

GxP-Compliant Windows 11 Migration Checklist for Pharmaceutical Companies

1. Planning & Governance

- ☐ Form a cross-functional migration team (IT, QA, CSV, business)
- ☐ Identify all GxP-relevant systems running Windows 10
- ☐ Define the scope and objectives of the migration project
- ☐ Establish a timeline considering the October 14, 2025 EOL deadline
- ☐ Inform regulatory stakeholders, if needed

2. System Inventory & Classification

- ☐ Document all systems (hardware and software) using Windows 10
- ☐ Classify systems by GxP impact: High / Medium / Low
- ☐ Identify third-party applications that may require revalidation

3. Risk Assessment

- ☐ Perform a risk assessment for continued use and migration
- ☐ Include security, data integrity, business continuity, and compliance risks
- ☐ Document risk mitigation strategies

4. Validation Strategy

- ☐ Determine if revalidation is required (full or partial)
- ☐ Create/update validation documentation including:
 - ☐ Validation Plan
 - ☐ Requirements Traceability Matrix (RTM)
 - ☐ IQ/OQ/PQ protocols
- ☐ Execute validation activities and obtain QA approval

5. Testing & Qualification

- ☐ Perform OS installation and configuration testing (IQ)
- ☐ Conduct operational testing (OQ) for system functionality
- ☐ Validate performance in a controlled environment (PQ)

6. Documentation Updates

- ☐ Update SOPs, user manuals, and training materials
- ☐ Revise system configuration and validation documentation
- ☐ Archive documentation per data retention policies

7. Training & Change Control

- ☐ Train users on the updated system or interface
- ☐ Initiate a change control record for traceability
- ☐ Review change control with QA and obtain approval

8. Post-Migration Review

- ☐ Conduct a post-migration review or audit
- ☐ Monitor system performance and GxP compliance
- ☐ Finalize and close change control