CSV • Annex 11 • Go-live readiness

CSV vs Annex 11 Checklist

From GxP Impact to System Release

A practical checklist for QA, validation, IT quality, and system owners preparing GMP computerised systems for inspection.

> Use this as a pre-release review before the system goes live.

Why the checklist matters

CSV proves intended use. Annex 11 proves controlled GMP operation. Inspectors expect both to connect.

01 **Weak validation documentation creates audit risk**

02 **Poor data integrity controls weaken trust in records**

03 **Unclear ownership makes lifecycle control harder**

Best review question

Can we show one traceable story from intended use → risks → requirements → testing → release → periodic review?

Evidence beats paperwork volume

Step 1: decide whether the system is in scope

Start with use, data, and region before writing validation documents.

GxP process?

Batch, QC, QA, manufacturing, release

GMP data?

Creates, stores, changes, or transmits regulated records

EU GMP use?

EU/EEA product, site, or regulated activity

Validation scope

CSV only, Annex 11 mapping, or no GMP validation

> Quick rule: if a system supports regulated GMP decisions, build a CSV package. If it supports EU GMP activities, map Annex 11 clauses explicitly.

CSV vs Annex 11 in one view

Use this distinction to avoid duplicate documents and missing controls.

CSV focus

- Validation strategy
- URS, risk assessment, testing
- Traceability matrix
- Validation report and release

Annex 11 focus

- Validated state
- Access, audit trail, signatures
- Supplier and outsourced service control
- Backup, continuity, periodic review

One set of documents should show both system fitness and controlled GMP operation.

Step 2: build the minimum evidence set

The document pack must be risk-based, traceable, and usable during inspections.

Validation Plan	Scope, roles, risk strategy, deliverables
URS	Intended use, GMP functions, data integrity needs
Risk Assessment	Patient safety, product quality, data integrity impact
Test Evidence	IQ/OQ/PQ or scripted/unscripted risk-based testing
Release Report	Open deviations, acceptance, limitations, approval

Step 3: prove data integrity by design

Do not treat ALCOA+ as theory. Translate it into system capabilities.

ID

Unique user identity

RBAC

Role-based access

AT

Audit trail enabled

B/R

Backup and restore tested

READ

Readable records

REV

Record review procedure

> Inspection question: can users change, delete, export, sign, or approve GMP data without traceability?

Step 4: check supplier and cloud control

Vendor documentation helps, but the regulated company remains accountable for use.

- Supplier qualification completed
- Quality or service agreement in place
- Cloud hosting, backup, and security responsibilities defined
- Vendor release notes and changes reviewed by QA/CSV
- Data ownership, access, retrieval, and exit plan documented

Do not validate the vendor claim. Validate your intended use.

Step 5: test what matters before release

Testing depth should follow risk, not habit.

1

Low risk

Supplier evidence + config check

2

Medium risk

Scripted testing for key functions

3

High risk

Detailed scenarios + negative testing + QA review

> Must-have tests: audit trail, permissions, electronic signatures, critical calculations, interfaces, backup/restore, and error handling.

Step 6: use a go-live release gate

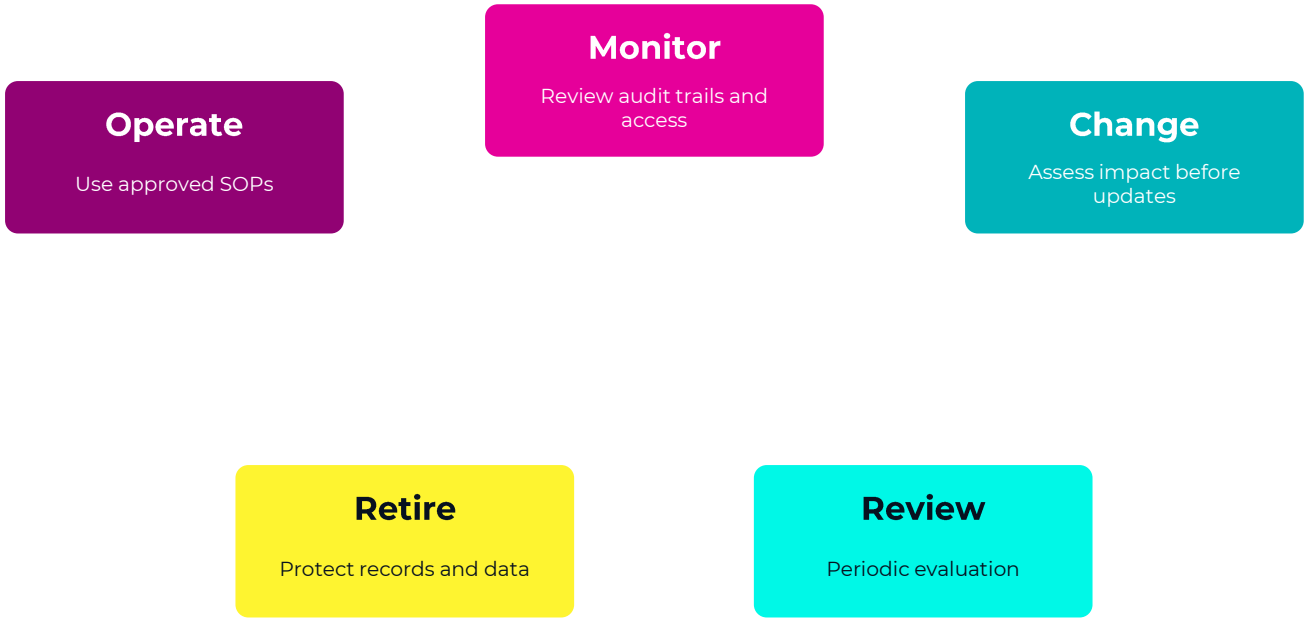
A system is not ready because testing ended. It is ready when quality accepts the residual risk.

- All critical deviations closed or justified
- Validation report approved by QA and system owner
- SOPs, work instructions, and training effective
- Backup, restore, security, and support confirmed
- Operational handover and periodic review scheduled

Output: approved system release memo with known limitations, support model, and next review date.

Step 7: maintain the validated state

Annex 11 readiness continues after go-live.



Validated state is a lifecycle, not a launch event.

Schedule reviews by system risk and inspection impact.

One-page checklist for article download

Use the PowerPoint as a gated or ungated practical item inside the article.

1. **GxP impact and EU scope confirmed**
2. **URS and risk assessment approved**
3. **Annex 11 clause mapping completed**
4. **Data integrity controls tested**
5. **Supplier/cloud oversight documented**
6. **Release gate approved**
7. **Periodic review scheduled**

Ready for inspection?

Use the checklist to connect validation evidence, Annex 11 controls, and lifecycle ownership before go-live.

Learn CSV, GMP, QA and validation skills with Pharmuni

Reference sources to link in article

- EU GMP Annex 11 current text
- EU/PIC/S revised Annex 11 draft
- ISPE GAMP 5 2nd edition
- FDA Data Integrity Guidance
- Pharmuni Validation courses