



INTUITIONLABS / RESEARCH & PRACTICAL GUIDANCE

CSA vs CSV: Validating AI Systems Under FDA Guidance

Build practical AI for pharma and biotech with IntuitionLabs. We help life-science teams turn complex information and workflows into useful software, governed knowledge systems and AI tools.

Published by IntuitionLabs · 2026-02-07 · computer software assurance · csa vs csv · ai validation · fda guidance · machine learning compliance · gxp validation · life sciences software · risk-based validation · automated system validation

Original article: <https://intuitionlabs.ai/articles/csa-vs-csv-validating-ai-systems-fda-guidance>



In this article

1. Executive Summary
 2. Introduction
 3. Historical and Regulatory Context
 4. The FDA CSA Guidance Framework
 5. Comparison: CSV vs. CSA (Traditional vs. Risk-Based Validation)
 6. Applying CSA to AI-Enabled Systems
 7. Case Examples / Scenarios
 8. Implications, Data, and Future Directions
 9. Conclusion
-

Executive Summary

Computer Software Assurance (CSA) is FDA's risk-based guidance for software used in medical-device production and quality management systems. The current **February 2026 guidance** supersedes the September 2025 final guidance. Its recommendations are nonbinding; the applicable statutory and regulatory obligations remain separate. The **Quality Management System Regulation (QMSR)**, effective February 2, 2026, incorporates ISO 13485:2016.

CSA builds on established validation principles. FDA's **2002 software-validation guidance** already integrates lifecycle management with risk management. The practical task is to define intended use, assess foreseeable failures, select suitable assurance activities, retain objective evidence, and control changes.

For AI-enabled production or quality software, assess the actual model and deployment. FDA distinguishes locked models from continual-learning models; changing input data is a separate source of drift. Interpretability also depends on the system. The **FDA glossary** explains these distinctions. The examples below illustrate assurance planning; they do not establish compliance or promise time or cost savings. Pharmaceutical and biotechnology adaptations require their own applicable requirements.

Introduction

In the life sciences industries – pharmaceuticals, biotech, and medical devices – **computerized systems** are ubiquitous. Companies use software and automated data processing for everything from manufacturing execution and quality management to clinical trials and regulatory reporting. For medical-device production and quality management software, the QMSR requires validation for intended use under the applicable ISO 13485 provisions (**FDA guidance**). Assess pharmaceutical, biotechnology, and clinical-trial requirements separately. The classic approach to validation, known as Computerized System Validation (CSV), has been in place for decades. Rigid stage gates, exhaustive scripting, and excessive documentation are burdensome implementation habits rather than defining CSV principles. FDA's 2002 *General Principles of Software Validation* guidance recommends integrating lifecycle management and risk management and does not prescribe a specific lifecycle model (**FDA guidance**).

Validation coverage should reflect software complexity and safety risk ([FDA guidance](#)). The comparison below treats exhaustive scripting and excessive documentation as implementation habits; it provides no measured industry-wide effort split or savings benchmark.

FDA's current [CSA guidance](#) supersedes the September 24, 2025 final guidance. CSA applies risk-based validation to medical-device production and quality management software ([FDA guidance](#)). It clarifies assurance planning within established lifecycle validation rather than replacing it. FDA's earlier guidance already calls for evaluating the effects of software changes across the system ([2002 guidance](#)).

This report focuses on **AI-enabled systems** used in production and quality management. Distinguish initial training from deployment behavior: a locked model does not change with use, while a continual-learning model has a defined learning process for changing its behavior. Data drift refers to changing input distributions, which can degrade performance ([FDA glossary](#)). Assess interpretability and controls for the actual model and deployment.

CSA seeks to establish and maintain confidence that software is fit for its intended use ([FDA guidance](#)). For AI-enabled software, use that objective to frame the assurance plan; the examples below are planning aids rather than evidence of compliance or measured savings.

The following sections cover regulatory context and the FDA assurance framework, followed by:

- **CSA vs. CSV:** Implementation habits and risk-based assurance planning. www.fdpi.org
www.mastercontrol.com www.fdpi.org
- **CSA for AI Systems:** Deployment behavior, input-data drift, interpretability, monitoring, and change control, with an adapted literature comparison. www.biotech-asia.org www.biotech-asia.org
- **Case Examples:** Hypothetical visual-inspection and quality-monitoring assurance plans.
www.mastercontrol.com www.ideagen.com
- **Implications & Future Trends:** Related AI frameworks, quality-team practices, and validation tools.
www.nist.gov www.fda.gov www.fdpi.org ispe.org

Historical and Regulatory Context

Evolution of CSV and “Least Burdensome”

FDA's 2002 *General Principles of Software Validation* guidance already integrated lifecycle management and risk management. Validation coverage was to reflect software complexity and safety risk, with evaluation of changes throughout the lifecycle ([FDA guidance](#)). Risk-based validation did not originate with CSA.

For current medical-device requirements, use the [QMSR](#), which took effect February 2, 2026 and incorporates ISO 13485:2016. References to the earlier Quality System Regulation describe the historical baseline.

Parallel international developments also emphasized risk-based validation. [EU GMP Annex 11](#) calls for lifecycle risk management that considers patient safety, data integrity, and product quality. The Commission's [Volume 4 index](#) identifies the applicable Annex 11 document. Its separate [consultation](#) presents draft revisions to Chapter 4 and Annex 11 and a proposed Annex 22 on artificial intelligence; consultation drafts should be distinguished from the listed GMP guidance.

The Birth of CSA Guidance

FDA's current *Computer Software Assurance for Production and Quality Management System Software* guidance was issued February 3, 2026. It supersedes the September 24, 2025 final guidance; 2025 is part of the history, rather than the current regulatory baseline ([FDA guidance](#)).

The guidance supplements the 2002 software-validation guidance and supersedes its Section 6 on automated process equipment and quality system software. CSA supplies recommendations on meeting applicable obligations; it does not create a new binding rule. The separate QMSR rule is the regulatory change ([FDA guidance](#); [QMSR](#)).

The FDA CSA Guidance Framework

The guidance applies to medical-device production and quality management software. It does not provide device-software design and development verification or validation recommendations ([FDA guidance](#)). Its assurance process can be summarized for planning as follows:

1. **Identify intended use and scope.** Determine whether the software directly supports, or is used as part of, device production or the quality management system before classifying its process risk.
2. **Assess foreseeable failures.** A function poses **high process risk** when failure may produce a quality problem that foreseeably compromises safety. For **not-high-process-risk** functions, tailor assurance to the process risk; this category is not a blanket exemption from testing.
3. **Choose assurance activities.** Use testing and other evidence appropriate to the assessed risk. Evaluate relevant supplier evidence and decide what additional activities the manufacturer needs.
4. **Retain sufficient objective evidence.** Record intended use, risk assessment, activities, results, issues, and the acceptability decision. Include controls for maintaining the validated state and evaluating changes.

For in-scope software, FDA points to **ISO 13485:2016 subclauses 4.1.6, 7.5.6, and 7.6** as applicable validation provisions under the QMSR. The guidance also separately addresses software changes and additional assurance considerations; the four points above are a practical summary ([FDA guidance](#)).

CSA applies risk-based validation principles to production and quality management software, with flexibility in testing and objective evidence ([FDA guidance](#)).

Key Elements of CSA Guidance

Reviewing the final guidance and related commentary, several themes emerge:

- **Risk stratification is binary but flexible.** The draft guidance itself described risks as simply “*high*” or “*non-high*” (based on patient safety impact) (www.fdl.org). In practice, many organizations implement more granular scales (e.g. high/medium/low) consistent with their SOPs (sqa.org). Tailor assurance for high-process-risk functions to medical-device risk and for not-high-process-risk functions to their process risk.

- **Focus on outcomes and data integrity.** Rather than validating every internal calculation, CSA suggests prioritizing outcomes that affect product quality, patient safety, or critical records. One industry commentary summarizes it: under CSA, “*functions that directly impact product quality, patient safety, or data integrity*” are the priority for testing (www.ideagen.com). This aligns with predicate rules (e.g. cGMP requirements for good data practices) and helps avoid pointless chores.
- **Use relevant supplier evidence.** Assess the supplier and the evidence against the manufacturer’s intended use, then determine any remaining assurance activities. A certification alone does not establish suitability for that use ([FDA guidance](#)).
- **Incorporate automation and continuous monitoring.** The guidance is technology-neutral, but it acknowledges modern tools. Expert sources note that CSA “leverages principles such as risk-based testing, unscripted testing, continuous performance monitoring, and data monitoring” (www.mastercontrol.com). In practice, this could mean using automated validation tools, instrumented test frameworks, or real-time system health dashboards to watch for deviations over time. A one-time qualification exercise does not replace lifecycle validation controls.
- **QA involvement throughout.** CSA calls for integrating the Quality function (QA/IT) early in projects. Rather than QA arriving only after testing, CSA teams typically engage QA during planning and risk assessment, making sure compliance considerations are baked in from the start. This cultural shift is often highlighted in CSA training materials.
- **Lean documentation.** The guidance’s stance is that records should contain “*sufficient objective evidence*” but no more than necessary (www.fdli.org) (bluemountain.io). FDA explicitly encourages companies to document the reasoning behind their risk assessments and test scope, but to avoid unnecessary detail on how each test was conducted if it doesn’t add value. One consultant summarizes this as writing “*lean validation deliverables...with documentation commensurate to the actual level of risk.*”

Scope of CSA Guidance

The guidance concerns software used as part of medical-device production or the quality management system. Enterprise or cloud deployment alone does not establish applicability; intended use determines scope. Device-software functions require separate consideration ([FDA guidance](#)).

General-business software unrelated to production or the quality management system is generally outside these validation provisions. Scope assessment precedes process-risk classification. Within scope, distinguish high process risk using the safety-linked threshold above and assess other functions proportionately to their process risk.

Comparison: CSV vs. CSA (Traditional vs. Risk-Based Validation)

The following table contrasts burdensome implementation habits with assurance planning. These habits are not FDA’s established CSV principles: the [2002 guidance](#) already calls for risk-based coverage and lifecycle validation.

Aspect	Documentation-heavy implementation habits	Risk-based assurance planning
Approach	Uniform testing can obscure differences in intended use and risk.	Base coverage on software complexity and safety risk.
Testing Methodology	Scripts can become a checklist disconnected from the risk assessment.	Select methods appropriate to the intended use and assessed risk.
Documentation	Repetitive records can obscure the evidence supporting acceptance.	Keep evidence sufficient to demonstrate successful completion of validation plans and procedures.
Effort Allocation	Avoid treating illustrative percentages as measured project benchmarks.	Set effort from the actual scope and risk; do not assume a promised percentage saving.
Quality Oversight	Late review can leave quality questions unresolved.	Plan validation early and maintain lifecycle controls.
Use of Vendor Evidence	Retesting vendor work without reviewing its relevance can duplicate effort.	Evaluate relevant vendor evidence against intended use and determine any additional assurance needed.

Table 1: Comparison of Traditional CSV and Risk-Based CSA approaches (sources: FDA guidance and industry analysis (pharmaconnections.in) (www.fdl.org) (www.mastercontrol.com) (bluemountain.io)).

CSA clarifies assurance methods within validation. Existing obligations remain separate from its nonbinding recommendations ([FDA guidance](#)).

Applying CSA to AI-Enabled Systems

AI/ML models differ in deployment behavior. A locked model remains fixed in use; continual-learning models have a defined process for changing behavior. **Data drift** concerns changes in the input distribution and can affect performance without retraining. Interpretability should also be assessed for the actual model rather than assumed absent ([FDA glossary](#)).

For AI used in medical-device production or quality management, consider the following assurance-planning activities:

- **Intended use definition:** CSA's first step – clarify how the system will actually be used – forces teams to articulate the goals of the AI. For example, if an AI model flags defective parts on a production line, the intended use is “to accurately identify defects that escape other methods.” This clarity highlights which functions are safety-critical (e.g. defect detection algorithms) and which are not (e.g. the UI dashboard design). Knowing use and context is especially vital for AI, since good performance may hinge on particular data scenarios.
- **Risk-weighted assurance:** Consider foreseeable false positives and false negatives in context. Use the safety-linked high-process-risk threshold, with assurance for other functions proportionate to their process risk ([FDA guidance](#)).

- **Continuous monitoring & maintenance:** CSA philosophy embraces periodic reevaluation. In the context of AI, this naturally extends to *continuous validation*. Industry experts advise that AI models should be monitored in production for signs of drift or errors, and if thresholds are crossed, the model is re-assessed. Lifecycle controls and evaluation of changes were already part of FDA's [2002 validation guidance](#); they are not unique to CSA. The Sonawane & Baviskar analysis underscores this: traditional systems rely on “*periodic review*”, whereas AI/ML systems require “*continuous monitoring (e.g., drift detection)*” ([www.biotech-asia.org](#)). Similarly, CSA documentation should record plans for ongoing surveillance of high-risk AI functions.
- **Use of structured data and automation:** Many modern AI development processes (often called *MLOps*) involve automated pipelines and tools. CSA permits leveraging these: for example, automated test-case generation or even AI-driven validation tools (see below) can become part of assurance activities. The emergent ISPE Pharmaceutical Engineering article argues that AI can actually assist validation by automating requirement interpretation and test generation ([ispe.org](#)). While the FDA guidance does not mandate AI tools, it certainly does not forbid their use in CSA planning or testing.
- **Vendor and prior work:** Evaluate the supplier and relevant evidence against the intended use. Determine remaining assurance needs, including integration, configuration, and data compatibility; do not infer suitability from an unspecified approval or certification ([FDA guidance](#)).

The special attributes of AI sometimes necessitate expanded risk considerations. In addition to typical functional failures, AI validation must address issues like data quality, bias/fairness, and transparency. The Sonawane & Baviskar table (Table 2 below) highlights this: among **AI/ML Systems**, *risk management* explicitly includes “*Bias, drift, fairness, transparency*” ([www.biotech-asia.org](#)) – risks rarely covered in pre-structured software tests. CSA plans for AI systems should therefore explicitly incorporate checks for dataset representativeness, operational bias monitoring, and traceability of algorithm changes.

Table 2. Adapted literature comparison of validation requirements for Traditional Software, Automated Systems, and AI/ML Systems ([www.biotech-asia.org](#)) ([www.biotech-asia.org](#)).

Validation Component	Traditional Software Systems	Automation/MES/PLC Systems	AI/ML Systems
User Requirements (URS)	Static; defined functions and workflows	Includes hardware logic, interlocks	Goal-based; includes learning objectives and data quality metrics (www.biotech-asia.org)
Qualification (IQ / OQ)	System & environment setup; function testing	Hardware/network config; alarm sequencing	Environment setup; data pipeline validation; algorithm training/test benchmarks (www.biotech-asia.org)
Performance Qualification	Application-specific workflows; steady tests	Simulated production scenarios	Model generalization and real-world performance (www.biotech-asia.org)
Risk Management	Known failure modes (I/O, access, etc.)	Plus mechanical/control-loop risks	Includes AI-specific risks: bias, drift, fairness, transparency (www.biotech-asia.org)
Change Control	Software versioning; documented releases	Configuration of HMI, PLC changes	Model updates; retraining procedures; feature changes (www.biotech-asia.org)

Validation Component	Traditional Software Systems	Automation/MES/PLC Systems	AI/ML Systems
Lifecycle Monitoring	Periodic review (annual audits, etc.)	Maintenance logs, periodic revalidation	Continuous monitoring (e.g. drift detection tools, MLflow monitoring) (www.biotech-asia.org)

Adapted literature comparison, not measured comparative performance data. Source: Sonawane S. S. and Baviskar M. D. (2025), "Risk-Based Validation of Software, Automation and Artificial Intelligence in Pharmaceuticals," Biotech Res Asia 22(4) ([publisher](#)).

Use Table 2 as a planning aid. Select requirements, datasets, performance criteria, monitoring, and change controls for the actual system and intended use rather than treating its categories as universal mandates.

Expert Perspectives

Industry thought leaders resonate with the view that CSA and AI are natural partners. For example, Jak Kane writes that *"artificial intelligence is no longer a futuristic concept in life sciences"* and that many companies want to avoid long CSV cycles for AI (www.ideagen.com). He asserts, *"The CSA framework [is] uniquely suited to AI validation"*, enabling shift from exhaustive validation to targeted testing (www.ideagen.com). He emphasizes exactly the points above: focus on safety/quality-critical AI functions and continuous vigilance.

Other industry commentary describes risk-based assurance as a way to focus validation effort. One industry blog contrasts CSV vs CSA in bullet form (citing a "paradigm shift"): traditional CSV is *"documentation-oriented"*, whereas CSA stresses *"critical thinking, risk-based assurance, and efficiency"* (pharmaconnections.in). It further highlights that CSA will enable *"leveraging...innovative tools such as AI, machine learning, and digital twins"*, while upholding compliance (pharmaconnections.in). This point is echoed by formal frameworks: for instance, FDA and IMDRF guidelines on AI (GMLP) recognize that AI/ML development is *"iterative and data-driven"*, requiring specialized controls (www.fda.gov); The applicability of CSA still depends on the software's production or quality management intended use.

FDA identifies joint FDA/Health Canada/MHRA GMLP principles released in October 2021 and the IMDRF final document released in January 2025 ([FDA GMLP record](#)). These address AI-enabled medical-device development. CSA concerns device-production and quality management software; deployment does not bring a device-software function into its scope ([FDA scope](#)).

Case Examples / Scenarios

While published case studies of CSA adoption are limited, we can illustrate how organizations might apply CSA to AI-related systems, consistent with the guidance and expert advice above.

Example 1: AI-Powered Visual Inspection System. A medical device manufacturer brings in an AI vision system to inspect printed circuit boards (PCBs) for defects during production. A hypothetical assurance plan could be:

1. **Intended Use:** Determine that the vision system's role is to detect critical defects on PCBs which could impair device safety. Other features (e.g. image capture settings or user interface) are secondary.

2. **Risk Assessment:** Assess whether missed defects could cause a quality problem that foreseeably compromises device safety. Assess report printing and other functions separately; their risk depends on intended use and downstream controls.
3. **Assurance Activities:** For the defect algorithm, perform thorough functional testing using a representative sample of known good/bad boards – possibly including simulation of tricky edge cases. Check the AI model's threshold settings. Evaluate relevant camera calibration evidence and supplier capabilities, then determine additional integration and configuration checks. Assess UI functions proportionately to their process risk.
4. **Documentation:** Record the risk rationale, test results (e.g. defect detection accuracy achieved), and approval. Because this is high-risk, keep detailed records of the test data and outcomes. For other functions, retain evidence appropriate to their assessed risk.

In this hypothetical plan, test coverage follows intended use and foreseeable failure effects. Supplier evidence is a starting point for deciding the manufacturer's remaining assurance work, rather than automatic permission to omit testing ([FDA guidance](#)).

Example 2: Machine-Learning Quality Dashboard. A biotech firm implements an ML-based analytics tool that monitors process parameters (temperature, pH, etc.) in bioreactors and predicts batch failures. This is a pharmaceutical/biotechnology adaptation of risk-based assurance principles, outside the direct scope of FDA's device CSA guidance. Map the applicable requirements separately: [21 CFR 211.68](#) addresses computer input/output accuracy checks and written calibration and inspection records for drug manufacturing. A hypothetical planning exercise could be:

- **Intended use:** Identify if and when the analytics tool triggers alerts for conditions likely to produce out-of-specification product.
- **Risk:** Assess the effects of missed batch failures and the role of human review. Assess report exports separately, including whether they feed quality decisions or required records.
- **Assurance:** Devise test cases with historical batch data to measure predictive accuracy. Possibly run the model on held-out data blind to confirm it would have caught known failure events. Check export accuracy and record integrity in the actual workflow.
- **Monitoring:** Plan to monitor the model's performance over time; define investigation and reassessment triggers for changes in performance, inputs, or the model.

These are hypothetical planning examples, not evidence of a client implementation, achieved efficiency gain, or regulatory acceptance. Keep intended use, risk reasoning, evidence, acceptance decisions, and change controls reviewable. Direct FDA CSA applicability remains limited to medical-device production and quality management software ([FDA scope](#)).

Implications, Data, and Future Directions

Industry Trends and Data

Cloud and AI deployment do not establish regulatory scope or a validated state. For each proposed system, identify intended use, applicable requirements, and the evidence needed for assurance. FDA's current guidance covers medical-device production and quality management software ([FDA record](#)).

Treat project costs and validation durations as project-specific planning inputs. Avoid using unsupported industry-wide adoption percentages, inconsistent historical market forecasts, or illustrative effort splits as evidence of measured outcomes.

Alignment with AI and Quality Standards

FDA's [GMLP record](#) distinguishes the October 2021 joint FDA/Health Canada/MHRA principles from the January 2025 IMDRF final document. Keep device-AI development frameworks separate from CSA's production and quality management scope.

The applicable framework follows intended use and jurisdiction, not whether an AI system is deployed at a site or across an enterprise. FDA's CSA guidance is not a comprehensive compliance mechanism for all such systems ([FDA scope](#)).

Risk-based validation predates CSA. FDA's [2003 Part 11 guidance](#) recommends documented risk assessment, and [EU GMP Annex 11](#) applies risk management throughout the computerized system lifecycle.

Advantages and Challenges

Benefits: Use proportionate assurance to focus effort on intended use and assessed risk. Project outcomes vary; this discussion supplies no measured savings benchmark. FDA describes risk-based assurance recommendations rather than guaranteed time, cost, or safety gains ([FDA guidance](#)).

Challenges: Transition is not without risks. Companies worry that an inspector might not accept the new approach. FDA has tried to allay this, with senior staff publicly stating that risk-based methods are acceptable and that CSA is consistent with FDA requirements (www.fdl.org). Nonetheless, companies must invest in training "critical thinking" skills for their validation teams and clearly document their rationale. Internal audit functions must adapt to review risk analyses rather than checklists of attachments. There is also the risk of *under-testing*: if a risk assessment fails to identify a hidden hazard, it could result in software issues later. Thus, CSA requires sound judgment, clear responsibility, and appropriate competence.

Regulatory baseline and planning: Work from the current February 2026 guidance and the QMSR. Treat predictions about future guidance, worldwide adoption, or vendor products as speculation unless supported by specific evidence. Evaluate any assurance tools and supplier evidence for the actual intended use; an advertised template or certification is not a substitute for that assessment ([FDA guidance](#)).

Overall, the implications are profound. Regulatory compliance is moving from a paperwork-intensive model to a quality-focused model. Technology advances like AI not only necessitate this change but can also be harnessed within CSA itself. For example, Pharmaceutical Engineering commentary suggests that AI can

assist in CSV/CSA by auto-generating test cases when business processes and risk criteria are well-defined (ispe.org). In turn, the industry's upcoming workforce will need skills in both advanced analytics and quality engineering, blending roles that were once separate.

Conclusion

CSA is a risk-based approach to assurance for medical-device production and quality management software. The current [FDA guidance](#) is nonbinding and should be read alongside the applicable requirements. It builds on established validation principles rather than replacing lifecycle and risk management with a new compliance exemption.

For AI-enabled systems, make intended use, deployment behavior, data conditions, evidence, and change controls explicit. Evaluate supplier evidence for the actual use and decide what remaining assurance activities are necessary. Maintain the validated state throughout operation; a one-time qualification exercise or vendor certification alone does not establish it ([FDA guidance](#)).

The hypothetical examples and adapted literature table are planning aids. They do not establish compliance, regulatory endorsement of clinical use, or measured efficiency gains. Pharmaceutical and biotechnology applications need a separate assessment of their applicable requirements.

References: Sources are linked inline. The current FDA CSA guidance and applicable regulatory requirements take precedence over industry commentary when determining scope and legal obligations.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-management-system-software>
2. <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr>
3. <https://www.fda.gov/media/73141/download>
4. <https://www.fda.gov/science-research/artificial-intelligence-and-medical-products/fda-digital-health-and-artificial-intelligence-glossary-educational-resource>
5. <https://www.fda.gov/media/188844/download>
6. <https://www.fdi.org/2023/05/advancing-the-transition-to-computer-software-assurance/>
7. <https://www.mastercontrol.com/gxp-lifeline/risk-based-computer-software-assurance-guidance/>
8. <https://www.biotech-asia.org/vol22no4/risk-based-validation-of-software-automation-and-artificial-intelligence-in-pharmaceuticals/>
9. <https://www.ideagen.com/thought-leadership/blog/ai-enabled-systems-and-csa--future-proofing-your-gxp-compliance>
10. <https://www.nist.gov/speech-testimony/balancing-knowledge-and-governance-foundations-effective-risk-management-artificial>
11. <https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles>
12. <https://ispe.org/pharmaceutical-engineering/january-february-2026/how-ai-will-transform-computerized-system>

13. https://health.ec.europa.eu/system/files/2016-11/annex11_01-2011_en_0.pdf
14. https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en
15. https://health.ec.europa.eu/consultations/stakeholders-consultation-eudralex-volume-4-good-manufacturing-practice-guidelines-chapter-4-annex_en
16. https://sqa.org/sqa/sqa/News___Announcements/QualityMatters/2024/Technical/2024-1_CVIC_CSA.aspx
17. <https://bluemountain.io/blog/fdas-csa-guidance-is-final-what-it-means-for-your-validation-strategy/>
18. <https://pharmaconnections.in/use-of-ai-in-csa-approach-and-csa-new-guidelines-transforming-pharma-compliance/>
19. <https://www.fda.gov/medical-devices/artificial-intelligence-enabled-medical-devices/good-machine-learning-practice-medical-device-development-guiding-principles>
20. <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-D/section-211.68>
21. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application>

THE PUBLISHER

About IntuitionLabs

IntuitionLabs is an AI consulting, custom software development and data engineering firm serving pharmaceutical, biotechnology, medical-device and other life-science organizations. We work with clinical, regulatory, medical-affairs, commercial, quality and IT teams to connect technology decisions with the work people need to accomplish.

AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

Software, data and life-science workflows

IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

Enterprise platforms and regulated delivery

We provide Veeva services, application support, managed services, integrations and custom applications, alongside enterprise content work involving platforms such as Egnyte. For regulated workflows, our services include GxP enablement, computer-system validation and software development addressing 21 CFR Part 11 requirements. The applicable controls, validation responsibilities and acceptance criteria are defined for each engagement.

Work with IntuitionLabs

Explore [AI enablement](#), [pharma and biotech software development](#), [data engineering and BI](#), and [Veeva services](#). [Contact IntuitionLabs](#) to discuss your workflow, information sources and implementation needs.

IntuitionLabs publishes educational research to help life-science teams make informed technology decisions. Coverage of a product or organization does not imply a client relationship, endorsement or partnership.

Website: <https://intuitionlabs.ai>

This article is educational. Verify consequential medical, legal, financial, regulatory and technical decisions with appropriate professionals and the cited primary sources. Company services are described separately from the article's research findings.