PQS GDocP Record Review Checklist

Practical educational worksheet for reviewing pharmaceutical GMP records and documentation controls

Record / Form:		Document No. / Version:	
Batch / Activity:		Review date:	
Prepared by:		Reviewer:	

1. Core GMP record review

Check	Review question	Status / evidence
[ ]	Is the current approved form/SOP/version being used?	[ ] Yes [ ] No [ ] N/A
[ ]	Are entries legible, permanent and understandable throughout the record?	[ ] Yes [ ] No [ ] N/A
[ ]	Were entries made when the activity occurred, or are late entries properly handled?	[ ] Yes [ ] No [ ] N/A
[ ]	Are required signatures/initials, dates and times present and attributable?	[ ] Yes [ ] No [ ] N/A
[ ]	Are measured values recorded as actual values where required, without vague reconstruction?	[ ] Yes [ ] No [ ] N/A
[ ]	Are corrections traceable and is the original information still readable?	[ ] Yes [ ] No [ ] N/A
[ ]	Are blanks, unused spaces and N/A entries handled according to procedure?	[ ] Yes [ ] No [ ] N/A
[ ]	Are attachments, calculations, printouts and supporting records identifiable and linked?	[ ] Yes [ ] No [ ] N/A
[ ]	Can a qualified reviewer reconstruct what happened, by whom, when and under which instruction?	[ ] Yes [ ] No [ ] N/A

PQS review rule: A record is not complete merely because every box contains text. The entries must represent what actually happened and preserve a reliable chronology.

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2. Right vs Wrong scenario review

Scenario	Interpretation	Reviewer note
Value recorded directly at the time of observation in the controlled record.	Good practice	
Value reconstructed from memory hours later without explanation.	Documentation red flag	
Paper error corrected while original remains readable; correction is attributable and dated.	Generally acceptable if procedure allows	
Correction fluid or erasing hides the original entry.	Documentation red flag	
Current controlled SOP used after required training/effectivity.	Good practice	
Obsolete printed SOP remains in use.	Document-control red flag	
Field truly not applicable and documented according to procedure.	Good practice	
Missed required field later changed to N/A without assessment.	Documentation red flag	

3. Blank Field / N/A decision

Situation	Meaning	Action
Field genuinely does not apply.	Not applicable	Mark/close according to approved procedure.
Activity occurred but entry was not made at the time.	Late/missing documentation	Do not mark N/A; follow late-entry/missed-entry process using factual evidence.
Activity may not have been performed.	Potential missed GMP activity	Escalate/assess; do not invent data.
Unused blank paper space remains.	Potential for later addition	Close/strike unused space as required by procedure.
Electronic field is disabled because it does not apply.	System-controlled N/A	Confirm controlled/validated logic as applicable.

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4. Correction decision guide

Decision point	Reviewer question	Evidence / status
Type of issue	Is this a transcription error, missing entry, late entry, missed activity, calculation error or electronic change?	
Original preserved	Can the original information still be read/reconstructed?	[ ] Yes [ ] No
Factual basis	Is the corrected/late information supported by factual evidence rather than memory?	[ ] Yes [ ] No
Attribution	Are initials/signature, date/time and reason present when required?	[ ] Yes [ ] No
Electronic trace	If electronic, is the change history/audit trail retained where applicable?	[ ] Yes [ ] No [ ] N/A
Quality-system impact	Does this correction represent a deviation, missed step or event needing assessment?	[ ] Yes [ ] No

5. Document lifecycle control review

Stage	Evidence to check	Status
Draft	Approved template, owner, document ID, controlled drafting process.	[ ] OK [ ] Issue
Review / Approve	Authorized technical/quality review and approval before use.	[ ] OK [ ] Issue
Issue / Train	Correct version distributed; training/effective date controlled.	[ ] OK [ ] Issue
Use / Record	Entries complete, contemporaneous, attributable and traceable.	[ ] OK [ ] Issue
Revise	Revision history, reason for change, approval and implementation.	[ ] OK [ ] Issue
Retire / Archive	Superseded versions removed from use; required records retained/retrievable.	[ ] OK [ ] Issue

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6. Electronic-record documentation checks

Check	Control point	Status / evidence
[ ]	Unique user identity and appropriate role-based access are used.	[ ] Y [ ] N [ ] N/A
[ ]	Critical changes remain traceable through system history/audit trail where applicable.	[ ] Y [ ] N [ ] N/A
[ ]	Electronic signatures are controlled where applicable.	[ ] Y [ ] N [ ] N/A
[ ]	Original electronic records and relevant metadata are retained.	[ ] Y [ ] N [ ] N/A
[ ]	Backup, retention, archival and retrieval controls are defined and effective.	[ ] Y [ ] N [ ] N/A
[ ]	The computerized system is validated/controlled as appropriate for its intended GMP use.	[ ] Y [ ] N [ ] N/A

7. Review observations / documentation event

Observation:	
Record location / field:	
What should have occurred:	
What actually occurred:	
Supporting evidence:	
Quality / product impact:	

8. Action plan / disposition

Action	Owner	Due date	Closure / evidence

Final disposition:
[ ] Record acceptable after review
[ ] Correction required under approved procedure
[ ] Documentation event / deviation assessment required
[ ] Quality Unit escalation required

Educational resource: This checklist does not replace approved documentation procedures, batch-record review requirements, electronic-record controls, formal deviations or Quality Unit decisions.