IntuitionLabs

INTUITIONLABS / RESEARCH & PRACTICAL GUIDANCE

GxP SaaS Release Validation: Evidence and Burden Index

> 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 · 2026-09-19 · gxp saas release validation · computer software assurance · saas validation · gxp change control · regression testing · supplier assessment · validation evidence · quality agreements · release management

Original article: https://intuitionlabs.ai/articles/gxp-saas-release-validation-index

In this article

Executive Summary

This report evaluates how much **release-validation evidence** a regulated buyer can find, and where that evidence sits, for 12 software-as-a-service (SaaS) products used in laboratory, quality, clinical, and regulatory work. It is an evidence-availability index, not a product ranking. The observation window closed on **September 19, 2026**. A public artifact earns 2 points, an explicitly described but customer-gated artifact earns 1, and an unknown remains U. Unknown means that the research did not verify public evidence, not that the supplier lacks the control. No supplier response was received in the observation window, so every scored item comes from a fetched first-party page.

The regulatory baseline supports this distinction. The US Food and Drug Administration (FDA) issued final Computer Software Assurance (CSA) guidance on **February 3, 2026** for computers and automated data-processing systems used as part of medical-device production or the quality management system (fda.gov); it describes a risk-based approach (fda.gov), not a supplier certification. FDA says guidance does not create legally enforceable responsibilities (fda.gov). Part 11 applies to electronic records created, modified, maintained, archived, retrieved, or transmitted under agency record requirements, and to electronic records submitted to FDA under the FD&C Act or Public Health Service Act (ecfr.gov); for applicable closed electronic-record systems, 21 CFR 11.10 includes validation for accuracy, reliability, and consistent intended performance (ecfr.gov). ISPE likewise says ultimate GxP accountability stays with the regulated company (ispe.org).

The strongest public patterns are concrete and operational. **Veeva Vault** publishes impact and known-issue materials and describes a validation package (rn.veevavault.help). **Oracle Clinical One** publicly describes a Product Verification Pack for every release except patches (docs.oracle.com), but the pack itself is gated. **Qualio** documents an approximately quarterly cadence and month-prior communication (docs.qualio.com). **Benchling** documents about **48 hours** of patch notice (help.benchling.com), while **LabWare** states at least **30 days** of notice for its QA/QC SaaS implementation (labware.com). Those figures are not directly comparable because they describe different release types.

Procurement should therefore contract for a release calendar, notice by change class, an impact assessment mapped to configured use, a preproduction window, objective test evidence, known-issue access, application programming interface (API) deprecation rules, rollback or continuity procedures, and data-repatriation timing. ISPE identifies functional impact assessments (ispe.org) and planned-maintenance lead time (ispe.org) as agreement fields. The practical burden model is release frequency multiplied by triage time, plus impacted releases multiplied by regression time, plus annual supplier-governance work. Buyers should populate it from their own inventory and labor rate, because the public evidence does not support universal testing-hour benchmarks.

Introduction and Background

GxP is the collective shorthand for regulated good practices in areas such as manufacturing, laboratories, and clinical work. A SaaS supplier operates much of the underlying platform, while the regulated customer controls intended use, configuration, procedures, roles, and the decision to accept a release. The National Institute of Standards and Technology definition captures the infrastructure split: the consumer does not manage or control the underlying cloud infrastructure (csrc.nist.gov). That operational split does not transfer regulated accountability.

Release validation is therefore a recurring evidence problem. A system owner must determine what changed, whether configured GxP processes are affected, what supplier testing can be leveraged, what customer checks remain necessary, and whether production use can continue. FDA recognizes that customers may have limited access to supplier information (fda.gov). PIC/S places ultimate responsibility for available validation evidence on the regulated user (picscheme.org).

The buyer decision is not simply which vendor has more documents. It is which supplier practice reduces uncertainty in the customer's specific change assessment, and which practice merely shifts work behind a portal, contract, or customer test step. The analysis covers GxP SaaS supplier release evidence, SaaS validation regression testing burden, GxP software release validation requirements, vendor supplied validation documentation for SaaS, GxP cloud software change control, risk based regression testing for GxP systems, SaaS supplier assessment for GxP, and continuous validation of GxP SaaS. IntuitionLabs is an adjacent life-sciences implementation and advisory firm, not an option in this product sample. Its public service description covers implementation and support of Veeva applications (intuitionlabs.ai), and its advisory scope includes technology roadmapping (intuitionlabs.ai). That perspective informs the governance questions, but it is deliberately absent from the vendor matrix.

Methodology and Scoring Rubric

Inclusion rule and observation window

The sample includes 12 named SaaS or cloud products that satisfy three conditions: the product supports a laboratory information management system (LIMS), electronic laboratory notebook (ELN), electronic quality management system (eQMS), clinical trial management system or electronic data capture (CTMS/EDC), regulatory information management (RIM), or adjacent GxP data platform; the supplier maintains a first-party public web presence; and at least one release-management or validation-evidence statement could be

verified. Benchling describes its Notebook as a validated cloud-native environment (benchling.com), while LabVantage identifies SaaS validation for pre-packaged LIMS offerings (labvantage.com). These examples show why category and delivery model were verified before release evidence was coded.

Research used pages retrievable without a customer contract, plus public pages that explicitly describe gated artifacts. The cutoff and retrieval date for every matrix citation was September 19, 2026. Historic pages were retained when they remained the only official public statement, but their dates are shown. Public absence was coded U, never converted into a claim that a control does not exist. No directly verified vendor correction or questionnaire response arrived in the observation window. A supplier may submit first-party correction evidence for **30 calendar days** after publication; accepted corrections should retain the original snapshot and a dated change note.

Ten-field rubric

Table 1 defines the reproducible coding scheme. Each field gets **2 public points** when the artifact or rule is readable publicly, **1 gated point** when a public first-party page confirms that a customer-only artifact exists, and **U** when the research could not verify either. The public evidence score has a maximum of **20**.

Field	What qualifies	Why the customer needs it
Cadence/history	Dated schedule or sufficiently complete release archive	Predicts annual triage volume
Advance notice	A stated lead time or dated prerelease calendar	Supports staffing and change-control timing
Machine-readable notes	Feed, API, or structured downloadable changelog	Enables controlled ingestion and comparison
Impact classification	Supplier assessment by feature, risk, or GxP relevance	Narrows customer impact analysis
Known issues	Current disclosure, public or explicitly gated	Informs acceptance and workaround review
Validation pack	Defined requirements, plan, traceability, or qualification set	Supports supplier-evidence leverage
Executed test evidence	Results or objective evidence, not only test descriptions	Supports assurance conclusions
Rollback/continuity	Restore, rollback, or tested continuity rule	Defines response when acceptance fails
API/deprecation	Version stability, retirement, or notice policy	Protects integrations and automated evidence flows
Quality agreement clarity	Publicly defined release responsibilities or contract metrics	Prevents responsibility gaps

The rubric measures documentary access, not software quality, validation status, or regulatory compliance. FDA recommends examining intended use at feature and function level (fda.gov) and using risk analysis to select assurance activities (fda.gov). A high public score cannot replace those customer-specific decisions.

Regulatory Context for SaaS Change Control

Within its medical-device production and quality-management-system scope, the **2026 FDA CSA guidance** expressly encompasses cloud models (fda.gov). It recognizes iterative and continuous testing across the lifecycle (fda.gov) and says records should contain sufficient objective evidence that software was assessed and performs as intended (fda.gov). It also says documentation need not exceed what is necessary for the identified risk (fda.gov).

That is the basis for risk-based regression, not a rationale for skipping change assessment. FDA defines regression analysis as determining the impact of a change (fda.gov) and regression testing as rerunning test cases that previously executed correctly (fda.gov). Automated traceability and testing may be objective evidence (fda.gov), while suitable unscripted scenario testing is also contemplated (fda.gov).

European requirements reinforce lifecycle control. EU GMP Annex 11 says risk management should apply throughout the computerized-system lifecycle (health.ec.europa.eu), formal agreements must exist with relevant third parties (health.ec.europa.eu), supplied commercial-product documentation should be reviewed (health.ec.europa.eu), and configuration changes should follow a controlled procedure (health.ec.europa.eu). The Commission's index still lists the January 2011 revision (health.ec.europa.eu).

ISPE turns those principles into procurement fields. Its SaaS quality-agreement article says the agreement should not delegate GxP accountability to the provider (ispe.org), should identify customer-accessible environments (ispe.org), and should allow preproduction impact assessment (ispe.org). Customer testing remains commensurate with GxP risk (ispe.org).

Vendor Evidence Availability Index

Table 2 reports the coded snapshot. P means public evidence, G means a public page confirms gated or customer-only evidence, and U means unknown after the documented search. The parenthetical score is public points plus gated points, out of 20. Each row cites representative first-party evidence rather than implying certification.

Product, category	Cadence, notice, and notes	Impact, issues, pack, tests	API, continuity, agreement	Availability result
Veeva Vault, quality/clinical/RIM	P cadence, P notice, U machine-readable notes	P impact, P issues, G pack, G tests (rn.veevavault.help)	P API, U continuity, U agreement (general.veevavault.dev)	**12/20**, 2 gated, 3 unknown
Oracle Clinical One, EDC	P cadence, P notice, U machine-readable notes	P impact, G issues, G pack, G tests (docs.oracle.com)	U API, U continuity, U agreement	**9/20**, 3 gated, 4 unknown
Qualio, eQMS	P cadence, P notice, U machine-readable notes	P impact, U issues, G pack, U tests (docs.qualio.com)	U API, U continuity, U agreement	**7/20**, 1 gated, 6 unknown
Greenlight Guru, eQMS	P cadence, P notice, U machine-readable notes	P impact, U issues, G pack, G tests (greenlight.guru)	U API, U continuity, U agreement	**8/20**, 2 gated, 5 unknown

Product, category	Cadence, notice, and notes	Impact, issues, pack, tests	API, continuity, agreement	Availability result
MasterControl Insights, eQMS analytics	P cadence, U notice, U machine-readable notes	U impact, G issues, G pack, U tests (labs.mastercontrol.com)	U API, U continuity, U agreement	**4/20**, 2 gated, 7 unknown
OpenClinica 4, EDC	P cadence, U notice, U machine-readable notes	P impact, G issues, U pack, U tests (servicedesk.openclinica.com)	U API, U continuity, U agreement	**5/20**, 1 gated, 7 unknown
Benchling Validated Cloud, ELN	P cadence, P notice, U machine-readable notes	P impact, U issues, G pack, U tests (help.benchling.com)	P API, U continuity, U agreement (docs.benchling.com)	**9/20**, 1 gated, 5 unknown
LabVantage SaaS LIMS	U cadence, U notice, U machine-readable notes	U impact, U issues, G pack, U tests (labvantage.com)	U API, U continuity, U agreement	**1/20**, 1 gated, 9 unknown
IDBS Polar/E-WorkBook, ELN	P cadence, U notice, U machine-readable notes	G impact, P issues, U pack, U tests (help.idbs.com)	P API, U continuity, U agreement (help.idbs.com)	**7/20**, 1 gated, 6 unknown
Tetra Data Platform, lab data	U cadence, G notice, U machine-readable notes	P impact, U issues, G pack, G tests (developers.tetrascience.com)	P API/deprecation, U continuity, U agreement (developers.tetrascience.com)	**7/20**, 3 gated, 5 unknown
LabWare QA/QC SaaS LIMS	P cadence, P notice, U machine-readable notes (labware.com)	U impact, U issues, G pack, U tests	U API, U continuity, U agreement	**5/20**, 1 gated, 7 unknown
Sapio lab informatics, LIMS/ELN	U cadence, U notice, U machine-readable notes	U impact, U issues, G pack, U tests (sapiosciences.com)	U API, U continuity, U agreement	**1/20**, 1 gated, 9 unknown

The table should be read by evidence pathway, not rank order. Public impact assessments and API policies can reduce discovery time before a contract. Gated packs may still be highly useful once access, delivery timing, permitted reliance, and update obligations are contractual. The matrix also shows a recurring blind spot: no sampled supplier demonstrated machine-readable release notes in the fetched public evidence, so that field is U across all 12 products.

Release Cadence, Notice, and Gated Evidence

Cadence statements are meaningful only when release classes are separated. Veeva states that Vault receives a comprehensive release approximately every four months and performs regression testing for each release (veeva.com). Veeva CDMS also says prerelease vaults became available **four weeks** before general availability starting with 25R3 (cdmshelp.veeva.com). Qualio identifies February, May, August, and November 2026 launch-train windows (docs.qualio.com), while Uncountable says it ships a validation kit with every quarterly release (uncountable.com).

Patch cadence may be much faster. Greenlight Guru describes maintenance releases as typically weekly and provides item-level risk statements (greenlight.guru). MasterControl's public FAQ points customers to monthly Insights notes (labs.mastercontrol.com). The burden implication is not that weekly is worse than quarterly. It is that the quality agreement needs a release taxonomy, because minor maintenance with a reliable impact statement may consume less customer effort than an opaque quarterly bundle.

Notice ranges in this dataset illustrate the taxonomy problem. Benchling documents approximately **48 hours** before patch deployment (help.benchling.com). Oracle posts minor-release themes about **two months** in advance (docs.oracle.com). LabWare states at least **30 days** for a new QA/QC SaaS implementation (labware.com). These are different events, so a pooled average would be misleading.

Validation Packs, Test Evidence, and Regression Scope

The most useful supplier pack exposes both design intent and executed evidence. Veeva CDMS says validation documents are available during prerelease (cdmshelp.veeva.com). Oracle says its Product Verification Pack includes requirements testing documentation with objective evidence (docs.oracle.com). TetraScience describes requirements, traceability, validation scripts, and a verification and validation summary report (developers.tetrascience.com).

The customer still needs a configured-use bridge. Qualio says its Quality Director reviews each launch train for features that may require revalidation (docs.qualio.com). Oracle says its Release Implementation Assessment identifies potential impact and provides mitigation plans (docs.oracle.com). TetraScience says a GxP assessment is performed for each platform release (developers.tetrascience.com). These supplier analyses can seed, but not replace, the customer's mapping to enabled modules, interfaces, records, reports, and procedures.

A proportionate regression decision should document:

- **Trigger:** feature, defect fix, platform, configuration, security, data model, or API change.
- **Use mapping:** affected user requirement, workflow, interface, record, report, and control.
- **Risk:** consequence to patient, product quality, data, and regulated process.
- **Supplier leverage:** applicable requirements, traceability, environment, execution date, and result.
- **Customer evidence:** focused scripted test, scenario test, automated check, review, or documented no-test rationale.
- **Decision:** accept, defer an optional feature, apply a controlled workaround, or invoke continuity provisions.

For medical-device production or quality-management-system software within the CSA guidance's scope, FDA says manufacturers are responsible for determining the appropriate assurance activities (fda.gov).

API, Deprecation, Rollback, and Quality Agreements

Integrations can create validation work even when the user interface barely changes. Veeva says all non-Beta Vault API versions remain unchanged (general.veevavault.dev). Benchling states that necessary breaking changes to stable APIs generally receive **6 to 12 months** of lead time (docs.benchling.com) and gives beta

endpoints a **30-day** deprecation period (docs.benchling.com). TetraScience states at least **six months** of notice for deprecating generally available features or components (developers.tetrascience.com).

Public rollback procedures were not verified for the 12 sampled products. That U code should trigger a contractual question, not an adverse inference. The UK's Medicines and Healthcare products Regulatory Agency says arrangements must exist to restore software or systems to their original validated state (assets.publishing.service.gov.uk) and that contractual business-continuity arrangements should be tested (assets.publishing.service.gov.uk).

A release quality agreement should answer, in controlled language:

- **Classification:** Which release types exist, and what makes a change GxP relevant?
- **Notice:** How many calendar days apply to each type, including urgent changes?
- **Environment:** When does the customer receive a representative preproduction tenant?
- **Evidence:** Which plans, requirements, traceability records, protocols, and results arrive with each class?
- **Issues:** Where are known issues published, and how are late discoveries communicated?
- **Acceptance:** Can optional features be deferred, and what happens if customer acceptance is incomplete?
- **Integration:** What API stability and deprecation periods apply?
- **Continuity:** What restore, rollback, fallback, and recovery objectives are tested?
- **Exit:** How long is allowed for data repatriation? ISPE identifies this explicitly (ispe.org).
- **Correction:** Who can challenge an impact classification, and by when must the supplier respond?

Data Analysis and Evidence

The index yields three decision-useful calculations. First, the 12-product sample produces **240 possible public points** across 10 fields. The table records **75 evidence points**, or **31.25%** of the theoretical maximum. Of those, **56** are public points and **19** are gated points. This is a documentation-access measure derived from Table 2, not a population estimate and not a compliance rate.

Second, public support clusters around cadence, notice, impact, and validation-pack descriptions. Machine-readable notes were verified for **0 of 12** sampled products, and a general public rollback procedure was verified for **0 of 12**. By contrast, every product met the inclusion rule through at least one release or validation statement. The zeroes mean no qualifying public evidence was verified by the cutoff, not that the control is absent.

Third, numeric notice data cannot responsibly be compressed into a vendor league table. The observed statements span about **48 hours** for Benchling patches (help.benchling.com), **30 days** for LabWare's described implementation notice (labware.com), **four weeks** for Veeva CDMS prerelease vaults (cdmshelp.veeva.com), and roughly **two months** for Oracle minor-release themes (docs.oracle.com). They describe different events. The correct analytical move is stratification by release class.

Customer regression-impact worksheet

Table 3 provides a calculation that a system owner can populate without invented benchmark hours. It separates unavoidable triage from release-specific testing.

Input or output	Symbol and formula	Customer-supplied evidence
Releases per year	R	Supplier calendar and actual prior-year count
Triage hours per release	T	Time records for note review and impact meeting
Share affecting configured GxP use	A	Prior impact assessments, from 0 to 1
Regression hours per impacted release	H	Current approved test inventory and execution history
Annual supplier-governance hours	G	Audit, periodic review, agreement, and access administration
Loaded hourly rate	C	Finance-approved internal or blended rate
Annual hours	**R × T + R × A × H + G**	Calculated scenario output
Annual labor cost	**(R × T + R × A × H + G) × C**	Calculated scenario output

The model makes the supplier-evidence effect visible. Better structured notes may reduce T. Reliable impact classification may reduce uncertainty in A. Reusable objective evidence may reduce H, but only where scope, environment, configuration, and acceptance criteria align. A sensitivity analysis should vary A and H, because those assumptions often dominate. FDA's position that documentation should not exceed evidence necessary for the risk supports this proportional approach (fda.gov).

Implications and Future Directions

The immediate implication for procurement is that portal access is a commercial term with validation consequences. Oracle says known issues are available only in My Oracle Support (docs.oracle.com). IDBS says its Polar Release Impact Assessment requires Community credentials (help.idbs.com). TetraScience directs users to request GxP package access through its Trust Center (trust.tetrascience.com). Buyers should test access during diligence, identify named recipients, and specify continued access through termination and record-retention periods.

The second implication is technical. Machine-readable release evidence could make controlled comparison and traceability more efficient, but this review did not verify such a feed in the sample. A downloadable spreadsheet is not automatically machine-readable in a governed sense. Buyers should specify stable identifiers, release and correction timestamps, change class, affected module and API, GxP relevance, known-issue links, and supersession history. FDA recognizes automated traceability and electronic work capture as objective evidence (fda.gov).

The third implication is governance over time. Annex 11 calls for periodic evaluation of the validated state (health.ec.europa.eu), and ISPE says releases must use formal change control (ispe.org). The index should therefore be versioned, with dated source logs, archived vendor responses, disclosed conflicts, and a public correction window. Recalculation should preserve the prior snapshot so buyers can distinguish a supplier change from a research correction.

Frequently Asked Questions (FAQs)

Does a vendor validation pack validate the customer's SaaS use?

No. It can supply reusable evidence, but the customer must connect that evidence to intended use, configuration, data, integrations, procedures, and risk. ISPE recommends leveraging supplier knowledge and documentation (ispe.org), while retaining regulated accountability.

What is continuous validation for GxP SaaS?

It is a lifecycle operating model in which every relevant supplier release is captured, triaged, assessed, evidenced, approved, and linked to periodic review. It does not mean continuous full regression. FDA recognizes evidence from iterative and continuous testing (fda.gov).

How should unknown evidence be treated in vendor selection?

Unknown should become a diligence question and, if material, a contractual deliverable. It should not be scored as proof of absence. The buyer should request a sample pack, verify portal access, record the product edition and environment, and obtain a written response within the correction window.

What most reduces regression-testing burden?

No single artifact does. The useful combination is stable change identifiers, module-level impact, known issues, representative preproduction access, traceable supplier results, and an API deprecation policy. Greenlight Guru says automated test results are available to customers (greenlight.guru); whether they reduce customer testing depends on applicable scope and risk.

Conclusion

The evidence index reframes GxP SaaS release validation as an observable supply-chain interface. Across 12 products and 10 fields, public documentation was uneven and customer-gated evidence was common. The dataset supports comparisons of access and specificity, not conclusions about product quality or compliance. Its most useful distinctions are public versus gated, release type versus generic cadence, and supplier testing versus evidence applicable to configured use.

Regulated buyers should require a release taxonomy, advance notice, a representative test environment, feature-level impact, known-issue access, traceable execution evidence, API and deprecation rules, continuity procedures, and data-exit timing. They should then measure their own burden with release count, triage time, impacted-release share, regression inventory, governance effort, and an approved labor rate. That produces a defensible release-readiness plan without inventing universal testing-hour benchmarks.

The index should be maintained as a dated, correction-friendly dataset. New supplier responses should be published separately from public-source findings, gated artifacts should be verified under contract, and unknowns should remain unknown until evidence appears. That discipline preserves the practical value of supplier documentation while keeping validation decisions risk based, intended-use specific, and owned by the regulated company.

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/media/188844/download
2. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-management-system-software
3. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11/subpart-A/section-11.1
4. https://intuitionlabs.ai/articles/21-cfr-part-11-electronic-records-signatures-overview
5. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11/subpart-B/section-11.10
6. https://ispe.org/pharmaceutical-engineering/march-april-2022/quality-agreements-saas-solutions-intended-gxp-use
7. https://rn.veevavault.help/en/gr/archive/25r3/about-the-25r3-release/
8. https://docs.oracle.com/en/industries/life-sciences/clinical-one/release-notes/product-verification-pack-pvp.html
9. https://docs.qualio.com/en/articles/6996702-qualio-launch-trains
10. https://help.benchling.com/hc/en-us/articles/14638731364237-Benchling-Validated-Cloud-Communications
11. https://www.labware.com/pt/lims/saas/qaqc
12. https://csrc.nist.gov/glossary/term/Software_as_a_Service
13. https://picscheme.org/docview/3444
14. https://intuitionlabs.ai/
15. https://www.benchling.com/notebook
16. https://www.labvantage.com/press-release/labvantage-adds-vendor-validation-to-its-software-as-a-service-lims/
17. https://www.fda.gov/media/73141/download
18. https://health.ec.europa.eu/document/download/8d305550-dd22-4dad-8463-2ddb4a1345f1_en
19. https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en
20. https://general.veevavault.dev/vault-api/getting-started/endpoint-structure/
21. https://docs.oracle.com/en/industries/life-sciences/clinical-one/release-notes/get-access-known-issues-list.html
22. https://docs.qualio.com/en/articles/6633565-qualio-validation-overview
23. https://www.greenlight.guru/software-validation-guidance
24. https://labs.mastercontrol.com/insights-help/Content/Get%20Started/FAQ.htm
25. https://servicedesk.openclinica.com/support/solutions/articles/158000452227-openclinica-4-release-notes-2026
26. https://docs.benchling.com/v2-beta/docs/stability
27. https://help.idbs.com/DocumentationPortal/Polar/LATEST/en/26-x-polar-platform-release-notes.html
28. https://help.idbs.com/DocumentationPortal/Polar/LATEST/en/what-s-new-e-workbook-api-documentation.html

29. https://developers.tetrascience.com/docs/tetrascience-gxp-offerings
30. https://developers.tetrascience.com/docs/tetrascience-release-types
31. https://www.sapiosciences.com/news/sapio-sciences-announces-full-gxp-validation-of-its-unified-lab-informatics-platform-and-suite-of-solutions/
32. https://www.veeva.com/eu/wp-content/uploads/2025/12/Veeva_Vault-Validation_Features-Brief_EU.pdf
33. https://cdmshelp.veeva.com/lr/rn/general-releases/25r3/
34. https://www.uncountable.com/solution-briefs/compliance-gxp
35. https://docs.oracle.com/en/industries/life-sciences/clinical-one/release-notes/want-know-whats-every-release-more.html
36. https://docs.qualio.com/en/articles/6666258-executing-qualio-validation
37. https://docs.oracle.com/en/industries/life-sciences/clinical-one/release-notes/download-release-implementation-assessment-document.html
38. https://assets.publishing.service.gov.uk/media/5aa2b9ede5274a3e391e37f3/MHRA_GxP_data_integrity_guide_March_edited_Final.pdf
39. https://trust.tetrascience.com/
40. https://intuitionlabs.ai/articles/deviations-capa-change-control
41. https://ispe.org/publications/guidance-documents/gamp-5-guide-2nd-edition

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