5 Steps to Successful CAPA Process

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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
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

1. Deviations/OOS/Failure Problem Occurs
2. Determine Root Cause
3. Determine Corrective Action
4. Initiate CAR
CAPA Process Map

1. CAR Respondent(s) and Approver(s) Determined
2. Respondent(s) Provides Corrective Responses, Root Cause Verification, and Implement Due Dates
3. 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

1. Respondent(s) sign-off when implementation is complete
2. Effectiveness is reviewed and signed-off
3. CAR Closed
• Five Step Approach
Where Companies Have Difficulty

- Identify
- Implement
- Review
- Verify
- Analyze
Why? Incorrect Root Cause Identified!

- Identify: Problem but not root cause
- Implement: CA wrong
- Review: PA does not work
- Verify: Problem recurrence
- Analyze: Not done
More than 50% of the Warning Letters and Form 483s issued by the FDA are for CAPA violations!
HELP ME THINK THIS THROUGH

THE BUILDING BLOCKS TO BETTER BUSINESS

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TESTIMONIALS

We have confidence that Business Intelligence Solutions can deliver what our business needs. As a trusted business partner, they have deep domain experience.

Business Intelligence Solutions is an experienced company with a proven track record that created sustainable business value for our company and shareholders.

Business Intelligence Solutions is flexible, offering innovative solutions and engagement models that saved our company money. They have a proactive problem solving approach.