RTM audit checklist

Ten checks and two walks, in the order an auditor takes them. Run it on your own matrix before the inspection does, or hand it to a supplier with their protocols.

SYSTEM	MATRIX REVISION	DATE	REVIEWED BY

1 The ten checks · each one is a finding when it fails

☐ **Every requirement has a test. No blanks.**	Filter the matrix for empty test cells. Each blank is a missing test, or a requirement that should not exist.
☐ **Every test has a requirement or specification behind it. No orphans.**	List the tests, not the requirements. A test with no link is a test nobody asked for, and the auditor will ask why it was run.
☐ **Links go level by level: `URS→FS→DS→IQ`, not `URS→IQ`.**	A direct URS→DS or URS→IQ link means the FS is missing, or the requirement is really a design constraint.
☐ **Tests verify the level they belong to: IQ against the DS, OQ against the FS, PQ against the URS.**	An OQ test that "covers" a URS line directly skipped the FS. Check that the FS says something the URS does not.
☐ **Identifiers never renumber. A deleted requirement leaves a gap.**	Compare two revisions of the URS. If the numbers moved, every link below the change is suspect.
☐ **The matrix shows the revision of the requirement each test ran against.**	Pick a requirement revised after execution. The matrix must show the wording the test was executed against, not the current one.
☐ **Re-executed tests show the latest result; the history is kept.**	Find a failed test. The matrix points at the re-test, and the first run is still on file with its discrepancy.
☐ **Tests added during execution are in, with their reason.**	A test added on site after a discrepancy reaches the matrix with the reason it was added and the element it verifies.
☐ **Critical requirements are tested directly and in depth; the rest in proportion to risk.**	GMP impact and criticality are on the row. The critical ones have a direct test with a numeric acceptance criterion.
☐ **One source, one owner, produced on demand.**	Ask for the matrix now. If someone has to edit a spreadsheet first, there is more than one matrix, and they disagree.

2 The two walks · pick one row each way and follow it to the end

Down · from a requirement to a signed result

1. Pick a critical requirement: fill volume, sterility, data integrity.
2. Follow it to the specification that decomposes it. Is it more precise than the URS, or a paraphrase?
3. Follow it to the test. Is the acceptance criterion a number, a range or a state?
4. Open the executed test: result, evidence, executor, date, signature.
5. If it failed: the discrepancy, its closure, the re-test, and the design revision it ran against.

Up · from a test to the requirement behind it

1. Pick a test that looks odd: no obvious purpose, or added late.
2. Which specification does it verify? If none: why was it run?
3. Which requirement is behind that specification? If none: the test proves nothing anyone asked for.
4. Was the requirement worded the same way when the test was executed?

> **Both walks end at a revision.** The matrix is evidence only if it can name the wording of the requirement each test was executed against. A cell someone typed proves nothing; a link stored on the element, generated into the matrix, does.

3 Findings