QUALITY EVENTS BEST PRACTICES

Quality Events are issues or documented events which did not meet compliance standards.

BEGIN BY..

Initiating the event as soon as possible. The person directly involved or who received the quality event information should write the event.

WHAT ARE THE COMPONENTS OF AN INVESTIGATION?

SCOPE

Why is the event an investigation?

What did we deviate from?

How was the event identified?

Who identified the event?

Were there any other areas, customers, etc. impacted?

ROOT CAUSE

Evaluate all possible causes which lead to the quality event.

Factors include:

Training

Procedures

Processes

Materials

Who/What is under investigation?

What is the level of involvement?

Not a cause

Contributing factor

Root cause

IMPACT

Compliance with regulations
SOPs
Training
Validation Documentation

IMPACT ASSESSMENT

To maintain a Validated State, ask yourself, Are the requirements met?
Use the table below to assess.

	Yes	No
Project Documentation (Project Plan, etc.)	☐	☐
Risk Assessment	☐	☐
Vendor Qualification	☐	☐
Validation Documentation	☐	☐
Test Plan	☐	☐
Training	☐	☐
Operational Qualification	☐	☐
Performance Qualification	☐	☐
System SOPs and Guidelines	☐	☐
User Manuals	☐	☐

ACTIONS

Actions address the root cause, and contributing factors support eliminating the possibility of this issue occurring again.

EFFECTIVE CHECK

Effectiveness checks confirm the actions taken resolved the issue. An effectiveness check may take 30 or more days of observation to ensure resolved entirely.

KEEP IN MIND TO...

KNOW THE SOP
What was supposed to happen per the SOP?
What did happen?

JUST STATE THE FACTS
Write a statement of the pertinent details only.

ENSURE TICKET IS IN LOGICAL ORDER
1
2
3

LIMIT THE IMPACT
What was supposed to happen per the SOP?
What did happen?

DETERMINE CONTAINMENT VS. CORRECTIVE ACTION
Do your actions contain the issue until a solution?
Do your actions mitigate or resolve?