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# From CSV to CSA: Efficient GxP Computer System Validation Tactics Utilizing Computer Software Assurance Techniques

**Erik Staley, President and Principal Consultant, Valicom, Inc.**

**January 27, 2026**

## Summary

FDA's 2025 final guidance on Computer Software Assurance (CSA)[1] is written for medical device production and quality system software, but its efficiency principles translate well to drug and biologics environments operating under GLP, GCP, and GMP (herein, "drug GxP"). CSA's practical message -- both generally and as reflected in the guidance -- is to right-size validation and assurance activities: apply greater rigor where system/software failure could plausibly compromise product quality, patient safety, or data integrity, and reduce effort where failure would not.

This paper highlights practical efficiency opportunities enabled by a CSA-aligned approach and points readers to additional methods and supporting resources, including ISPE's GAMP® 5 2nd Edition[2] and other relevant industry guidance.

## Why CSA matters to drug GxP, even though the guidance is device-scoped

Although FDA's CSA guidance is scoped to systems used in medical device production and quality systems, drug and biologics organizations use many of the same technology platforms -- such as LIMS, eQMS, ERP/MES, EDC/eTMF, laboratory instruments, EDMS, and cloud services -- to create, maintain, and rely upon regulated records and to support GxP decision-making.

For many years, FDA has also directed drug organizations to the 2002 CDRH guidance *General Principles of Software Validation*[3]. FDA is expected to continue referencing that document for drug GxP contexts,

[1] U.S. Food and Drug Administration (FDA), *Computer Software Assurance for Production and Quality System Software. Final Guidance for Industry and FDA Staff*, September 24, 2025.

[2] International Society for Pharmaceutical Engineering (ISPE) ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems (2nd ed.), 2022. ISBN 978-1-946964-57-1.

[3] FDA, *General Principles of Software Validation: Final Guidance for Industry and FDA Staff,* January 11, 2002. FDA appended this Guidance to note that the CSA Guidance supersedes a portion of it.

even as it is updated to align with CSA concepts -- including replacement of a legacy section with a reference to the CSA guidance.

## Leveraging Efficiency Opportunities from Adapting CSA

For many years, FDA's recommendation that drug GxP organizations reference the CDRH Software Validation guidance encouraged adoption of validation practices originally developed for medical device software. When combined with conservative interpretations of 21 CFR Part 11 -- even despite FDA guidance narrowing its scope, interpretation, and enforcement[4] -- this often reinforced a "test everything" mindset, emphasizing extensive documentation and detailed testing with limited assurance value.

CSA, as both a concept and as articulated in the CSA Guidance, reinforces right-sized assurance: a least-burdensome, risk-based approach. It shifts organizations from documentation-centric validation to a leaner model that emphasizes evidence of fitness for intended use, with testing depth and formality proportional to patient/subject risks.

In 2022, in its 2nd edition to GAMP 5, ISPE has provided guidance well-aligned with CSA Guidance concepts, containing new and broadened chapters on topics such as critical thinking, risk, supplier management, and using tools and automation. The GAMP 5 revision also provides techniques for leveraging CSA-style assurance in regulated GxP environments.

## Applying CSA efficiencies to GLP, GCP, and GMP

CSA offers several practical "efficiency levers" that translate well to drug GxP environments:

### 1) Scope software and systems by intended use and assess risk at the right level

Start by defining the system's intended use in the regulated process and perform risk assessment at the system level. Where appropriate -- especially for highly configurable platforms -- extend the assessment to the specific features, functions, and operations used for GxP purposes.

**GAMP 5 tools that support this approach include**:

- Assignment of systems to GAMP hardware and software categories
- Quality risk management techniques
- The "Critical Thinking Through the Life Cycle" section

**Efficiency gains**: Avoiding from the get-go the single "validate the entire system for every conceivable use" approach, replacing it with activities bounded by intended use and risk.

[4] FDA, *Part 11, Electronic Records; Electronic Signatures – Scope and Application*, August 2003.

## 2) Employ flexibility in testing methods to fit risk and context

The CSA Guidance supports selecting the most efficient testing method that provides appropriate confidence for the risk. This opens up possibilities other than strict, immutable, manual validation protocols, and offers unscripted and automated testing alternatives:

- **Unscripted testing** (e.g., exploratory testing, error guessing, structured ad hoc execution) can be appropriate for **lower-risk** functions -- without a formal, step-by-step validation protocol -- provided execution and outcomes are adequately documented.
- **Scripted testing** (i.e., protocol-driven, preapproved test cases with strict acceptance criteria) can be reserved for **higher-risk** functions, interfaces, and failure modes.
- **Automated testing** (e.g., independent result-checking, automated browser sessions, API-level tests) can be appropriate when such tools are **validated/verified for its intended use**, produce **reviewable results**, and are **controlled** (versioned scripts, controlled environments, traceable outputs). These tools are particularly useful for:
  - **regression testing** after changes
  - **integration / end-to-end "PQ" workflows** across interfaces
  - **security and configuration checks** (where applicable)
  - **data integrity stress/negative testing** (e.g., verifying controls against truncation, corruption, or unexpected transformations)

**Tools from GAMP 5 include:**

- Appendix D5 examples for applying unscripted testing
- Automation in the efficiency-focused content, discussed in Appendix D9 on selecting and assessing software/tools used for automated testing

**Efficiency gains:** Reduce time spent creating, reviewing, and approving detailed protocols where they add little risk reduction -- while still applying scripted rigor where it matters.

## 3) Leverage existing controls to reduce redundancy in validation

Consider whether other established controls reduce the impact of software failure (e.g., independent checks and inspections, process controls, batch record reviews). Document those systems, and rationales for their uses and reliability.

**Efficiency gains**: Avoid dedicating validation effort to re-testing what other controls already effectively detect or prevent.

## 4) Leverage supplier controls and documentation – from trusted suppliers

The CSA Guidance encourages use of supplier-provided evidence to avoid duplicative assurance activities; however, this presupposes that suppliers are appropriately qualified. Supplier qualification should include activities such as audits (as appropriate), review of prior experience with the supplier, and evaluation of the supplier's overall reputation and prevalence within the

industry. Once qualified, relevant supplier system/software development life cycle (SDLC) deliverables may be leveraged, along with applicable certifications the supplier has attained.

**Available tools from GAMP 5 include** scoped supplier qualification activities in the "Supplier Activities" chapter.

**Efficiency gains:** Avoid re-testing or recreating assurance evidence when a qualified supplier has already generated relevant, fit-for-purpose information.

### 5) Move to digital objective evidence over paper and printed screenshots

The CSA Guidance encourages digital retention of objective evidence from testing and validation:

> *"...FDA* recommends *incorporating the use of digital records, such as system logs, audit trails, and other data generated and maintained by the software, as opposed to paper documentation, screenshots, or duplicating results already digitally retained by the software when establishing the record associated with the assurance activities."*
>
> – CSA Guidance, p. 20

**Efficiency gains:** In many cases, you're simultaneously validating that a system's logs, audit trails, and electronic signatures function correctly. Why not use those capabilities to provide evidence of their own correct function?

## Some cautions

### Staying lean without becoming lax

CSA efficiencies are not simply "do less testing." They are "do the right testing to the appropriate extent -- and retain the right evidence." Key guardrails include:

- **Ensure risk assessments are defensible:** clearly justified, documented, reviewed, and approved.
- **Do not underscope:** feature- and function-level scoping must still cover all **GxP-critical intended uses**, including configurations, interfaces, and data flows that affect regulated records or decisions.
- **Use supplier evidence judiciously:** rely on vendor documentation to an extent **proportional** to acceptable supplier qualification
- **Keep unscripted testing disciplined:** define objectives and acceptance criteria up front; capture what was tested, what was observed, any failures found, and how issues were resolved (or scientifically justified). *Unscripted does not mean undocumented.*

### Data integrity remains a source of high risk for drug GxP – and an FDA focus

Data integrity is referenced in the CSA Guidance, but often indirectly. In drug GxP, data integrity is frequently a primary risk driver -- often exceeding the risk profile typically seen in the device context.

This is especially true in GCP, where complex datasets must remain compliant with ALCOA+ expectations across collection, processing, analysis, reporting, and archival.

The CSA Guidance's intent is to right-size assurance activities in service of **product quality and patient safety**. In drug GxP environments, the integrity of data generated by preclinical studies, clinical trials, manufacturing systems, and laboratory testing can have an outsized impact on those outcomes. Practically, when the Guidance emphasizes **quality** and **safety**, teams should treat **data integrity** as an equivalent, explicit focal point when scoping, assessing risk, and determining evidence needs.

### Don't ignore Part 11 – despite superficial appearance, FDA isn't

FDA rarely *directly* cites Part 11 in Warning Letters. In practice, observations tied to electronic records and data integrity center on predicate-rule expectations, for example:

- **GLP**: Study director to ensure data are accurately recorded and verified [21 CFR §58.33(b)], equipment design and maintenance [§§58.61-63] [5]
- **GCP:** Accurate case histories [21 CFR §312.62(b)], record retention [§§312.57(c), 312.62(c)],
- **GMP:** Controls over computer systems [21 CFR §211.68(b)], lab records [§211.194]

**CSA is not a license to abandon Part 11**. Where electronic records and signatures are used to meet predicate-rule requirements, Part 11 expectations should be applied and evidenced in a manner that is commensurate with intended use, risk, and the specific predicate rules that govern the process.

## Conclusion

The familiar, traditional CSV approaches often became resource-intensive and generated extensive documentation, much of it having limited value. FDA's 2025 CSA guidance provides efficiency principles that translate directly to drug and biologics GxP by right-sizing assurance based on the plausible impact of system failure on product quality, patient safety, and data integrity.

Applying a CSA-aligned approach -- supported by resources such as ISPE's *GAMP® 5 Second Edition* and related guidance, with clear guardrails to ensure that "do less testing" never replaces "do the right testing" -- enables substantial efficiency gains while preserving disciplined, risk-based evidence.

[5] For expectations for validation, see FDA's *Compliance Program 7348.808: Chapter 48—Bioresearch Monitoring; Good Laboratory Practice (Nonclinical Laboratories)*, May 20, 2025

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## How can Valicom assist *you* with implementing CSA?

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| **Policy and framework development** | ✓ Designing and implementing a right-sized risk-based model<br>✓ Developing or fine-tuning policies re CSA and data integrity |
| **Gap analysis and remediation** | ✓ Assessing current state through comprehensive gap analysis<br>✓ Identifying compliance risks to prioritize remediation |
| **Risk Assessment** | ✓ Applying efficient, GAMP-aligned risk assessment techniques<br>✓ Management of residual risks |
| **Supplier qualification** | ✓ Developing or updating risk-based supplier qualification schemes<br>✓ Conducting audits and assessments for software, systems, instruments, and as-a-service SaaS / PaaS / IaaS vendors |
| **Lean SDLC documentation, protocol / test execution** | ✓ Validation plans, requirement specifications, risk assessments, design documents, unscripted testing, validation protocols -- incorporating CSA efficiencies with GAMP-aligned techniques<br>✓ Execution of test and validation plans<br>✓ Developing and using automated testing tools |
| **Leveraging vendor SDLC / validation assets** | ✓ Assessing, integrating, and supplementing vendor validation packages and SDLC documentation |
| **SOP development** | ✓ Developing, updating, and advising on procedures related to CSA, data integrity, and your quality operations |
| **Interim & embedded quality resources** | Providing experienced professionals for temporary or long-term roles:<br>-- Quality operations / QA / QC leadership<br>-- Validation specialists<br>-- Auditors<br>-- Technical writers |
| **Technology implementations** | ✓ Transitioning from paper and screenshots to digital objective evidence<br>✓ Lab equipment configuration and integration with CDS and LIMS<br>✓ CDS, LIMS, EDMS, and QMS implementations, whether on-premises, SaaS, or hybrid |
| **Auditing** | ✓ Inspection readiness, such as mock FDA PAI/PLI<br>✓ Due diligence |
| **Agency inspections and responses** | ✓ Audit and inspection support for FDA and others, and responding to agency observations |

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**For more information, contact:**

VALICOM, INC.

Erik Staley, President and Principal Consultant
San Diego, CA
es@valicom.com
(866) 730-9298