# Corrective and Preventive Actions

"A Five Step Approach"

Tonya White-Salters

# Topics to Be Covered

- What is CAPA?
- Governing authority
- Five steps to a good CAPA process
- Where companies have difficulty
- Example citations
- Recap…

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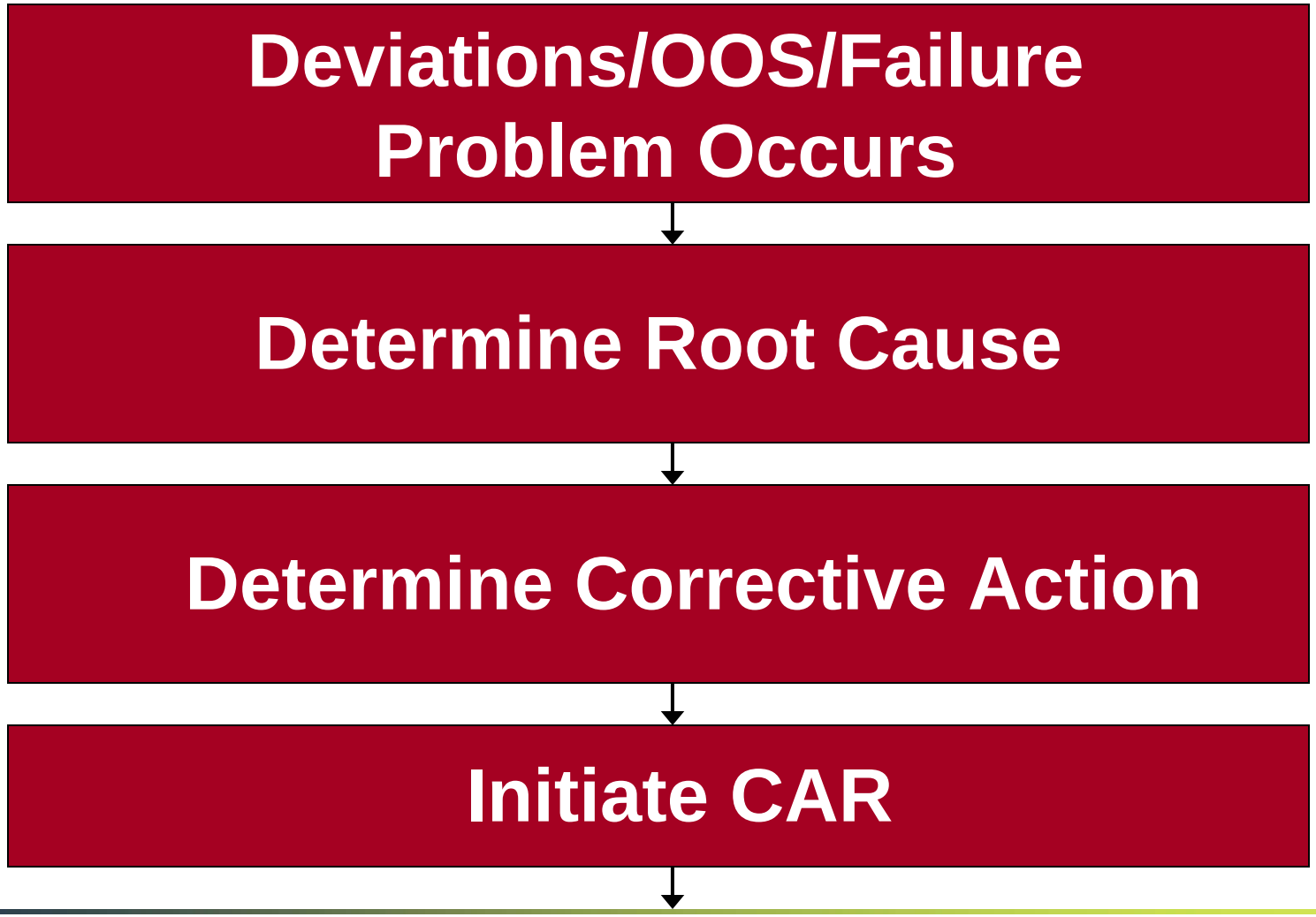
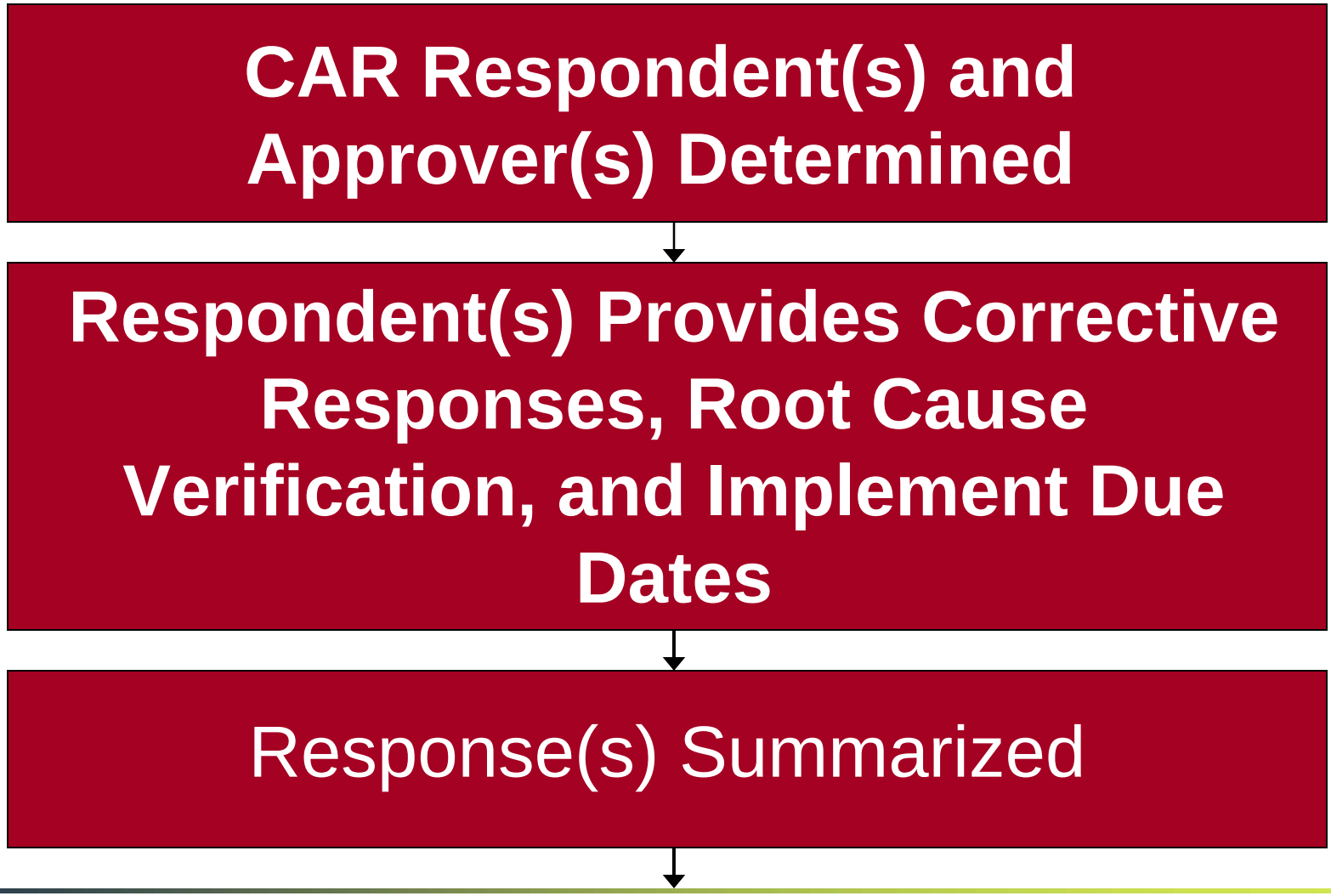
# What Is CAPA?

- Corrective Action
  - eliminate detected nonconformity
- Preventive Action
  - prevent nonconformity occurrence

# CAPA Process Map



# CAPA Process Map



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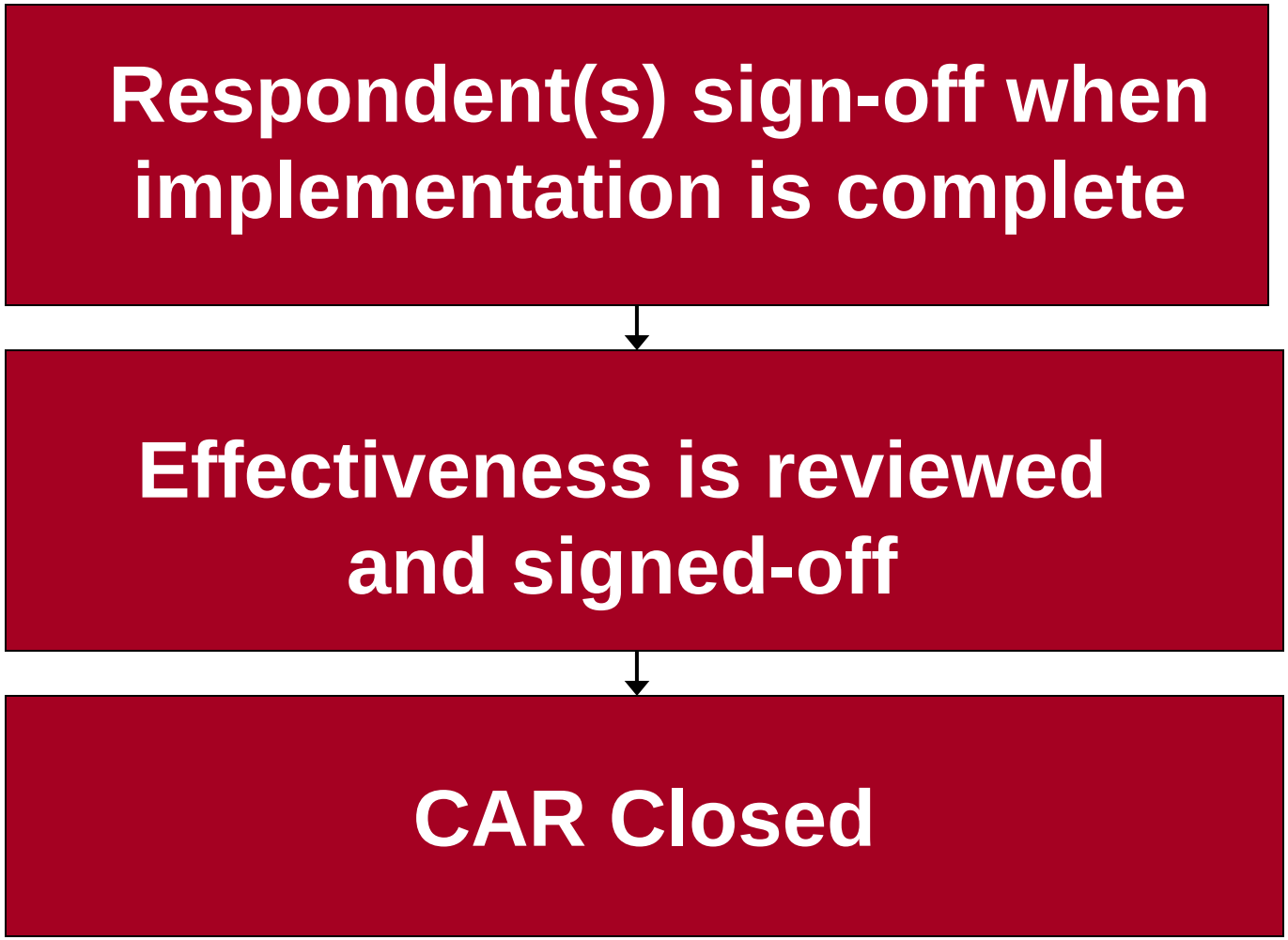


# Governing Authority, FDA CFR Part 211- Finished Pharmaceuticals

- **Subpart J – Records and Reports**

- **211.192** "Any unexplained discrepancy shall be thoroughly investigated. The investigation shall extend to other batches …that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include conclusions and follow-up."

# Governing Authority, ICH Q7A – Active Pharmaceutical Ingredients

## 6.5 - Batch Production Records

**6.53 -** "Written procedures should be established for investigating critical deviations or batch failures of intermediate or API to meet specifications. Investigations should extend to other batches."

# Governing Authority, FDA CFR Part 820 - Quality System Regulation

## Subpart J - Corrective and Preventive Action

(a) Manufacturer **shall establish procedures** for implementing **corrective and preventive action**. The procedures **shall include requirements** for:

# Governing Authority, FDA CFR Part 820 - Quality System Regulation

## Subpart J – CAPA cont.

(1) "**Analyzing processes**, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product" …"**identify** existing and potential causes of nonconforming product, or other quality problems"…"statistical methodology shall be employed to detect **recurring quality problems**"

# Governing Authority, FDA CFR Part 820 - Quality System Regulation

## Subpart J - Corrective and Preventive Action

(2) **“**Investigating the cause of nonconformities relating to product, processes, and the quality system;”

# Governing Authority, FDA CFR Part 820 - Quality System Regulation

"**Identify 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** actions are **effective**;"

# Governing Authority, FDA CFR Part 820 - Quality System Regulation

## Subpart J - Corrective and Preventive Action

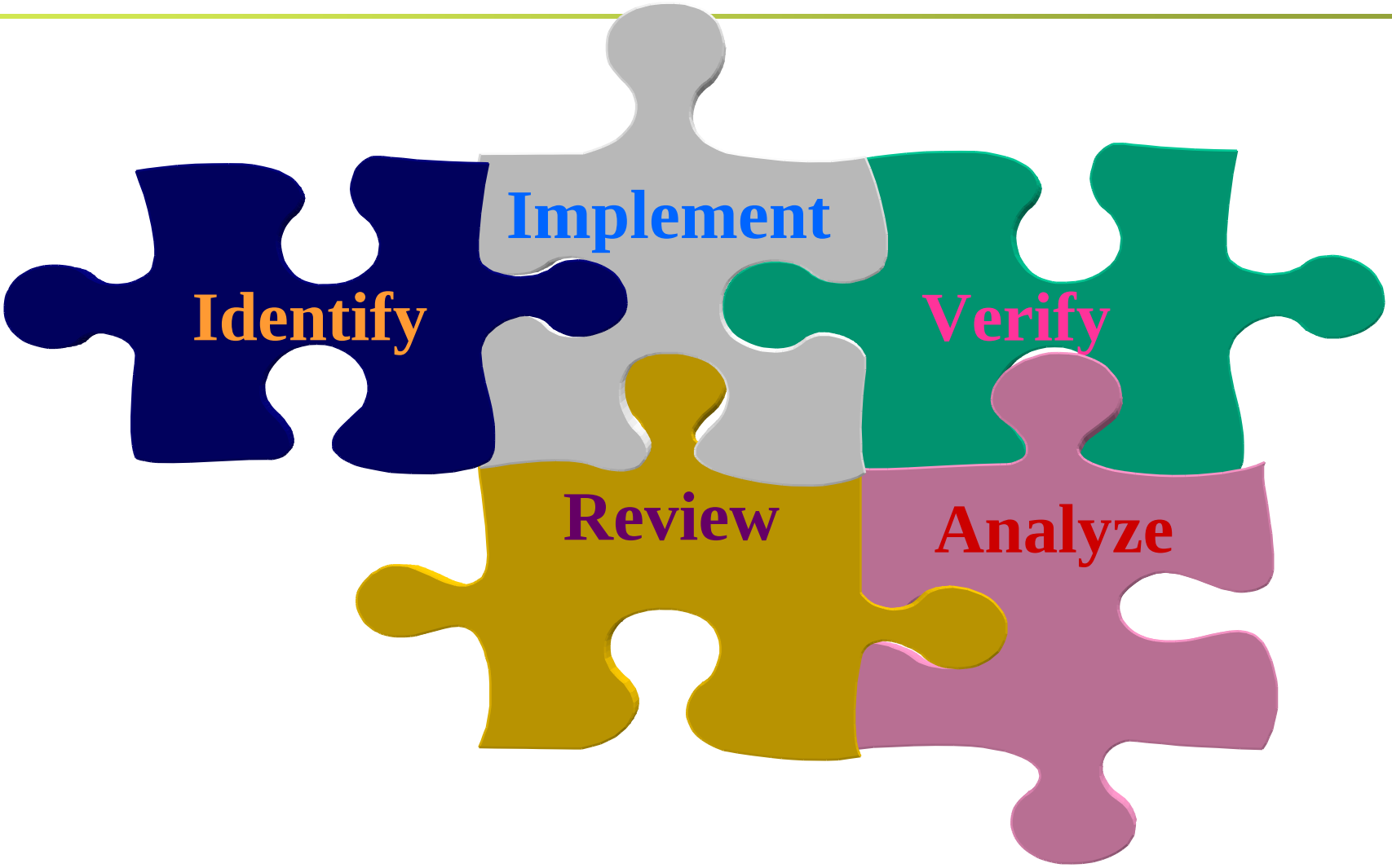
(5) "**Implement** and record changes in **methods** and procedures needed **to correct and prevent** identified **quality problems**;

# Governing Authority, FDA CFR Part 820 - Quality System Regulation

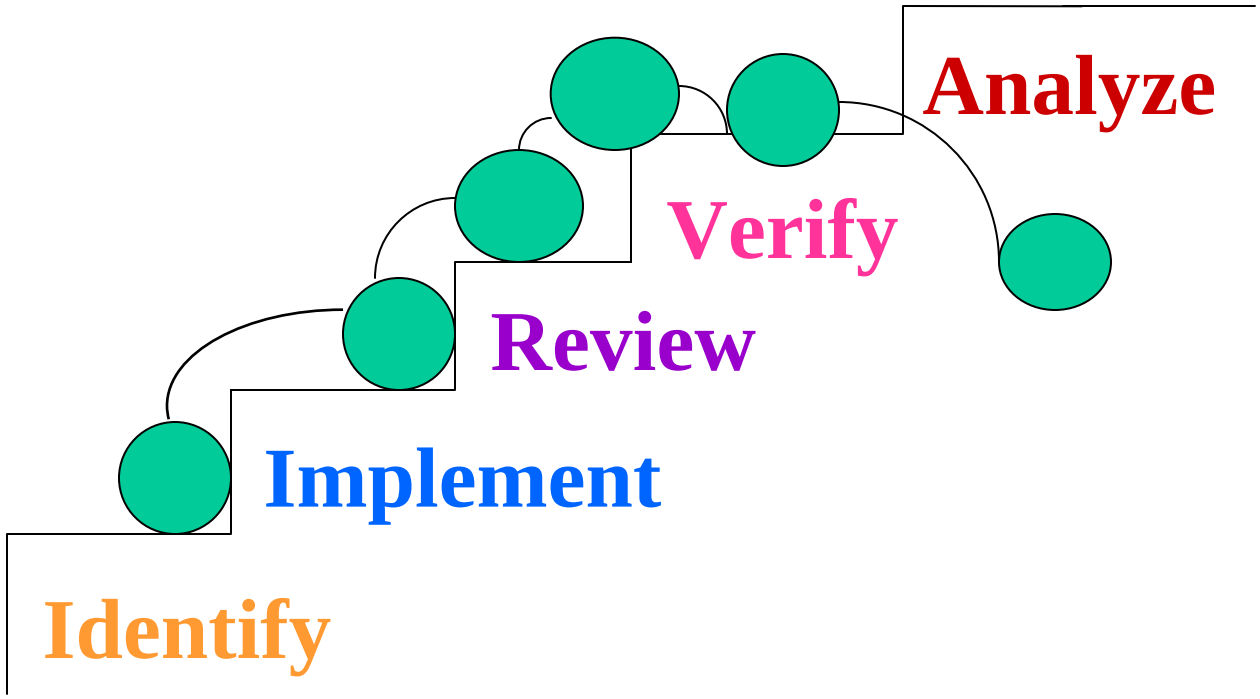
## Subpart J - Corrective and Preventive Action

(7) **Submitting** relevant **information** on corrective and preventive actions, for **management review**.

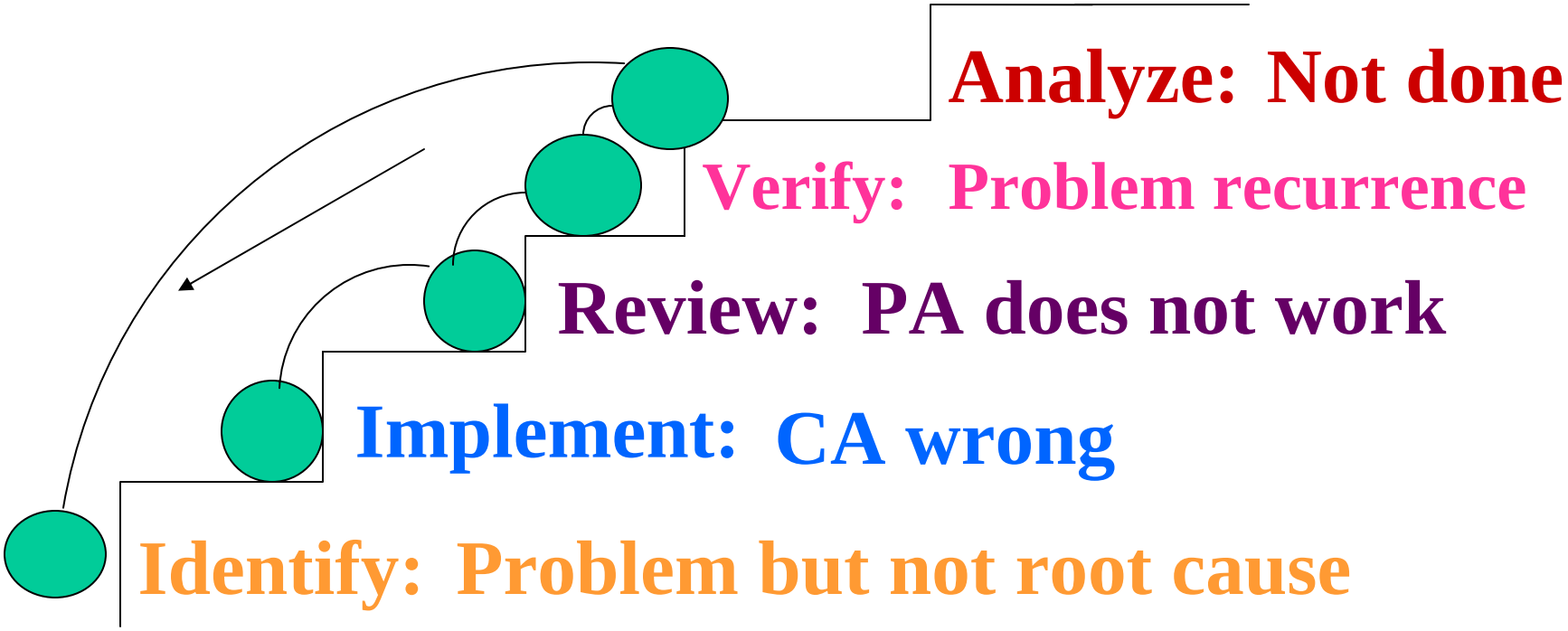
# Five Step Approach



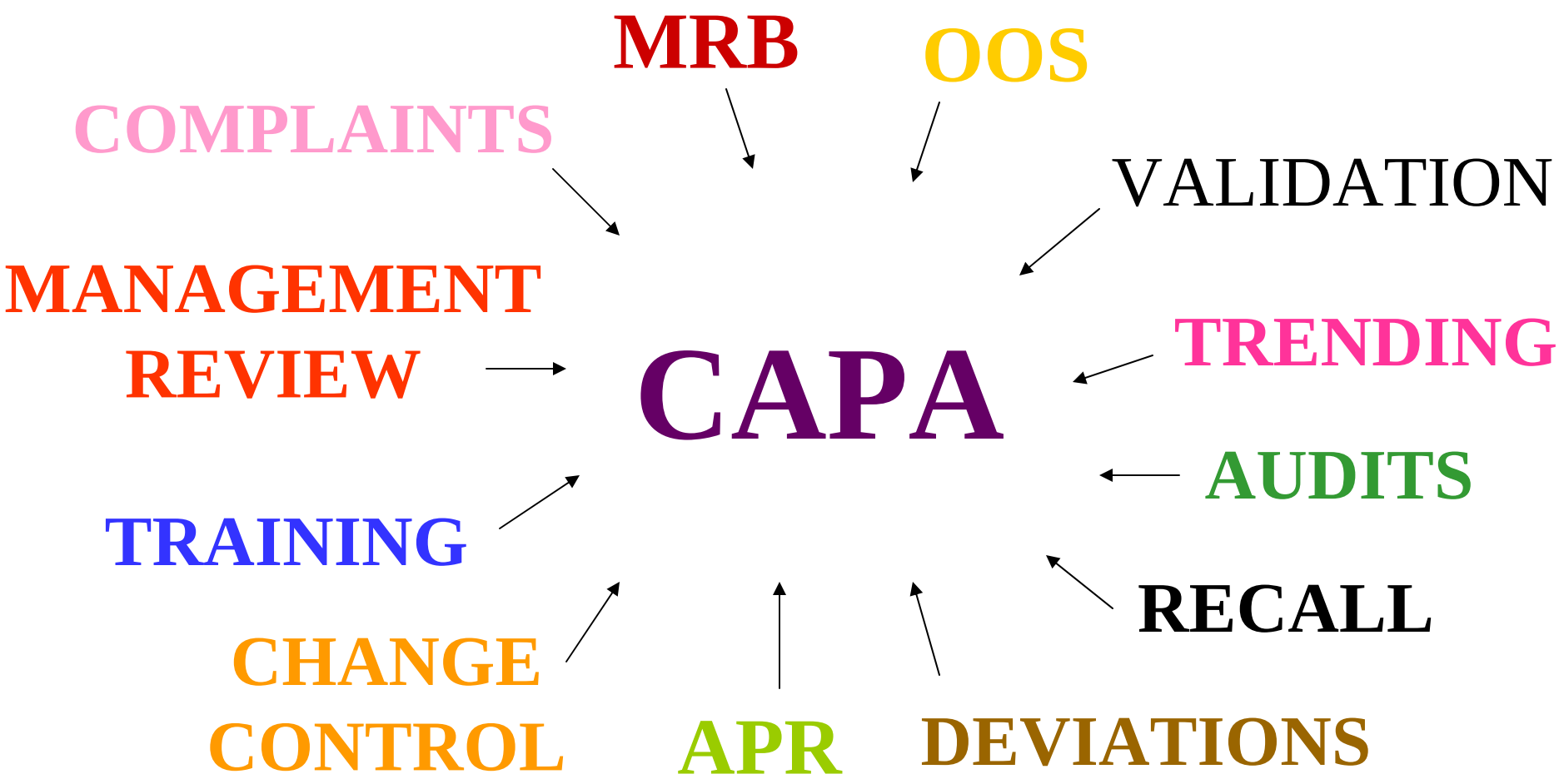
# Where Companies Have Difficulty



# Why? Incorrect Root Cause Identified!



# CAPA Subsystems



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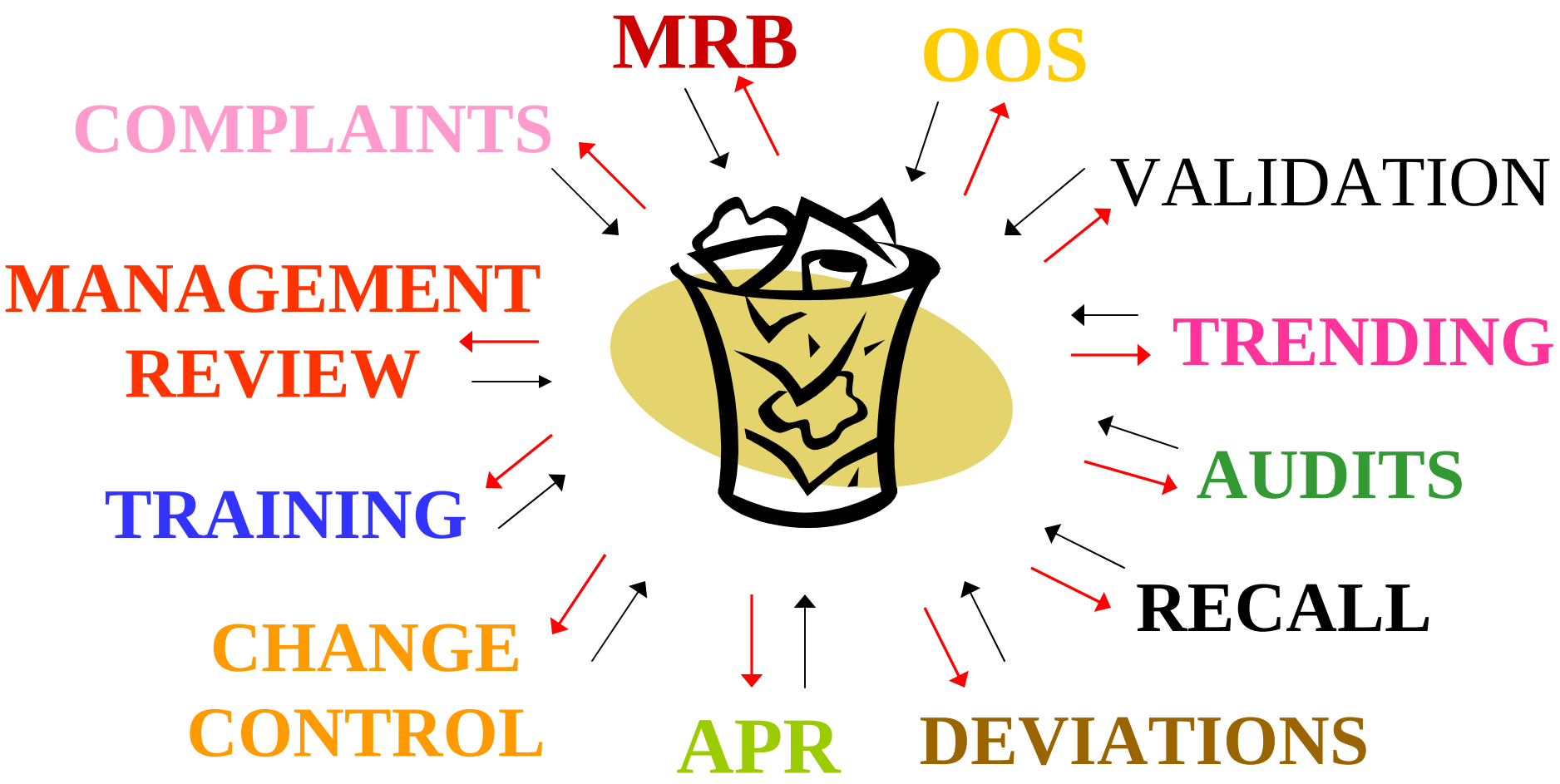

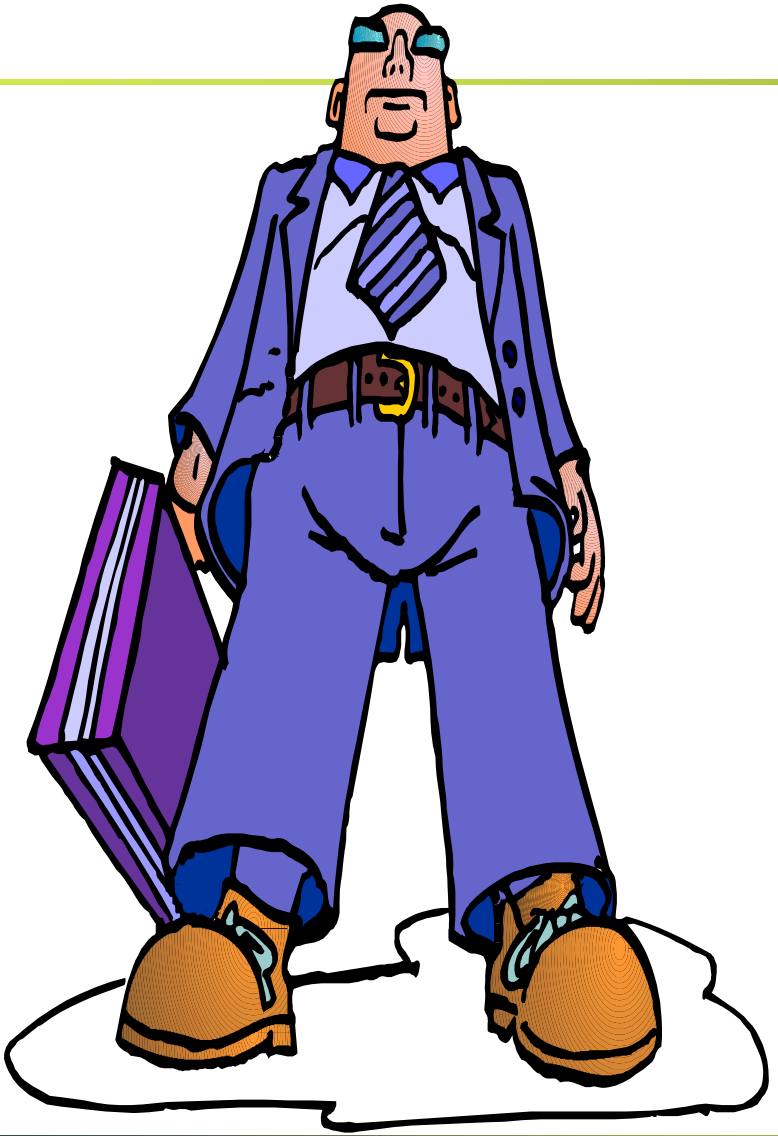

# Example Citations

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# Example Citations - CDER

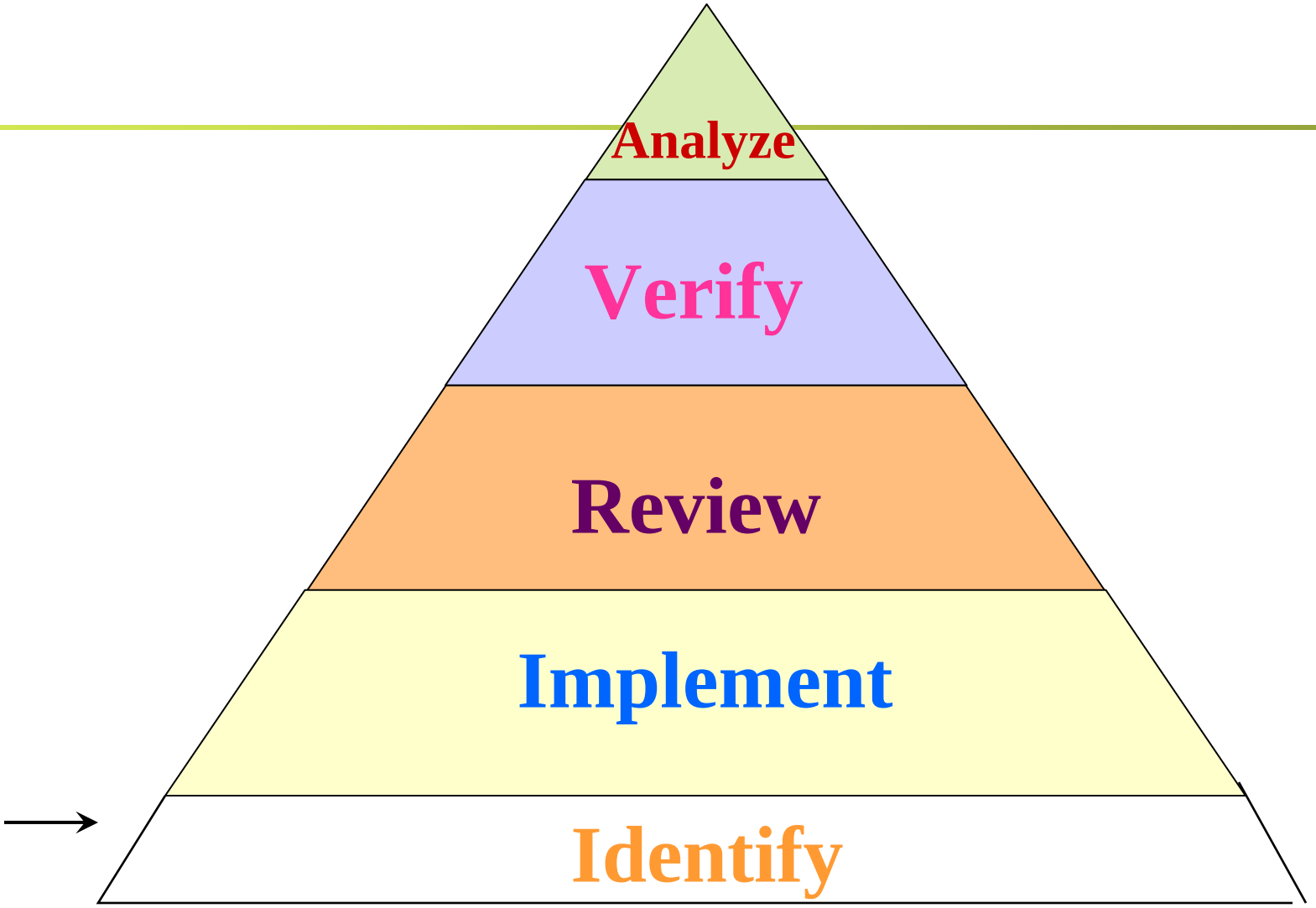
**Failure to implement corrective/preventive action or conduct a thorough investigation**

- **21 CFR 211.192**
- **21 CFR 820.100**

**Examples**

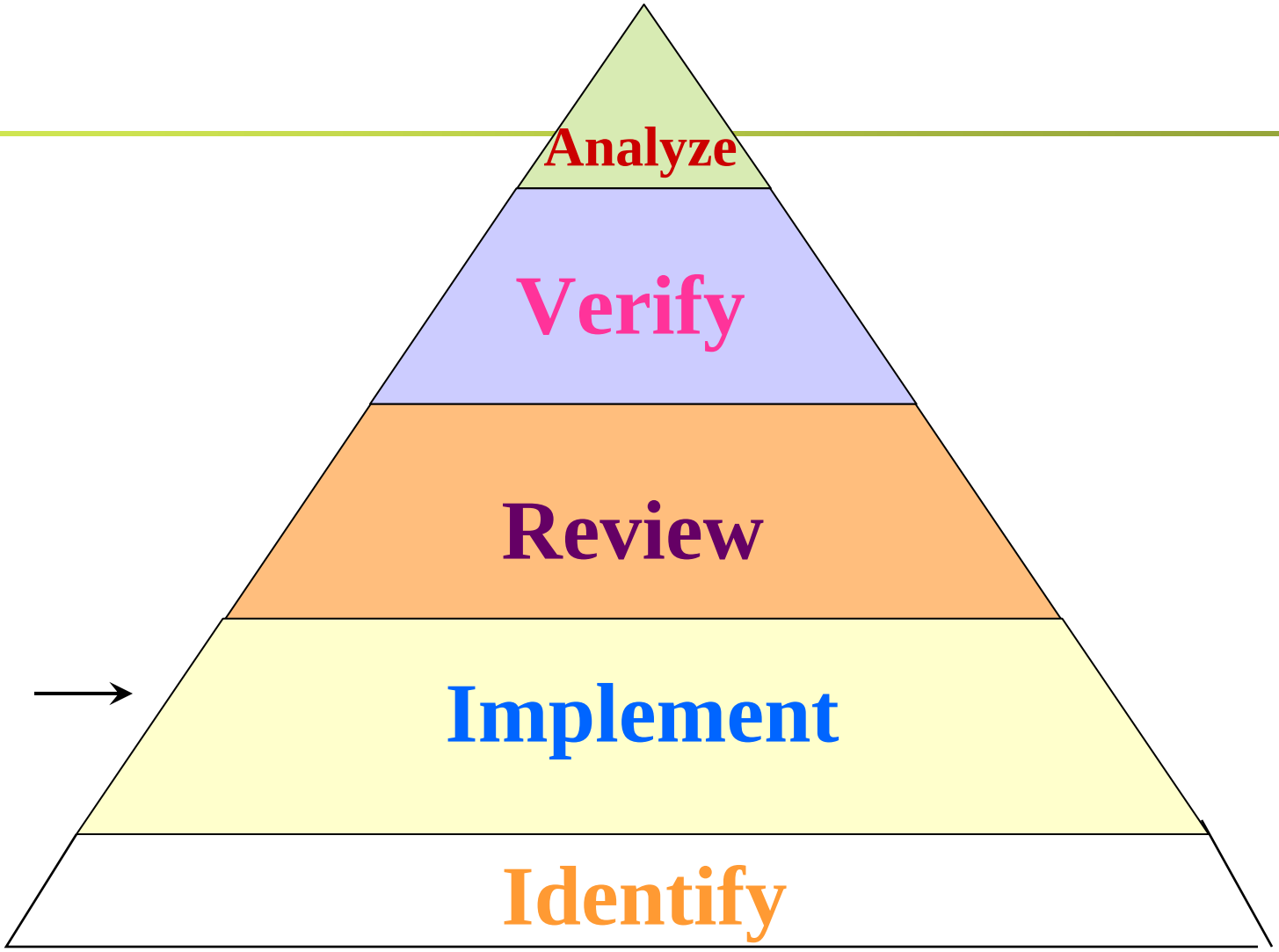
**Repeated test failures not investigated**

**Inadequate investigation of failed particulate inspection**


Analyze
Verify
Review
Implement
Identify

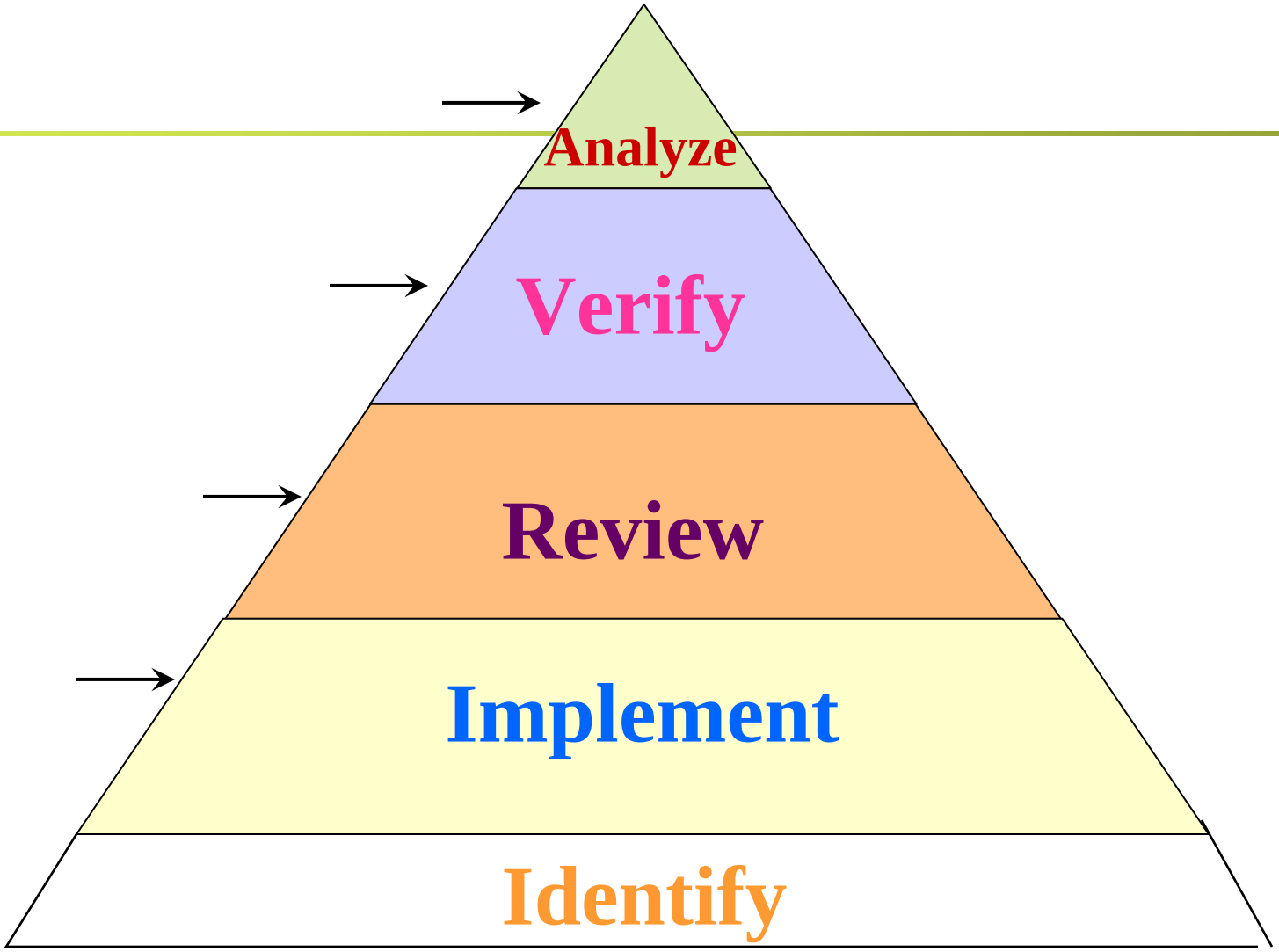
# Example Citation – CDER –Q7A

- “Failure to document corrective action regarding instrument calibration check which did not meet specification”


Analyze
Verify
Review
Implement
Identify

# Example Citation - CBER

- Failure to establish and maintain adequate procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a) and (b). For-example:
- (a) The procedure titled corrective Action Handling [redacted] was not approved and implemented to address corrective and preventive action and no established procedure was found to have been in place.


Analyze
Verify
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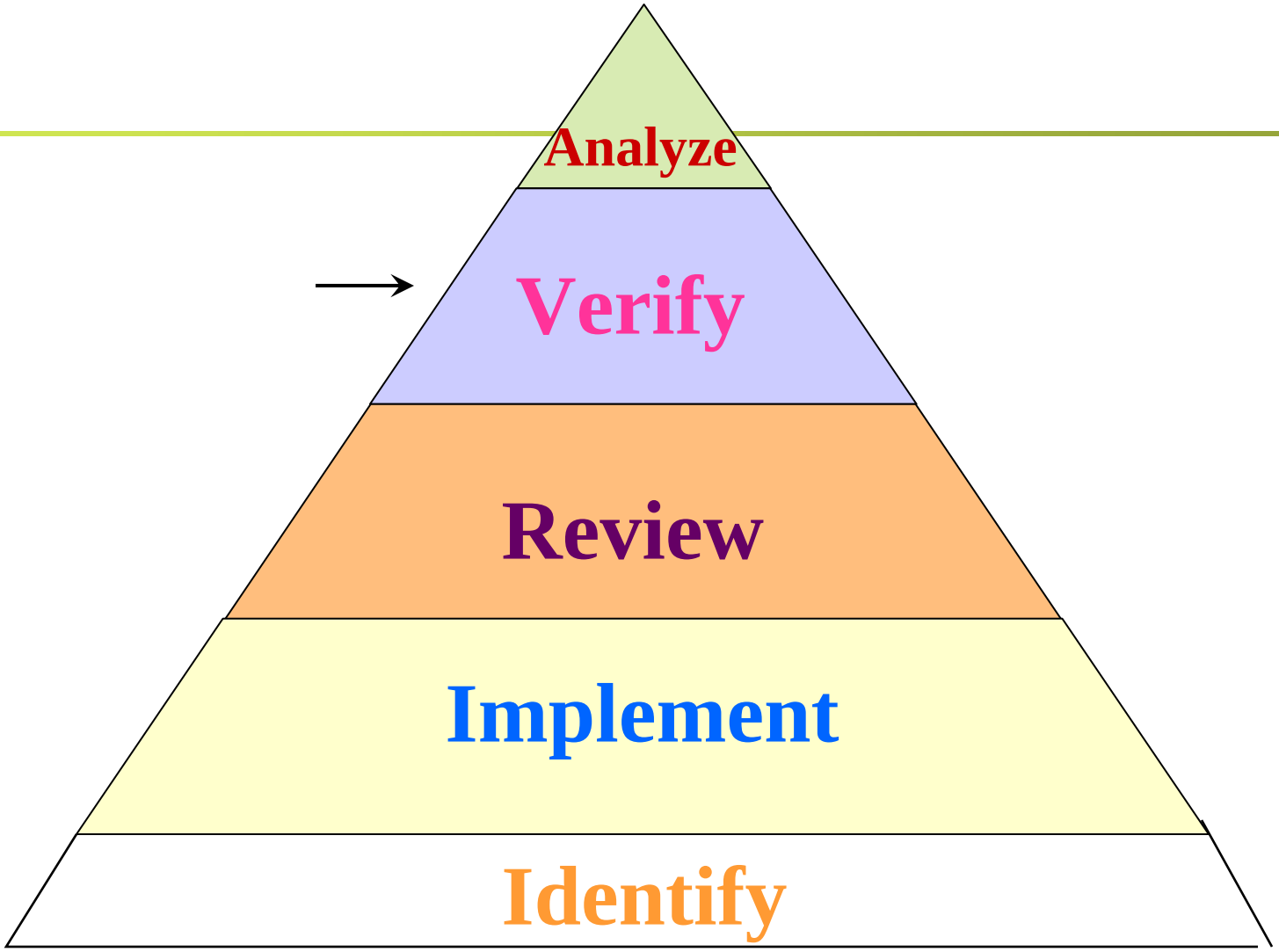
Implement
Identify

# Example Citation - CDRH

"Failure to adequately establish and maintain procedures for implementing corrective and preventive actions as required by 21 CFR 820.100(a)(1)"

Example : a. "Corrective Action Request # & # were not closed out by the QC Supervisor as required by (SOP) Corrective and Preventive Action, Rev 1; and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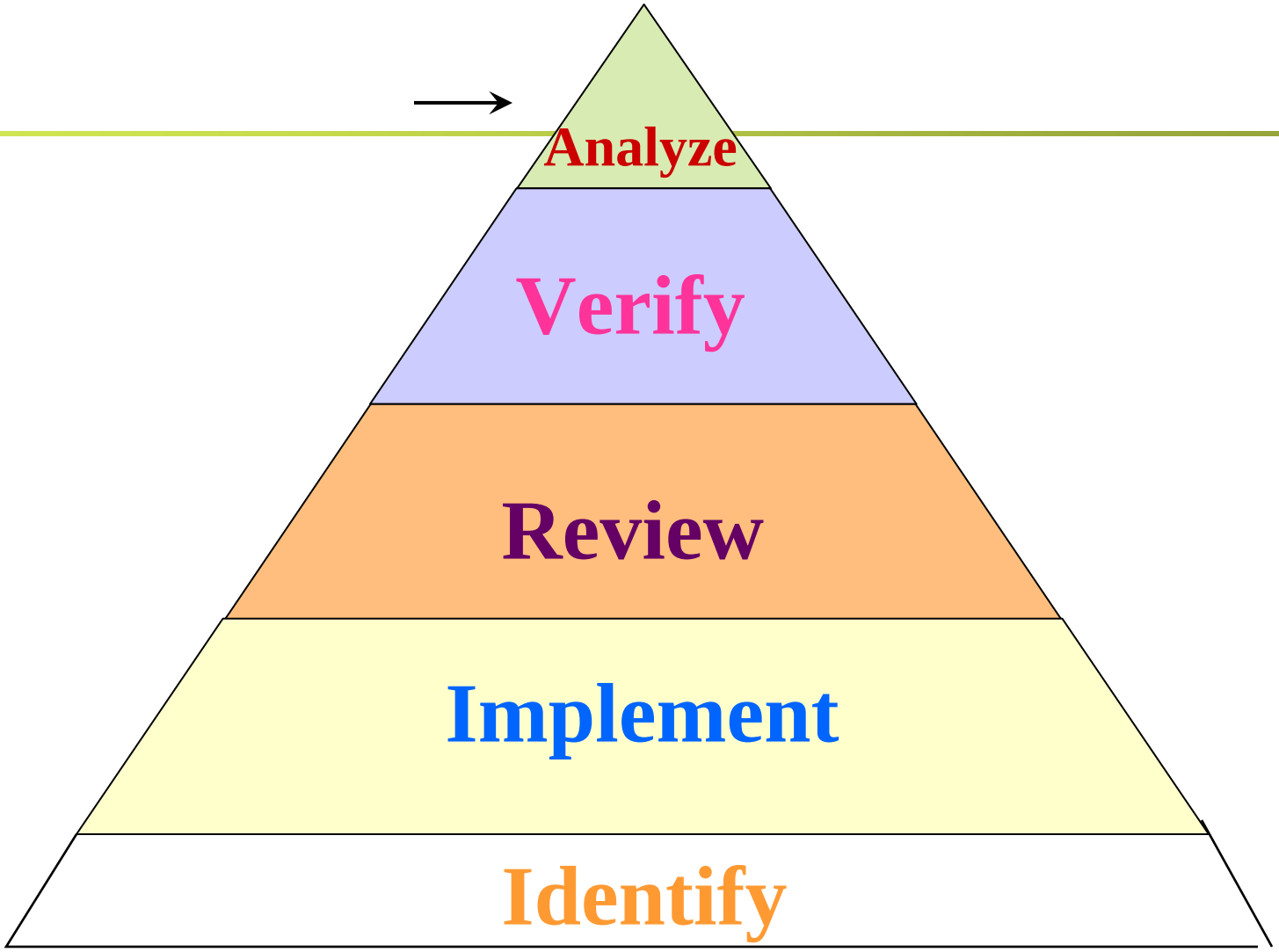
# Example Citation - CDRH

"Failure to adequately establish and maintain procedures for implementing corrective and preventive actions as required by 21 CFR 820.100(a)(1)"

Example :(b) (SOP) Corrective and Preventive Action, identifies repair reports as a source for identification of potential CAPA activities; however, repair reports are not being trended or reviewed for CAPA


Analyze
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# RECAP

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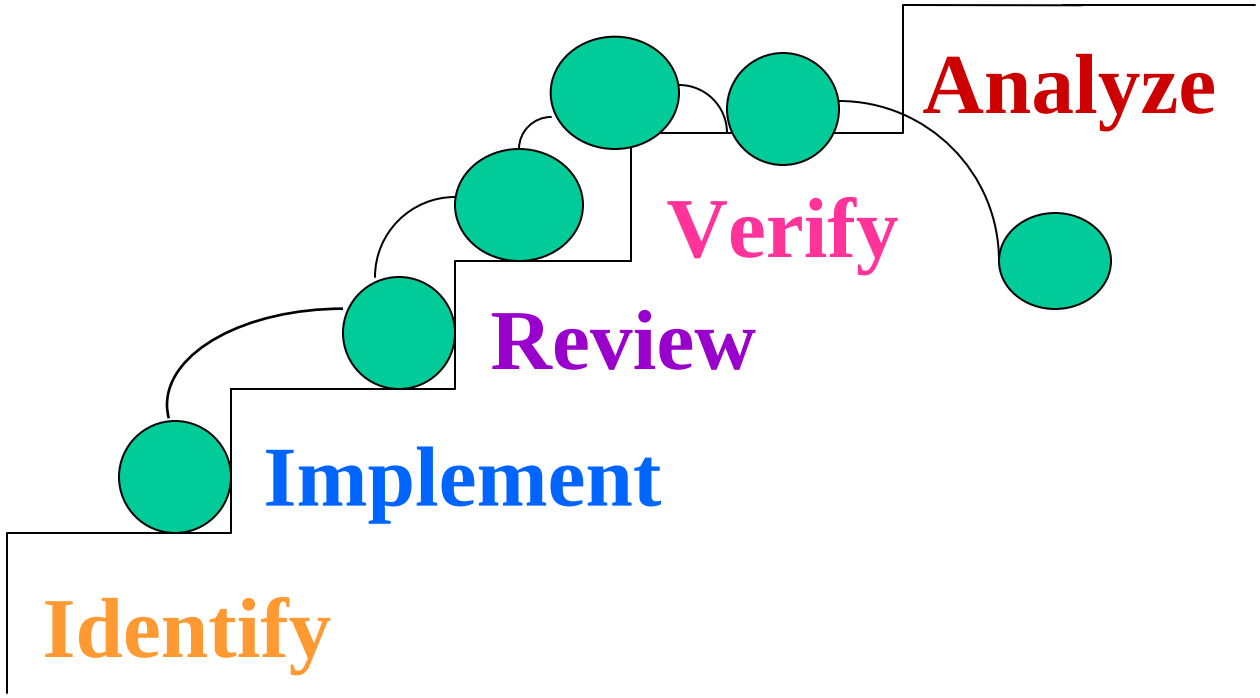
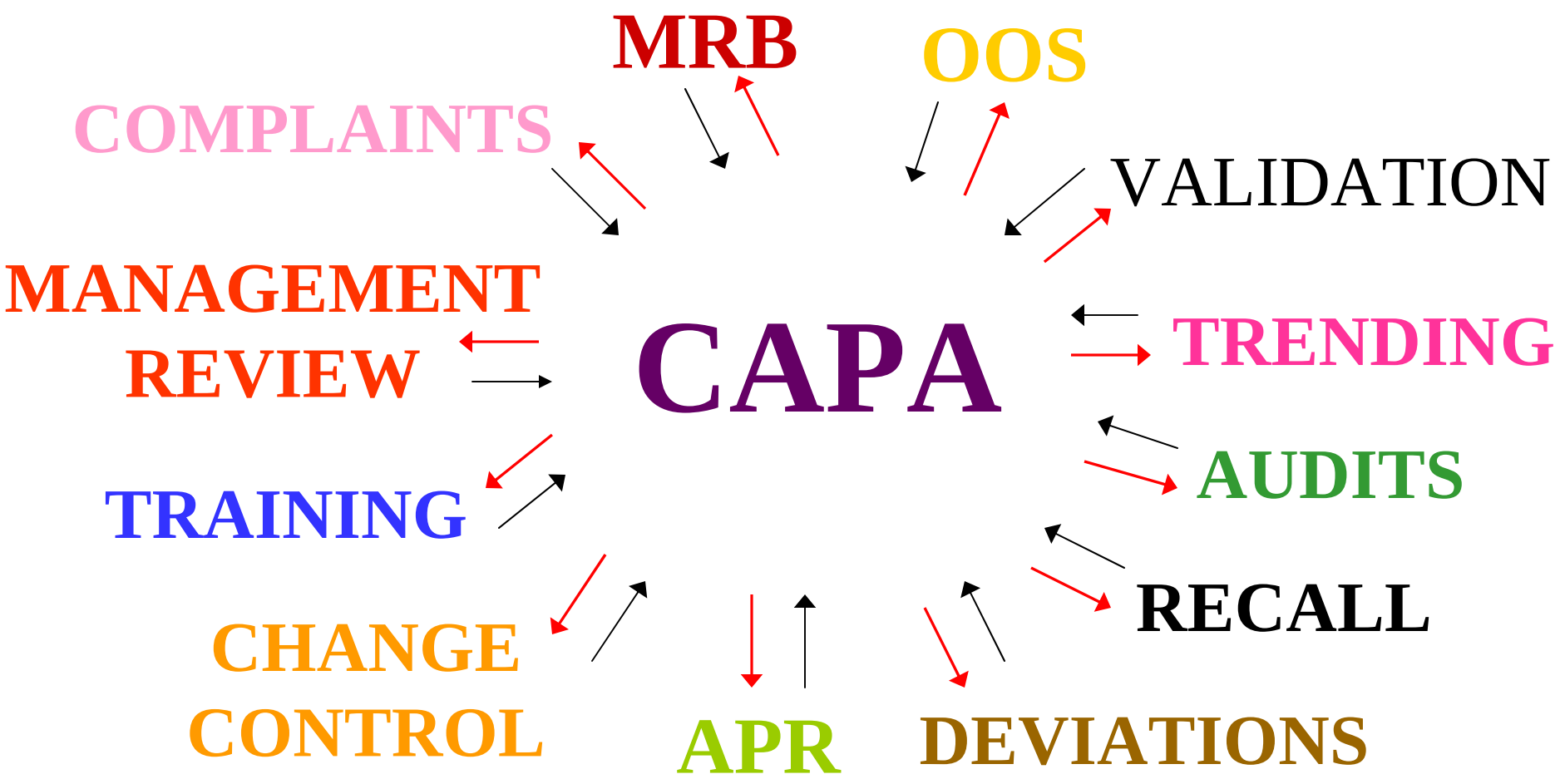
# Recap

## LACK OF ROOT CAUSE ANALYSIS



# CAPA Subsystems



# Questions?