PRACTICAL GMP TOOL

CAPA Effectiveness Check Planner

Define success before implementation. Collect evidence that tests the outcome. Make a defensible closure decision.

USE THIS PLANNER TO

01	02	03	04
Link actions to verified causes	Set outcome-based criteria	Choose a justified review period	Record the closure decision

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Version 1.0 | September 2026
pharmaopsacademy.com

HOW TO USE THE PLANNER

Plan the effectiveness check before closing implementation

Action completion answers whether the approved tasks were performed. An effectiveness check answers whether those tasks controlled the cause and delivered the intended quality outcome. Complete Sections 1-5 when the CAPA plan is approved. Complete Sections 6-8 after sufficient evidence has accumulated.

Stage	Purpose	Minimum output
1. Frame	Restate the problem, scope and supported causes.	Clear connection between failure, cause and risk.
2. Design	Define expected outcomes, indicators and acceptance criteria.	Criteria written before results are known.
3. Sample	Choose representative data and a meaningful review period.	Enough process opportunities to challenge the control.
4. Implement	Confirm actions are complete and the observation period may begin.	Approved start date and baseline.
5. Decide	Evaluate all results, unintended effects and residual risk.	Effective, partially effective, ineffective or inconclusive decision.

Good planning questions

- What observable change should occur if the action works?
- Which measure is closest to the original failure mechanism?
- How many batches, records, shifts or challenges are needed?
- What failure would require immediate escalation?
- Could the action create a new risk elsewhere?

Do not use this tool as a substitute for investigation, risk assessment, change control, validation or approved site procedures.

SECTION 1

Problem, causes and intended control

CAPA / investigation reference

Problem statement
State what happened, where, when, extent and expected requirement.

Affected and potentially affected scope
Products, batches, systems, equipment, departments, sites or time period.

Verified direct cause(s)

Contributing and systemic cause(s)

Patient, product, compliance and business risk

SECTION 2

Map each action to its intended outcome

Every material action should address a supported cause or reduce a defined risk. Add rows if required.

CAPA action	Cause or risk addressed	Expected observable outcome	Owner / due date

Why these actions are expected to work
Summarise the scientific, technical or process rationale.

Potential unintended effects
Identify related indicators that must not worsen.

SECTION 3

Predefine effectiveness criteria

Use direct performance evidence where possible. Training completion, procedure approval and equipment installation are implementation evidence, not proof of effectiveness.

Indicator	Baseline	Acceptance criterion	Data source / reviewer
Recurrence or failure measure			
Process / product performance			
Correct-practice observation			
Related adverse indicator			
Other risk-based measure			

Critical failure / early escalation rule
Define any single result that requires containment, impact assessment or reopening before the review period ends.

Decision rule
State what will constitute effective, partially effective, ineffective or inconclusive.

SECTION 4

Population, sample and review period

Population to be assessed
Define eligible batches, records, events, products, shifts, users, equipment or sites.

Sampling method and sample size
Explain selection, representation and any exclusions.

Minimum process opportunities
Examples: ten campaigns, sixty records, three maintenance cycles.

Minimum elapsed period
Include seasonal, campaign or stability considerations where relevant.

Required conditions
Shifts, products, operators, loads, suppliers, environmental conditions or worst cases.

Interim controls while evidence accumulates

SECTION 5

Implementation readiness

Readiness check	Yes / No / N/A	Evidence reference
Actions completed and approved		
Change control / validation complete		
Documents effective and obsolete versions removed		
Training and qualification complete		
Data sources available and reliable		
Baseline confirmed		
Quality approval to begin review period		

Effectiveness observation period starts

SECTIONS 6-8

Results, decision and follow-up

Evidence reviewed and results
List source records and include failures, exclusions, adverse trends and deviations from the plan.

Comparison with every predefined criterion

Decision	Select	Required response
Effective	[ ]	Close after residual-risk and Quality review.
Partially effective	[ ]	Add or revise actions; define another check.
Ineffective	[ ]	Contain, reassess impact and cause; reopen or initiate linked action.
Inconclusive	[ ]	Extend with justification, controls and a firm endpoint.

Decision rationale and residual risk

Follow-up actions / references

CAPA owner / date		Quality reviewer / date	