The 50-Question Pre-Inspection Compliance Checklist

Use this checklist with your QA team before any FDA, EU GMP, or national authority inspection. Print it, check off each item, and identify your highest-risk gaps.

HOW TO USE: Check each box. Circle gaps. Use the notes column to record findings.

DOCUMENTATION & SOPS — Q1-Q10

#	CHK	CHECKLIST ITEM	NOTES / FINDING
1	☐	All SOPs are current, approved, and version-controlled	
2	☐	SOPs reflect actual current practice (no gaps between document and reality)	
3	☐	All SOP revisions have a documented change history	
4	☐	Training on current SOP versions is complete for all relevant staff	
5	☐	SOPs are readily retrievable during an inspection	
6	☐	Batch records are complete, accurate, and contemporaneous	
7	☐	Raw data is retained alongside processed results	
8	☐	All forms and templates referenced in SOPs are current versions	
9	☐	Document retention periods are defined and being followed	
10	☐	Superseded SOP versions are archived and not available for use	

DATA INTEGRITY — Q11-Q20

#	CHK	CHECKLIST ITEM	NOTES / FINDING
11	☐	Audit trails are enabled in all GxP computerised systems	
12	☐	Audit trail reviews are performed regularly and documented	

13	☐	No shared logins exist in any GxP system	
14	☐	System access controls are reviewed periodically	
15	☐	All GxP data entries are attributable to the individual who made them	
16	☐	Original data is never deleted - only superseded with a clear audit trail	
17	☐	Electronic records are backed up and backup integrity is tested	
18	☐	Staff are trained on data integrity principles and requirements	
19	☐	Out-of-specification (OOS) investigation procedures are in place and followed	
20	☐	No paper records are reconstructed after the fact	

COMPUTERISED SYSTEMS (CSV) Q21-Q30

#	CHK	CHECKLIST ITEM	NOTES / FINDING
21	☐	All GxP computerised systems have a current validation status	
22	☐	Validation files are complete, signed, and accessible	
23	☐	Change control process covers vendor-initiated software updates	
24	☐	Computer system validation SOPs are current	
25	☐	Periodic reviews of validated systems are documented	
26	☐	User access provisioning and de-provisioning is controlled and documented	
27	☐	System downtime and contingency procedures are documented	
28	☐	All systems have a GAMP 5 category assessment on file	
29	☐	Supplier/vendor qualification is complete for all GxP SaaS providers	
30	☐	Data migration validations are complete for any recent system changes	

EQUIPMENT & FACILITIES Q31-Q36

#	CHK	CHECKLIST ITEM	NOTES / FINDING
31	☐	All critical equipment has a current qualification status (IQ/OQ/PQ)	
32	☐	Equipment calibration records are within schedule	
33	☐	Preventive maintenance is documented and up to date	

34	☐	Equipment logbooks are maintained and current	
35	☐	Facility qualification is current for all GMP areas	
36	☐	Temperature and environmental monitoring records are complete	

TRAINING — Q37-Q42

#	CHK	CHECKLIST ITEM	NOTES / FINDING
37	☐	Training matrix is current and reflects all active SOPs	
38	☐	All staff training records are complete and up to date	
39	☐	Training is documented before task performance (not retroactively)	
40	☐	Training effectiveness assessments are conducted and recorded	
41	☐	New SOP training is completed before the SOP goes into effect	
42	☐	Contractor and visitor training records are maintained	

DEVIATIONS & CAPA — Q43-Q50

#	CHK	CHECKLIST ITEM	NOTES / FINDING
43	☐	All open deviations have documented status and are not overdue	
44	☐	CAPA root cause investigations are documented with evidence	
45	☐	CAPA effectiveness checks are completed and documented	
46	☐	No CAPAs have been open for more than 6 months without justification	
47	☐	Complaint handling procedures are in place and documented	
48	☐	Change control records are complete for all recent changes	
49	☐	Trend analysis of deviations is performed periodically	
50	☐	Previous inspection CAPAs are all closed with documented evidence	