GxP ASSESSMENT CHECKLIST FOR SOFTWARE

Evaluate. Comply. Assure.

A comprehensive checklist to assess software systems for compliance with GxP regulations, industry standards, and best practices.

Ensure Compliance
Align with FDA, EU GMP, WHO GMP, and other GxP regulations

Reduce Risk
Identify gaps, mitigate risks, and ensure data integrity

Audit Ready
Be inspection-ready with a documented assessment

Improve Quality
Strengthen controls and drive continuous improvement

ASSESSMENT AREA	KEY CHECKS	STATUS
1. REGULATORY COMPLIANCE	• Applicable GxP regulations identified (e.g., 21 CFR Part 11, EU Annex 11, GMP) • Compliance requirements documented • Regulatory guidance and standards considered (e.g., GAMP 5)	[ ] Yes [ ] Partial [ ] No [ ] N/A
2. SYSTEM SECURITY	• User access management and role-based permissions • Strong password policy and account controls • System prevents unauthorized access • Security controls reviewed and tested	[ ] Yes [ ] Partial [ ] No [ ] N/A
3. DATA INTEGRITY	• ALCOA+ principles addressed (Attributable, Legible, Contemporaneous, Original, Accurate + Complete, Consistent, Enduring, Available) • Data is accurate, complete, and protected • Audit trail captures critical data actions • Time synchronization implemented	[ ] Yes [ ] Partial [ ] No [ ] N/A
4. VALIDATION & QUALIFICATION	• Validation plan documented • Risk assessment performed • IQ/OQ/PQ or equivalent completed • Validation summary report available	[ ] Yes [ ] Partial [ ] No [ ] N/A
5. CHANGE MANAGEMENT	• Change control process documented • Impact assessment performed for changes • Changes tested and approved before implementation • Changes logged and traceable	[ ] Yes [ ] Partial [ ] No [ ] N/A
6. DOCUMENTATION	• User requirements documented • Functional specifications available • System documentation is current and controlled • Policies and SOPs are in place	[ ] Yes [ ] Partial [ ] No [ ] N/A
7. TRAINING & SUPPORT	• User training program exists • Training records are maintained • Help and support processes are defined	[ ] Yes [ ] Partial [ ] No [ ] N/A
8. VENDOR MANAGEMENT	• Vendor is assessed and qualified • Vendor provides GxP compliance evidence • Service level and support agreements in place	[ ] Yes [ ] Partial [ ] No [ ] N/A
9. CONTINUOUS MONITORING	• System performance monitored • Issues and incidents tracked • Periodic review and revalidation performed	[ ] Yes [ ] Partial [ ] No [ ] N/A

ASSESS. ACT. ASSURE.
Use this checklist to ensure your software meets GxP standards and is audit-ready.

IDEAL FOR
• Pharmaceutical • Biotechnology
• Medical Devices • Laboratories
• CROs & GCP Organizations

COMPLIANCE METRICS
Excel | PDF Checklist
Track. Score. Improve.