GDP RECORD-REVIEW TOOL

Good Documentation Practices Record-Review Checklist

Review paper, electronic and hybrid records for completeness, chronology, traceability and reliable reconstruction of the work.

USE THIS WORKBOOK TO

01	02	03	04
Review records consistently	Detect meaningful gaps	Assess corrections and chronology	Escalate data-integrity risk

Prepared by S. BHATTI

Registered Pharmacist / Pharmaceutical Operations Leader

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SECTION 1

Record and review scope

Identify the record, activity, product, period, governing instruction and quality decision supported.

Scope element	Details	Reference
Record type / number / version		
Product, batch, sample, equipment or area		
Activity date and review period		
Applicable procedure / specification		
Related electronic or source records		
Decision supported by the record		

Risk-based review depth and rationale

SECTION 2

ALCOA+ record checks

The record should be attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring and available.

Principle	Review question	Finding / reference
Attributable	Can each action and change be linked to the responsible person?	
Legible	Can entries, values and meaning be read throughout retention?	
Contemporaneous	Were activities recorded when performed?	
Original	Is the first capture or verified true copy retained?	
Accurate	Do values, calculations and transcription match source evidence?	
Complete / consistent	Are all attempts, pages, events and chronology present?	
Enduring / available	Is the record protected and retrievable?	

ALCOA+ exceptions

SECTION 3

Entries, signatures and corrections

Corrections must preserve the original entry, reason, identity and chronology without obscuring data.

Check	Yes / No / N/A	Finding
Permanent approved ink / controlled electronic entry used		
Blank fields prevented or marked appropriately		
Signatures / initials identifiable and dated		
Corrections preserve original information		
Reason for change recorded where required		
No overwriting, erasure, correction fluid or backdating		
Late entries clearly identified and justified		

Correction or signature concerns requiring follow-up

SECTION 4

Completeness and reconstruction

A reviewer should be able to reconstruct materials, equipment, sequence, parameters, results, checks and exceptions.

Evidence area	Complete?	Reference / gap
Material identity, lot, quantity and status		
Equipment identity and status		
Critical times, temperatures and parameters		
Calculations, units and transcription checks		
In-process controls and results		
Line clearance, reconciliation and yield		
Attachments, printouts and electronic data		
Deviations and unexpected observations		

Reconstruction gaps and potential impact

SECTION 5

Electronic and hybrid-record linkage

Paper printouts are rarely the complete record when data originate or change electronically.

Control	Status	Evidence / concern
Paper record linked to electronic source data		
Audit trail reviewed where critical		
All repeats, aborted runs and invalidated data retained		
Manual transcription independently checked		
Metadata, calculations and versions traceable		
Scanned / true copies verified and controlled		
Interface or transfer errors assessed		

Electronic-data follow-up required

SECTION 6

Exception and impact assessment

Not every documentation defect has equal significance. Classify based on reliability, product impact, recurrence and intent.

Classification	Example	Response
Minor documentation defect	Isolated legibility or completion issue with reliable source evidence.	Correct where permitted and trend.
Significant record deficiency	Missing check, unexplained correction or incomplete reconstruction.	Assess impact and open deviation as required.
Potential integrity concern	Backdating, concealed data, unauthorised change or missing original.	Preserve evidence, escalate and expand scope.

Exception, impact and escalation decision

SECTION 7

Review, conclusion and approval

Close only when the evidence supports the decision and all unresolved risks have an accountable route forward.

Closeout confirmation	Yes / No / N/A	Reference
Scope and risk rationale are documented		
Required evidence is complete and traceable		
Exceptions were assessed and escalated appropriately		
Actions, owners and due dates are defined		
Residual risk is understood and accepted by Quality		
Review and approval are independent where required		

Overall conclusion and decision

Follow-up actions / monitoring / effectiveness checks

Final approval - name, role, signature and date
Quality Unit and responsible function