PHARMUNI CHECKLIST

20 Common Qualification and Validation Mistakes

A practical GMP review deck for QA, validation, manufacturing, engineering, and pharma learners.

Use it to spot weak evidence before audit or release.

OVERVIEW

The 20 mistakes to review first

Use this list as the article update backbone and the downloadable checklist logic.

1. Starting validation too early
2. Weak acceptance criteria
3. Copying vendor protocols
4. Poor URS traceability
5. Skipping risk assessment
6. Unapproved protocols
7. Untrained executors
8. Incomplete installation checks
9. Testing only normal operation
10. Confusing PQ and PPQ
11. Ignoring computerized controls
12. Weak deviation handling
13. Backdated or missing raw data
14. Changing protocol during execution
15. No calibration verification
16. Incomplete final reports
17. Ignoring change-control impact
18. No periodic review
19. Over-reliance on three batches
20. Weak QA ownership

MISTAKE 1

Starting validation too early

01

Common mistake

Process validation begins before equipment, utilities, software, or rooms are fully qualified.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Confirm DQ, IQ, OQ, PQ status before PPQ or routine validation execution.

Protocol | Evidence | QA approval

MISTAKE 2

Weak acceptance criteria

02

Common mistake

The protocol uses vague terms such as “acceptable,” “normal,” or “as expected.”

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Define measurable limits, ranges, sample sizes, and pass/fail rules before execution.

MISTAKE 3

Copying vendor protocols

03

Common mistake

Vendor tests are accepted without assessing site-specific use, risks, and GMP requirements.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Perform a site impact assessment and add tests linked to the user requirements.

MISTAKE 4

Poor URS traceability

04

Common mistake

Requirements are not clearly linked to design checks, tests, deviations, and final reports.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Build a traceability matrix from URS to DQ, IQ, OQ, PQ, and report conclusions.

MISTAKE 5

Skipping risk assessment

05

Common mistake

All functions are tested equally, while critical functions may not receive enough challenge.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Use quality-risk management to focus testing on patient, product, data, and compliance impact.

MISTAKE 6

Unapproved protocols

06

Common mistake

Execution starts before QA, system owner, and technical reviewers approve the protocol.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Lock protocol approval before testing and control any changes through documented revision.

MISTAKE 7

Untrained executors

07

Common mistake

Operators execute tests without documented training on the protocol, equipment, or SOP.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Verify training status before execution and attach evidence to the validation package.

MISTAKE 8

Incomplete installation checks

08

Common mistake

Utilities, drawings, materials, instruments, spare parts, and manuals are not fully verified.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Use an IQ checklist that confirms installation against approved design and site requirements.

Protocol | Evidence | QA approval

MISTAKE 9

Testing only normal operation

09

Common mistake

OQ avoids alarms, interlocks, boundary limits, failure modes, and worst-case conditions.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Challenge operating ranges, alarms, controls, and critical functions under justified conditions.

MISTAKE 10

Confusing PQ and PPQ

10

Common mistake

Equipment performance qualification is treated as the same activity as process performance qualification.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Separate equipment fitness-for-use evidence from process capability and batch-performance evidence.

MISTAKE 11

Ignoring computerized controls

11

Common mistake

PLC, HMI, SCADA, recipes, audit trails, access levels, and data flows are not assessed.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Include computerized-system validation expectations when software controls GMP activities or data.

Protocol | Evidence | QA approval

MISTAKE 12

Weak deviation handling

12

Common mistake

Protocol deviations are closed without root cause, impact assessment, or CAPA decision.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Document the event, evaluate GMP impact, justify acceptance, and define corrective actions.

Protocol | Evidence | QA approval

MISTAKE 13

Backdated or missing raw data

13

Common mistake

Test records do not show when, how, and by whom evidence was generated.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Apply ALCOA+ principles and ensure raw data are attributable, legible, complete, and contemporaneous.

MISTAKE 14

Changing protocol during execution

14

Common mistake

Teams change samples, limits, or steps informally when testing becomes difficult.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Use controlled amendments and document why the change does not compromise the objective.

MISTAKE 15

No calibration verification

15

Common mistake

Critical instruments used during qualification are out of calibration or not checked.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Confirm calibration status before use and record instrument IDs in test evidence.

Protocol | Evidence | QA approval

MISTAKE 16

Incomplete final reports

16

Common mistake

The report summarizes success but does not discuss deviations, exclusions, or unresolved risks.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Include objective results, deviation status, conclusions, residual risks, and approval decision.

MISTAKE 17

Ignoring change-control impact

17

Common mistake

Equipment moves, software updates, component changes, or process changes are not assessed.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Link every relevant change to requalification, revalidation, or documented no-impact justification.

Protocol | Evidence | QA approval

No periodic review

18

Common mistake

The validated state is assumed to remain valid without trend review or lifecycle monitoring.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Review deviations, maintenance, calibration, alarms, complaints, and performance trends periodically.

MISTAKE 19

Over-reliance on three batches

19

Common mistake

Three successful batches are treated as automatic proof of process validation.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Justify PPQ batch number and sampling based on process knowledge, risk, and variability.

MISTAKE 20

Weak QA ownership

20

Common mistake

Validation decisions are driven only by engineering or production without independent quality review.

Why it matters

This weakens inspection evidence and makes it harder to prove that the system, process, or method is fit for GMP use.

Better practice

Define QA approval points for protocols, deviations, reports, and release to routine use.

FINAL CHECK

Before you approve qualification or validation, ask:

1. Are the requirements approved and traceable?
2. Are critical risks reflected in protocol testing?
3. Are deviations investigated and justified?
4. Is the final report evidence-based and QA-approved?
5. Is there a plan to maintain the validated state?

Turn the article into a practical downloadable checklist, not only an educational definition page.