

# 5 Steps to Successful CAPA Process



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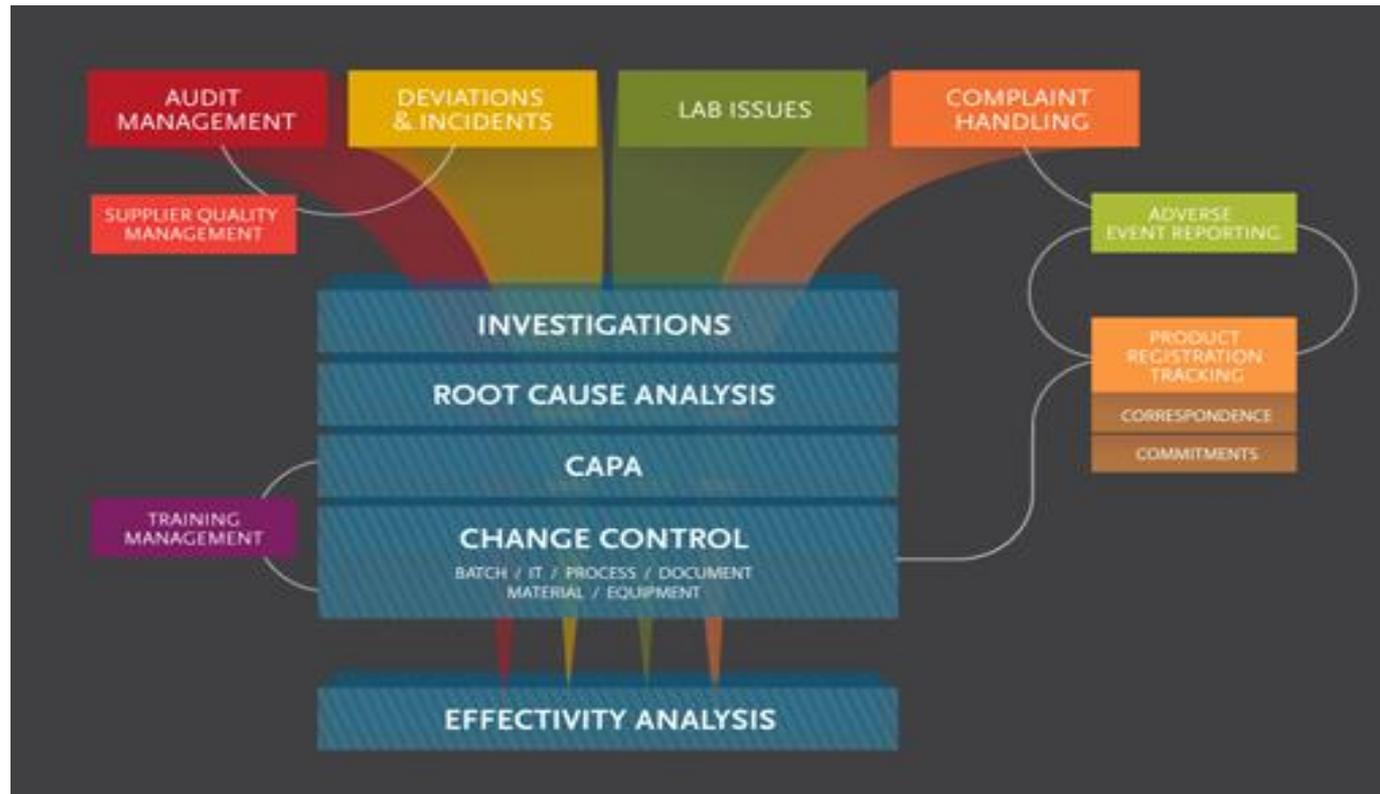
## TESTIMONIALS

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- Corrective and Preventive Action



## 5 Steps to Successful CAPA Process

# Agenda

- What is Corrective and Preventive Action
- Five Steps to a Successful CAPA Process
  - Identify
  - Implement
  - Verify
  - Review
  - Analyze
- Conclusion

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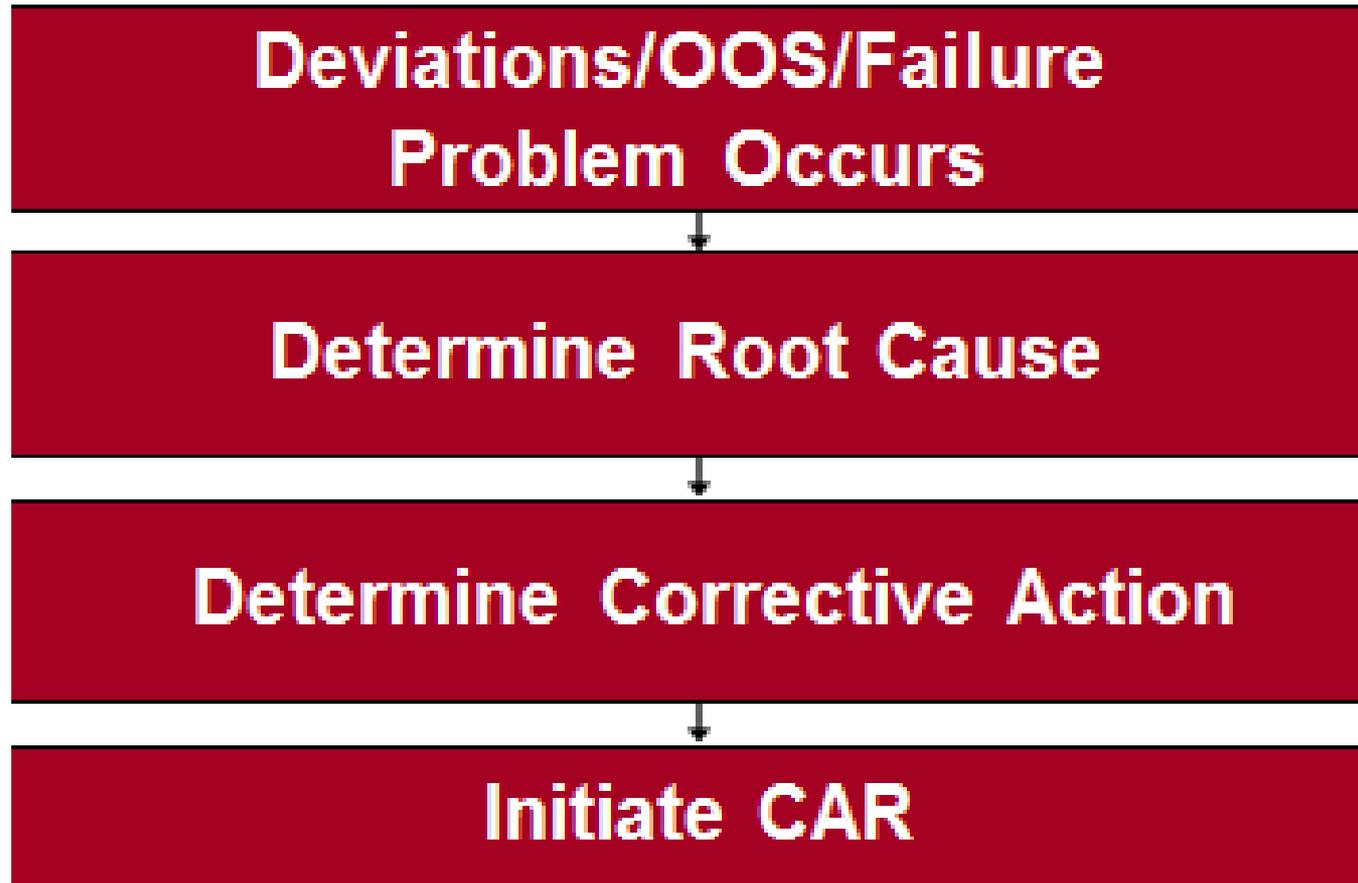


# What is CAPA

- Corrective and Preventive Action
- A concept found with **Good Manufacturing Practice (GMP)**, Corrective and Preventive Actions is comprised of two important sub-systems.
- Corrective Action addresses a nonconformance issue that has happened in the past in order to prevent its recurrence.
- Preventive Action however, focuses on preventing a discrepancy from occurring in the future.



# CAPA Process Map



# CAPA Process Map

CAR Respondent(s) and Approver(s) Determined



Respondent(s) Provides Corrective Responses, Root Cause Verification, and Implement Due Dates



Response(s) Summarized

# CAPA Process Map

**Response(s) Approved**



**Corrective Action**

**Implementation begins**  
**Respondent(s) review similar**  
**systems for Preventive Action**  
**Opportunities**  
**Effectiveness review date set**

# CAPA Process Map

Respondent(s) sign-off when implementation is complete



Effectiveness is reviewed and signed-off



CAR Closed

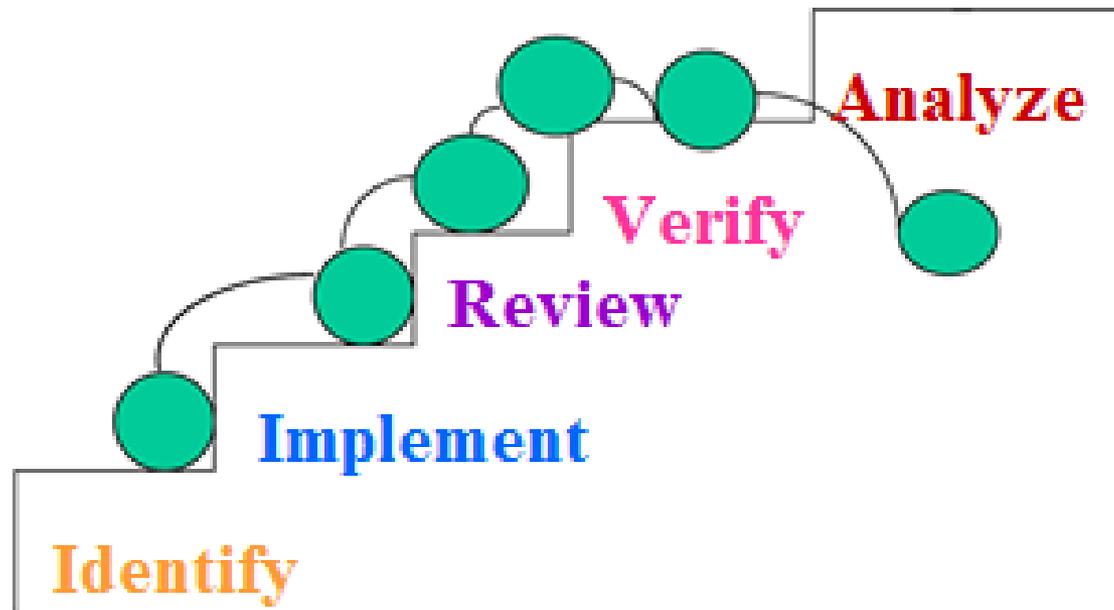
- Five Step Approach

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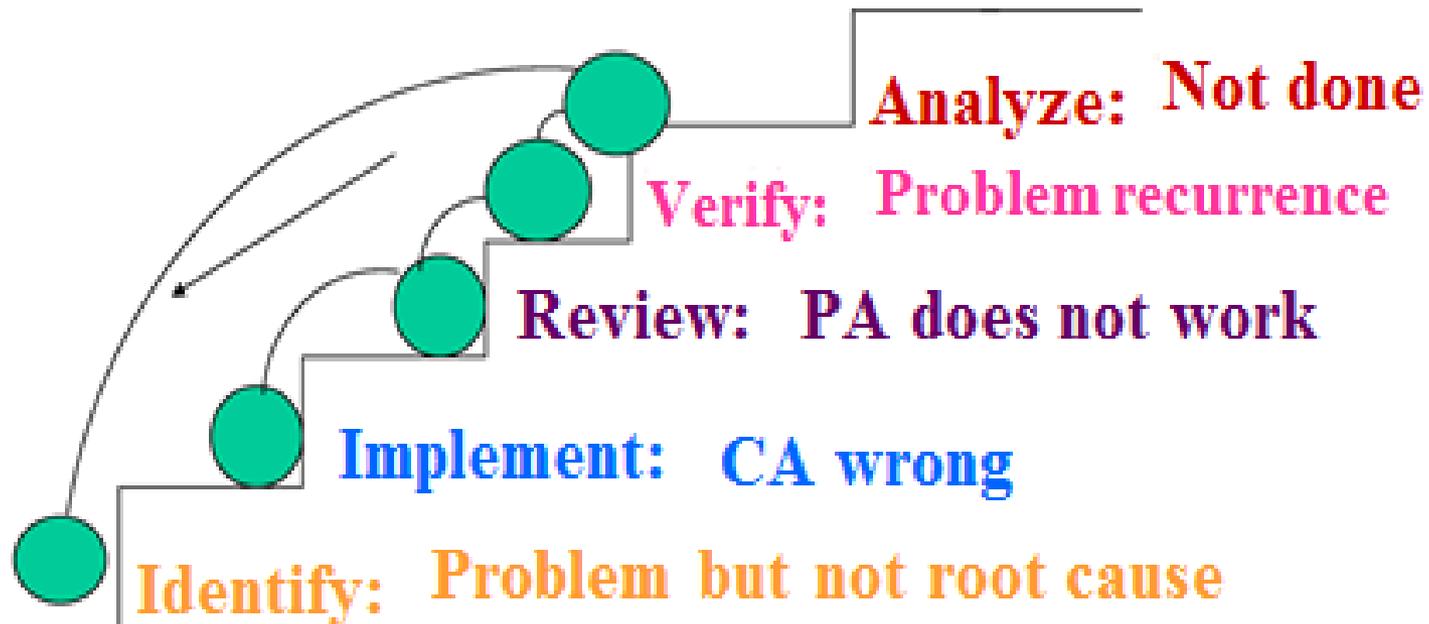


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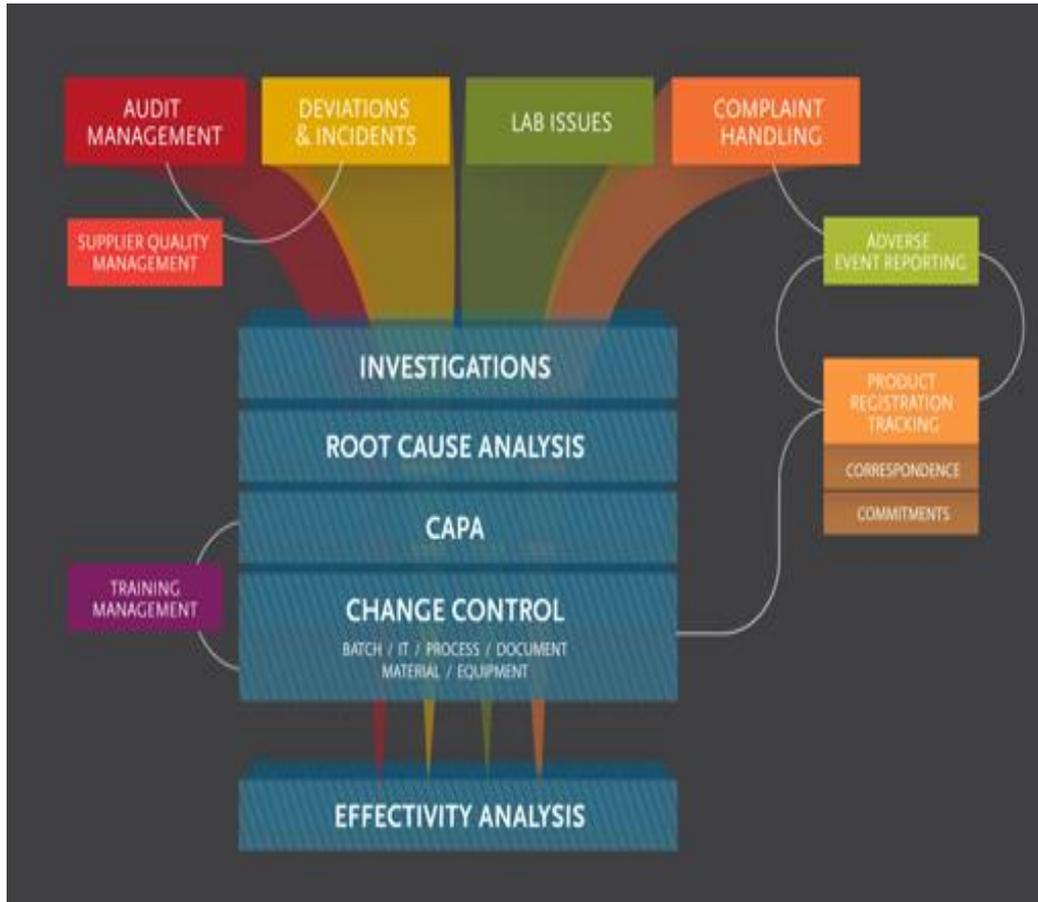
# Where Companies Have Difficulty



# Why? Incorrect Root Cause Identified!

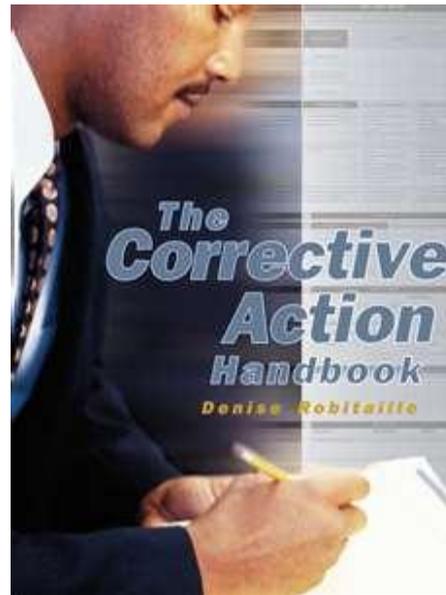


# CAPA Subsystems



More than 50% of the Warning Letters and Form 483s issued by the FDA are for CAPA violations!

# HELP ME THINK THIS THROUGH



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