PRACTICAL GMP TOOL

Deviation Investigation Decision Guide & Workbook

Describe the event precisely. Preserve the evidence. Test causal hypotheses. Build actions that address the system.

USE THIS WORKBOOK TO

01	02	03	04
Control the event and protect evidence	Write a neutral, testable problem statement	Reconstruct the timeline and test causes	Link CAPA and effectiveness to the cause

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DECISION GUIDE

From detection to evidence-based closure

A deviation is an unplanned departure from an approved instruction, expected condition or controlled state. Record facts first. Classification, cause and disposition must follow evidence rather than convenience.

Decision point	Action	Required output
Could product, patient, data or validated state be at immediate risk?	Stop or control the activity, segregate material, preserve the scene and notify Quality.	Time-stamped containment record and initial risk statement.
Is the event description factual and bounded?	Separate observations from assumptions; define what, where, when, extent and expected condition.	Neutral problem statement suitable for testing.
Is the scope supported by evidence?	Examine related batches, products, equipment, materials, shifts, records and time periods.	Documented inclusion and exclusion rationale.
Does evidence support a causal mechanism?	Test competing hypotheses and distinguish direct, contributing and systemic causes.	Cause statement linked to objective evidence.
Do proposed actions control the demonstrated causes?	Map correction, corrective action and prevention to each cause; define effectiveness evidence.	Approved CAPA, disposition and closure plan.

STOP RULE	Do not restart work, repair records, discard components, change settings or clean the area before evidence is protected and Quality authorises the next step, unless safety requires immediate action.

Suggested stage gates

Gate 1: event controlled and evidence secured. Gate 2: problem statement, classification and investigation plan approved. Gate 3: evidence and causal analysis reviewed. Gate 4: impact and disposition approved. Gate 5: actions and effectiveness plan accepted for closure.

SECTION 1

Event intake, containment and notification

Deviation reference / date and time detected

Product / material / batch / equipment / area / record

Observed event and expected requirement
State what was directly observed and cite the instruction, limit or expected condition.

Immediate response check	Yes / No / N/A	Evidence / owner
Activity stopped or placed in a controlled state where necessary		
Affected materials, product, records and equipment identified and secured		
Original paper, electronic, photographic and physical evidence protected		
Quality and responsible management notified within procedure timelines		
Safety, regulatory or market escalation assessed		
Temporary controls avoid destroying evidence or creating new risk		

Immediate correction / containment and authorisation
Record who acted, when, why, and any effect on the investigation.

SECTION 2

Define the event before explaining it

A useful problem statement is specific enough to investigate but neutral about cause. Avoid words such as negligence, carelessness, failure to follow or equipment fault unless evidence already demonstrates them.

Prompt	Record
WHAT happened?	
WHERE in the process, equipment, system or record?	
WHEN detected and when could it have started?	
WHO observed or was involved - without assigning blame?	
HOW MUCH / how many / which batches or records?	
WHAT SHOULD have happened? Cite the controlled requirement.	

Approved factual problem statement

Initial risk dimension	Low / Medium / High	Rationale / immediate control
Patient / user safety		
Product quality / identity / strength / purity		
Data integrity / traceability		
Compliance / validated state		

SECTION 3

Investigation plan and justified scope

Investigation objective and key questions

Evidence stream	Included records / samples / interviews	Owner / due date
People and shift conditions		
Procedures, forms and training		
Equipment, utilities and maintenance		
Materials, suppliers and storage		
Process parameters and in-process controls		
Electronic data and audit trails		
Prior events, trends and CAPA history		

Scope included
Products, batches, systems, sites, shifts and time period.

Scope excluded and evidence supporting exclusion

Investigation team	Role / independence / expertise	Signature / date
Investigator		
Subject-matter expert		
Quality approver		

SECTION 4

Reconstruct the timeline and test the controls

Arrange objective evidence chronologically. Include normal steps, handovers, waits, alarms, edits, interruptions, interventions and the moment the event was detected.

Date / time	Expected activity or state	What occurred / evidence reference	Gap or question

Control-barrier review
Which prevention, detection or recovery controls should have stopped or revealed the event? Did the control exist, function, get used and provide an effective response?

EVIDENCE RULE	Record contradictory and negative evidence as carefully as supporting evidence. An investigation that only collects facts supporting its first idea is confirmation bias.

SECTION 5

Test causal hypotheses - do not vote for a root cause

Candidate causal mechanism	Evidence supporting	Evidence contradicting / missing	Test or verification
People / task design			
Procedure / information			
Equipment / technology			
Material / environment			
Management system / workload			

Tool	Use when	Guardrail
Five Whys	A reasonably clear sequence needs deeper probing.	Validate every link; do not stop at operator action.
Fishbone	Multiple cause categories need structured exploration.	It generates hypotheses, not proof.
Fault tree	Several combinations could produce a defined top event.	Verify logic and basic events with evidence.
Barrier analysis	A hazard passed through expected preventive or detective controls.	Examine barrier design, use and response.

SECTION 6

Move beyond 'human error'

An action may describe how an event occurred, but rarely explains why the system allowed it. Assess the conditions shaping performance before choosing retraining or discipline.

Performance-shaping factor	Questions	Finding / evidence
Task and procedure	Is the step clear, usable, sequenced and practical at the point of work?	
Competence and experience	Was qualification relevant to the actual task and conditions?	
Workload and staffing	Were time pressure, fatigue, interruptions or handovers influential?	
Equipment and interface	Could design, labels, alarms, access or similarity invite error?	
Supervision and culture	Were escalation, challenge and stop-work behaviours supported?	
Organisational controls	Did planning, change control, maintenance or metrics create conditions?	

Direct cause - mechanism closest to the event

Contributing causes - conditions that increased likelihood or impact

Systemic / root cause - controllable system weakness supported by evidence

Cause statement: because [cause], [mechanism] occurred, resulting in [event / impact]

SECTION 7

Impact, disposition and cause-linked actions

Impact area	Conclusion	Evidence / reference
Affected batch / material / record		
Related batches, products and time period		
Patient / user and distributed-product risk		
Validated state / data reliability / regulatory impact		

Disposition decision and scientific rationale

Cause / risk	Correction or corrective action	Owner / due date	Effectiveness criterion / review period

ACTION TEST	If the cause statement disappeared, could a reviewer still explain why each action was selected? If not, the action-to-cause link is probably weak.

Residual risk and interim controls until actions are effective

CLOSEOUT CHECK

Before the investigation is approved

Confirm	Yes / No / N/A	Reference
Containment protected people, product, data and evidence		
The problem statement is factual and does not assume a cause		
Classification, timelines and scope follow risk and procedure		
Original records, electronic data, interviews and physical evidence are traceable		
Competing hypotheses and contradictory evidence were evaluated		
Human error was not accepted without assessing system conditions		
Cause statements distinguish direct, contributing and systemic causes		
Impact and disposition cover related products, batches and distributed product		
Actions address demonstrated causes and have measurable effectiveness criteria		

Final approval	Name / role	Signature / date
Investigation owner		
Technical / operations reviewer		
Quality Unit		

Primary references

21 CFR 211.192: Production record review - https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-J/section-211.192
EU GMP Chapter 1: Pharmaceutical Quality System - https://health.ec.europa.eu/document/download/bd7c4956-1a93-4d31-a14f-3d72fbef12ab_en
ICH Q9(R1): Quality Risk Management - https://database.ich.org/sites/default/files/ICH_Q9-R1_Guideline_Step4_2023_0126.pdf
ICH Q10: Pharmaceutical Quality System - https://database.ich.org/sites/default/files/Q10_Guideline.pdf

EDUCATIONAL USE This workbook does not replace approved procedures, product-specific scientific assessment, quality-unit authority or applicable regulatory requirements.