CAPA Summaries: Best Practice for Enhanced CAPA Compliance

Well managed Corrective and Preventive Action (CAPA) activities are essential to compliance to customer, regulatory and internal requirements.

The use of the CAPA Summary is an effective best practice in non-regulated and regulated industries alike, such as healthcare product manufacturing, outsourced services, etc. This Whitepaper will provide regulatory background and a sample CAPA Summary Template.

Investigations and CAPA Compliance Requirements

Per ISO 9001:2015, ISO 13485:2016, 21 CFR 820.100, EU PIC/S PI 002-3 and the FDA Guide to Inspections of Quality Systems (QSIT), auditors and investigators work to verify the following during audits or inspections of CAPA.

1. CAPA procedure(s) are implemented and followed.
2. Metrics and data sources are analyzed to identify existing product, service and quality issues that may require CAPA.
3. If sources of product and quality information are available to identify negative trends. Confirm data from such sources are analyzed to identify potential product, service and quality problems that may require preventive action.
4. Data received and used to support the CAPA process are complete, accurate and timely.
5. Statistical methods are employed (where necessary) to detect recurring quality issues. It is also important to determine if analyses is performed across different data sources to identify and understand the extent of product, service and quality issues.
6. Assure investigation procedures are followed and are balanced with the significance and risk of the issue. Verify that investigations are conducted to determine root cause (where possible). Confirm controls to prevent distribution of nonconforming product and / or service failures.
7. Determine if appropriate actions have been taken for significant product, service and quality problems identified from data sources.

8. Determine if CAPA actions are verified and/or validated for effectiveness before implementation.
9. Verify that CAPA for product, quality or service issues were implemented, documented and can be appropriately measured.
10. Determine if information about nonconforming product, service failures, quality issues and CAPA has been disseminated within the organization, including communication through management review.

Investigations and CAPA Implementation Recommendations

Based on regulatory expectations and best practices, the CAPA Summary is maintained to provide clear and concise summaries of Investigations and CAPAs. Below you will find considerations for your process for CAPA Summaries:

1. Investigation owners should be procedurally required to assure status of Investigations and CAPA activities are summarized and maintained up to date.
2. As most corporations use enterprise wide systems, the standardization of database fields to consistently produce CAPA Summary reports and information.
3. Monthly reviews should be held by the CAPA SME with Investigation and CAPA owners to provide awareness of investigation and CAPA age, to assess forward progress and provide records of review.
4. Target time frames for CAPA Summary updates should also be established in procedures.
5. The CAPA SME should also establish section-by section guidelines for CAPA Summary updates to set clear expectations for consistency of update.

Overall, implementation of CAPA Summaries helps provide organizations more consistent presentation, demonstrates evidence and true measurement of forward progress on Investigations and CAPA activities.

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CAPA SUMMARY- SAMPLE

Report Log#:_____ Stage: Effectiveness

Initiator / Owner:	**Investigation or CAPA Title:**	**Date**: xx/xx/xxxx

1. CAPA Description (Reference Form(s) xxxx, xxxx, xxxx)

Original NC Information:

Failure to investigate root cause(s), establish containment, and implement corrective and/or preventive actions related to trends of failures.

Source: Example: January 201x Audit Observation

2. Problem Statement (*Based on CAPA Description and initial information received).Who: Investigator was notified via xxx.*

What:	*Investigator noted that xxxx had not been established*
When:	*On January x, xxxx was noted as "not present"*
Where:	*Timbuktu, xxxx, Inc., xxxx*
How Often:	*Frequent, Systemic, etc. How often foes the occurrence occur? Are there patterns?*
How Large:	*What is scope of the problem? How many affected products, services, customers, processes, etc.?*
Impact:	*What are the consequences and overall impact of the issue or occurrence?*

3. CAPA Data Sources

Information: xxxxx, xxxxx, xxxxx

4. Affected Product, Service, Process and /or Containment

Affected Product Service or Process: *Containment:* xxxxxxxxxx ,xxxxxxxxx, xxxxxxxxx

As part of the xxxx xxxx remediation Plan, historical records received between 01/01/xxxx and 10/06/xxxx were reviewed.

5. Risk Assessment

Risk Level: *High Compliance Risk; Potentially High Product Risk.*

6. Investigation Plan

Interviewed personnel involved with Investigations. Reviewed current practice, assessed existing procedures and regulatory requirements to look for gaps.

7. Investigation Results

Root Cause Summary 1 - Cause for Occurrence:

There were inadequate procedures, resources and understanding regarding the receipt, documentation, evaluation, investigation and maintenance of XXXXXXXXX records.

Root Cause Summary 2 – Cause for Control System Failure: There was a lack of definition and training on the xxxxx process.

No trending or aging was being performed on xxxxxxx to evaluate impact of the xxxxxxx and facilitate the appropriate prioritization / investigation of xxxxxxxx.

8. CAPA Action Plan, Implementation and Effectiveness Monitoring

To build a compliant and sustainable process for xxxx, a multi-disciplinary team was formed including xxxx, xxxx, xxxx, xxxx and xxxx. As an example, the investigation team has managed its activities in the following manner…

- Phase I – Develop sustainable procedures
- Phase II – Evaluate trending and investigation procedures
- Phase III - Refine, trending, coding and implement electronic solution(s)

9. CAPA Verification Summary:

Action or Effectiveness	Objective Evidence	Completion Date
Action Description: *Develop SOPs and Forms*		
Completed Action: *Approved documents*		xx/xx/xxxx
Implementation Plan:		
Completed Actions: *Implemented SOPs/ Training*		xx/xx/xxxx
Effectiveness Plan: *Develop Verification Process*		
Effectiveness Summary: *Complete Effectiveness Verification*		xx/xx/xxxx

10. *CAPA Summary Approvals*

11. *References*

Whitepaper Bibliography / References:

FDIS ISO 9001:2015 – Section 10 Continuous Improvement
ISO 13485:2016- Section 8 – Measurement Analysis and Improvement
FDA QSIT Guide 1999 – Guide to Inspections of Quality Systems
FDA Compliance Policy Guide 7382-845
21 CFR 820.100 –Corrective and Preventive Action
PIC/S PI 002-3 – Recommendation on Quality System Requirements for Pharmaceutical Inspectorates

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