

# GxP Computerised Systems Checklist

A practical prompt for IT, Quality and system owners. The required depth should be proportionate to intended use, product quality, patient safety and data-integrity risk.

## Scope and ownership

|                          |                                                                                  |                   |
|--------------------------|----------------------------------------------------------------------------------|-------------------|
| <input type="checkbox"/> | The system's intended use and GxP relevance are documented.                      | Yes / Partly / No |
| <input type="checkbox"/> | Business process, system, data, Quality and technical owners are defined.        | Yes / Partly / No |
| <input type="checkbox"/> | Supplier responsibilities and service boundaries are understood.                 | Yes / Partly / No |
| <input type="checkbox"/> | A current inventory identifies versions, locations, interfaces and dependencies. | Yes / Partly / No |
| <input type="checkbox"/> | Lifecycle and end-of-support risks are reviewed.                                 | Yes / Partly / No |

## Risk-based lifecycle

|                          |                                                                       |                   |
|--------------------------|-----------------------------------------------------------------------|-------------------|
| <input type="checkbox"/> | Validation effort is proportionate to intended use and risk.          | Yes / Partly / No |
| <input type="checkbox"/> | Requirements are clear, testable and traceable to evidence.           | Yes / Partly / No |
| <input type="checkbox"/> | Supplier assessment supports the selected assurance approach.         | Yes / Partly / No |
| <input type="checkbox"/> | Testing covers critical functions, interfaces and failure conditions. | Yes / Partly / No |
| <input type="checkbox"/> | Release approval confirms required evidence and actions are complete. | Yes / Partly / No |

## Data integrity and security

|                          |                                                                        |                   |
|--------------------------|------------------------------------------------------------------------|-------------------|
| <input type="checkbox"/> | Access is unique, role-based and reviewed periodically.                | Yes / Partly / No |
| <input type="checkbox"/> | Privileged access is restricted, approved and monitored.               | Yes / Partly / No |
| <input type="checkbox"/> | Audit trails are enabled, protected and reviewed where required.       | Yes / Partly / No |
| <input type="checkbox"/> | Time synchronisation, backup, archival and restoration are controlled. | Yes / Partly / No |
| <input type="checkbox"/> | Data transfers and interfaces are reconciled and monitored.            | Yes / Partly / No |

## Operation and change

|                          |                                                                                     |                   |
|--------------------------|-------------------------------------------------------------------------------------|-------------------|
| <input type="checkbox"/> | Infrastructure, application and configuration changes follow controlled assessment. | Yes / Partly / No |
| <input type="checkbox"/> | Incidents, problems and deviations are recorded and investigated.                   | Yes / Partly / No |
| <input type="checkbox"/> | Periodic review confirms the system remains supported and fit for use.              | Yes / Partly / No |
| <input type="checkbox"/> | Business continuity and disaster recovery arrangements are tested.                  | Yes / Partly / No |
| <input type="checkbox"/> | Retirement preserves required records, metadata and readability.                    | Yes / Partly / No |

### Priority actions

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_

This checklist is general guidance, not legal, regulatory or security assurance. The appropriate controls depend on your organisation, risks, contracts and regulatory obligations.