CMO AUDIT / QUALITY GOVERNANCE

Pharmaceutical CMO Audit Evidence Checklist

A public, non-confidential decision aid for testing how a proposed quality system operates through investigations, change, technology transfer and supply pressure.

> Audit principle: do not stop at a procedure, certificate or presentation. Connect each audit question to a defined product, named legal entity and site, lifecycle stage, target market, responsibility model and source evidence.

Five evidence domains

01 Governance and escalation
Can the right functions make, document and escalate quality decisions?

Look for: quality-unit authority, management review, project governance, escalation routes and accountable owners

02 Investigation and CAPA
Does the system move from detection to root cause, action and effectiveness review?

Look for: deviation and complaint workflow, root-cause rationale, CAPA ownership, due dates, effectiveness checks and sponsor communication

03 Change control
Are technical and regulatory impacts assessed before implementation?

Look for: change classification, product/process knowledge, filing impact, risk assessment, approval, implementation evidence and post-change review

04 Technology transfer
Can knowledge and unresolved gaps be governed across sending and receiving teams?

Look for: transfer plan, gap log, analytical readiness, training, protocols, acceptance criteria, issue decisions and final report

05 Quality and supply reliability
Can quality data drive timely action under routine and disrupted conditions?

Look for: process and product metrics, material risk, testing and release interfaces, recurring issues, continuity actions and management review

Evidence maturity record

Level	What the auditor can record	What is still missing
0 - Not evidenced	No reliable source record was made available for the defined scope.	An owner, evidence request and decision date.
1 - Documented	A procedure or stated process exists.	Executed records and evidence that the process works in practice.
2 - Demonstrated	Relevant executed records show the process operating for a comparable scope.	Consistency over time, trend review or closure of material exceptions.
3 - Managed	Evidence is reviewed, trended, escalated and used for continual improvement.	Confirm applicability to the exact product, site and target-market pathway.

EVIDENCE REQUEST MATRIX

Ask for evidence, not adjectives

Domain	Evidence examples	Red flags	Audit follow-up
Governance	Organisation and quality-unit roles; management-review inputs and actions; escalation examples; project RACI.	Authority is unclear; recurring quality issues do not reach management; project and quality governance are disconnected.	Trace one issue from detection through escalation, decision, action and management review.
Investigation / CAPA	Selected deviation, complaint, OOS/OOT and CAPA records; root-cause tools; overdue and effectiveness-trend data.	Root cause defaults to operator error; CAPAs repeat; due dates are extended without risk rationale; effectiveness checks are superficial.	Sample closed and open records, test causal reasoning and verify that actions prevented recurrence.
Change control	Change procedures and executed changes; impact assessments; filing and validation decisions; implementation and post-change review.	Changes are approved after implementation; regulatory impact is unclear; cross-functional approvals are missing.	Trace a representative product-impacting change from proposal to post-implementation review.
Technology transfer	Transfer plan and report; knowledge and gap log; method-transfer package; training; protocols; acceptance criteria; issue decisions.	Document receipt is treated as transfer completion; gaps lack owners; methods and materials are not ready; acceptance criteria are undefined.	Test whether sending and receiving teams can explain the same control strategy and unresolved risks.
Reliability and metrics	Process and product monitoring; recurring deviation and CAPA trends; release and lead-time data; material and continuity risks; management actions.	Metrics are collected but not reviewed; supply events lack quality escalation; repeated trends have no improvement plan.	Ask what decision each metric supports and inspect evidence of timely action.

Cross-cutting audit tests

Test	Question to resolve
Identity and scope	Is the named contracting entity the same entity responsible for the proposed site and activities?
Product route	Do dosage form, presentation, process, equipment, utilities, laboratory, materials and scale assumptions align?
Target market	Who owns the filing, authority communication, testing, release, import and lifecycle obligations?
Data traceability	Can source records, review history, audit trails and retained data support the decision being made?
Agreements	Are quality and technical responsibilities, communications, changes, investigations, records, subcontracting and exit support explicit?

> Safe disclosure rule: initial screening should use a non-confidential project brief. Detailed formulae, process instructions, dossiers, raw confidential data and trade secrets belong in a controlled review after an appropriate confidentiality arrangement.

AUDIT DECISION RECORD

Convert observations into controlled decisions

Decision field	Record
Named legal entity and site	_____
Product / dosage form / presentation	_____
Lifecycle stage and target market	_____
Audit purpose and scope	_____
Decision	[ ] Go [ ] Conditional go [ ] Hold [ ] No-go
Material observation or gap	_____
Required evidence / corrective action	_____
Owner and acceptance criterion	_____
Target date and re-review route	_____

Selected primary references

U.S. FDA - CDER Quality Management Maturity. U.S. FDA - Quality Metrics for Drug Manufacturing. U.S. FDA - Contract Manufacturing Arrangements for Drugs: Quality Agreements. ICH Q10 - Pharmaceutical Quality System, including management of outsourced activities, CAPA, change management and management review. WHO TRS 1044, Annex 4 - Technology transfer in pharmaceutical manufacturing.

Discuss a non-confidential project fit

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