relationships between:

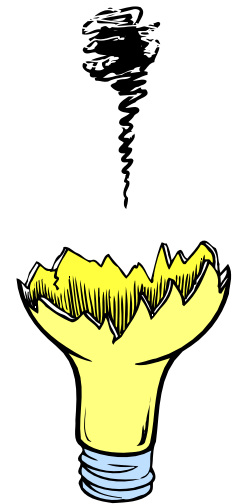
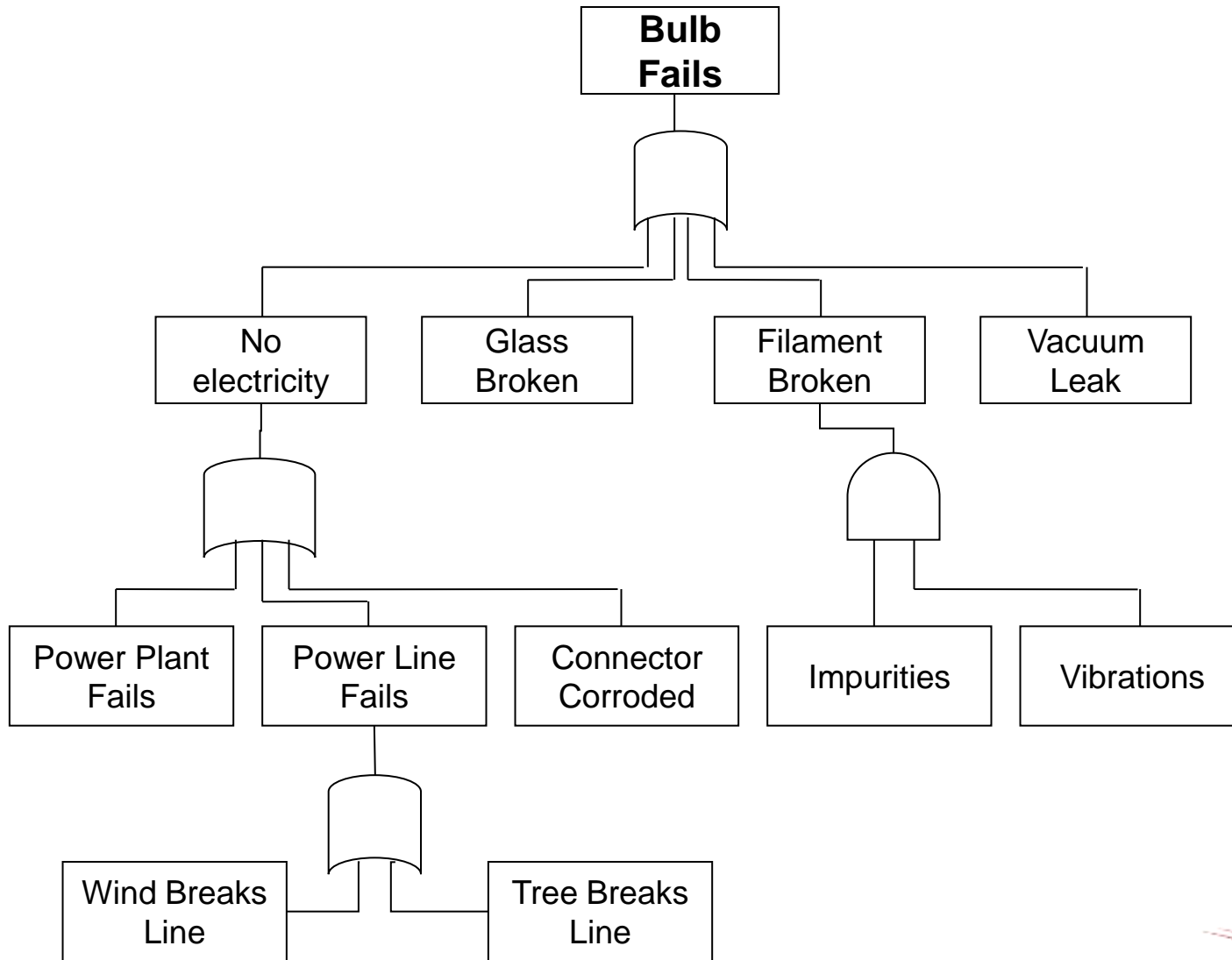
- equipment failures,
- human errors,
- and external events

Can combine to cause specific non-conformances

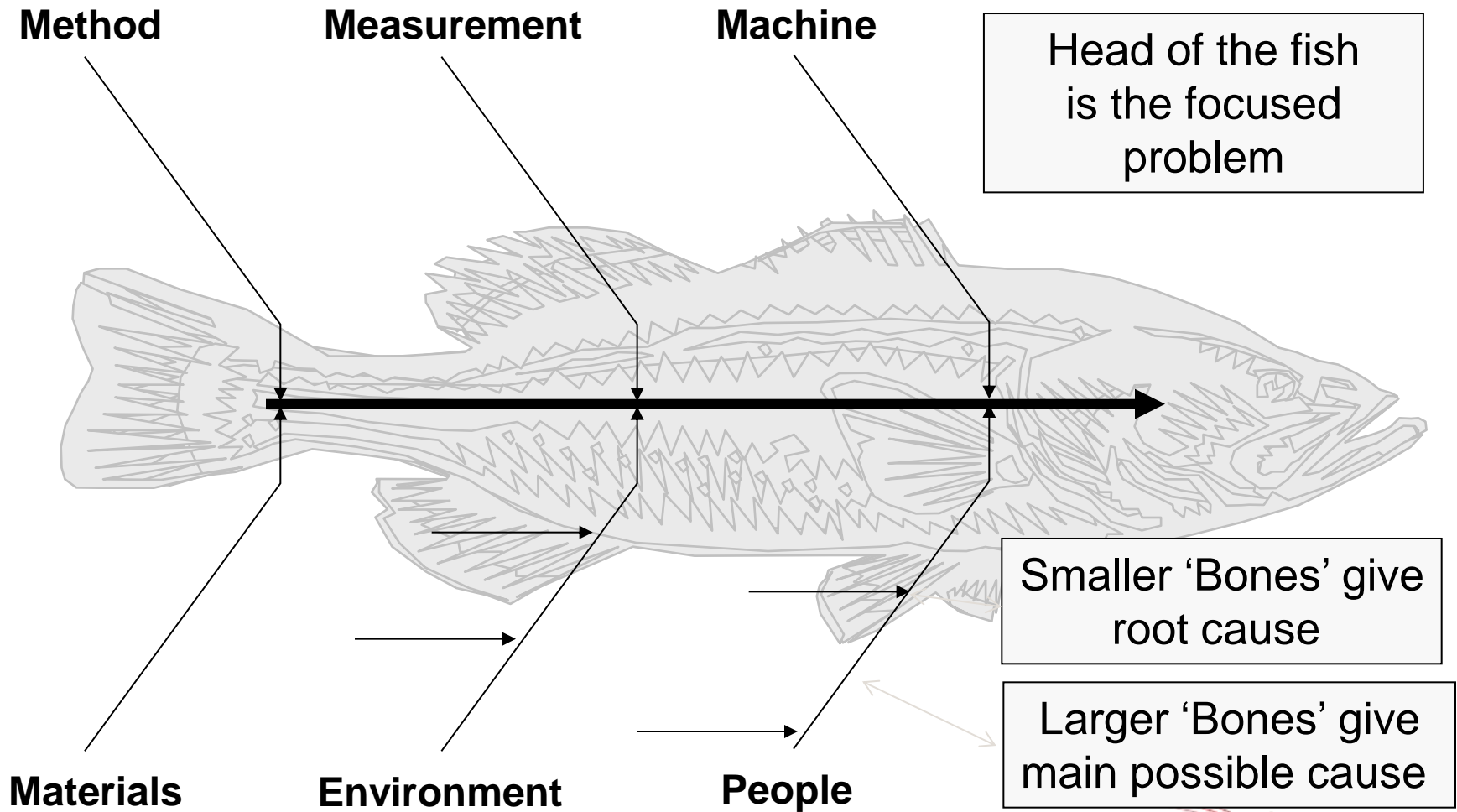
A more sophisticated form of the 5 Whys



Fault Tree Analysis (Example)



Cause and Effect Diagram (Ishikawa)



Cause and Effect Diagram (Ishikawa)

People

Ask : How the behavior of the people could have caused the problem?

Material

Ask : How the material/information used could have caused the problem?

Machine

Ask : How the machine/equipment/infrastructure used could have caused the problem?

Method

Ask : How the method/instruction used could have caused the problem?

Environment

Ask : How the operating environment could have caused the problem?

Measurement

Ask : How the measurement taken could have caused the problem?



5 Why Analysis

Ask the 5 WHY questions to find the root cause of the problem

1. Ask - Why did the problem occur
2. Ask - Why did 1 cause the problem
3. Ask - Why did 2 cause the problem
4. Ask - Why did 3 cause the problem
5. Ask - Why did 4 cause the problem

5 Why example

Problem Statement:

You are on your way home from work and your car stops in the middle of the road.

1. **Why** did your car stop?
 - Because it ran out of gas.

2. **Why** did it run out of gas?
 - Because I didn't buy any gas on my way to work.

3. **Why** didn't you buy any gas this morning?
 - Because I didn't have any money.

4. **Why** didn't you have any money?
 - Because I lost it all last night in a poker game.

5. **Why** did you lose your money in last night's poker game?
 - Because I'm not very good at "bluffing" when I don't have a good hand.



5 Why example

Problem statement:

Product X was mislabeled

1. **Why** was the product mislabeled?

- Because the wrong component was put in a tray

2. **Why** was a wrong component put in the tray?

- Because the component was left over from a previous lot

3. **Why** was a component left over from a previous lot?

- Because line clearance was not performed

4. **Why** was line clearance not performed?

- Because there is no requirement to verify line clearance activities

5. **Why** is there no requirement to verify line clearance activities?

- Because



8D Technique

- Problem-solving methodology for product and process improvement
- Structured into eight disciplines, emphasizing team synergy.
- Use Team Approach
- Describe the Problem
- Implement and Verify Short-Term Corrective Actions
- Define and Verify Root Causes
- Verify Corrective Actions
- Implement Permanent Corrective Actions
- Prevent Recurrence
- Congratulate Your Team



5. Identify & Implement CAPA

Record investigation & identify root cause

- Identify & agree actions
- Document the planned method of effectiveness for the agreed actions
- Implement actions
- Approve completion of actions
- Perform Effectiveness checks
- Evaluate & Close CAPA

Good Investigation Practices

Good Executive Summary:

- Clear & succinct Problem Statement
- Description of the depth of the problem
- Risk level assessed
- Brief chronology of significant events in the investigation
- Actions and conclusions that are supported by facts

Failure Investigation Lessons learned

- Stopping too soon in the process
- Not asking the why enough times-not getting to the true root cause
- Incomplete investigation
- Factors not considered / documented
- Associated lots not identified / evaluated
- Absence of root cause not justified
- Conclusions not supported by data



Failure Investigation Lessons learned

- Jumping to quick conclusions
- Does the investigation file contain opinions, assumptions, and guesses?
- Not having the “right” people involved
- DOCUMENTATION!



Conclusion

Ensure:

- Accurate problem statement
- Complete and documented investigation
- True root cause
- Adequate effectiveness checks



Q & A



Thank you