

Seven Steps to Creating an Effective CAPA Plan

Identification

- Define the problem. It can be a description of a potential or actual problem. If the problem has already occurred, be specific in describing the incident. Clearly state what should have occurred versus what actually occurred. Describe how this issue was uncovered.

Evaluation

- Determine the risk level of the problem. To assess risk, evaluate the probability of occurrence versus the severity of the problem. Describe the potential impact of the problem as it relates to subject safety, data integrity, protocol compliance, the University, etc.

Investigation Strategy

- Establish a written procedure for conducting an investigation of the problem. Describe the steps to be taken and who will be responsible for conducting them. Include the methods of root cause analysis to be used, such as “5-Whys”, “Fishbone/Ishikawa Diagram”, etc., interviews to conduct, and documents to review and collect. This procedure should be a systematic process such that nothing is overlooked or discounted. Outline the various areas that will be reviewed as part of this investigation. For example, personnel, equipment, supplies, written procedures, training processes, etc. should be reviewed as they relate to the problem. Describe how information gathered during the investigation will be documented.

Analysis

- Determine the root cause(s) and contributing causes of a problem by conducting a root cause analysis, such as “5-Whys”, “Fishbone/Ishikawa Diagram”, etc., as outlined in the written procedure established in the previous step. Collect evidence of these causes and document it. Remember there may be several causes to this problem.

Action Plan

- Develop a Corrective and Preventive Action (CAPA) Plan to mitigate or prevent each identified cause or contributing cause of the problem. Be specific in listing each action to be completed or implemented, who will be responsible for completing each action, and a due date for each action.

Implementation

- Allocate resources to implement each action listed in the CAPA Plan and document the implementation.

Effectiveness Check

- Verify that all actions outlined in the CAPA Plan were implemented, documented and that these corrective and preventive actions were effective in preventing the problem from occurring or recurring. Confirm and document the actions that were completed and if the problem has recurred. If the objectives of the CAPA Plan were achieved, then it is considered successful and the CAPA Plan can be closed. Document the CAPA closure.
- If the objectives of the CAPA Plan were not met or the problem has occurred or recurred, the CAPA Plan is considered ineffective and must be revised.