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ValGenesis vs Kneat Gx vs Veeva Validation Management

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Executive Summary

ValGenesis vs Kneat Gx vs Veeva Validation Management is a decision about where validation evidence will be created, connected, reviewed, and retained. **ValGenesis iVal** documents authoring, execution, and change-impact traceability within a broader modular suite. (www.valgenesis.com) **Kneat Gx** documents configurable validation workflows spanning commissioning, equipment, and computerized systems. (kneat.com) **Veeva Validation Management** emphasizes digital execution unified with QualityDocs and its quality management system. (www.veeva.com) These are overlapping propositions, with different implications for the surrounding quality architecture.

The most useful distinction is between a documented capability and a demonstrated evidence lifecycle. ValGenesis describes dedicated cleaning functionality through **iClean**. (www.valgenesis.com) Kneat documents cleaning calculations and analytical-instrument workflows. (kneat.com) Veeva documentation includes cleaning and method validation, but that scope alone does not establish an equivalent specialist calculation engine. (quality.veevavault.help) Buyers should test their own acceptance-limit rationale, reusable requirements, discrepancies, release gates, and review process. Unknown commercial entitlements should remain unknown until the proposal identifies them. (cdn.who.int)

As of **October 19, 2026**, the research established no numeric public list price for any contender. Kneat's filing dated **February 25, 2026** describes annual subscriptions priced in proportion to licenses and contracts typically lasting **three years** plus renewals. (investors.kneat.com) These are vendor-wide commercial disclosures, not a buyer-specific quotation. No independently controlled comparison of execution speed, migration effort, or total ownership cost was established. Older survey evidence also needs boundaries: KPMG and KENX surveyed **163 life-sciences professionals** in **September 2022**, with geography unstated, not a current census of software installations. (kpmg.com)

The recommendation is a conditional shortlist: examine ValGenesis for a modular validation-and-cleaning program, Kneat for configurable workflows across validation disciplines, and Veeva where connecting validation with an existing quality environment is valuable. Then apply the same requirements-to-evidence challenge to every finalist. The regulatory foundation is intended-use validation, risk-based assurance, and retrievable records, rather than software being compliant by itself. (health.ec.europa.eu) The United States

Food and Drug Administration's (FDA) current computer software assurance guidance concerns medical-device production and quality-management-system software; its scope should not be generalized to every pharmaceutical application. The report therefore proposes measurable demonstrations and leaves untested capabilities unscored. (www.ecfr.gov) (www.fda.gov)

Introduction and Background

Digital validation should replace the fragmented evidence chain, not merely the paper protocol. For buyers of paperless validation software for life sciences, the chain is the central selection requirement. For this report, it means managing requirements, risk decisions, tests, results, exceptions, approvals, and subsequent changes as related controlled records. USDM's lifecycle framing includes those activities and extends through maintenance and retirement. A protocol's final approval is therefore an intermediate milestone rather than the end of the evidence lifecycle. (www.usdm.com) (ispe.org)

The intended audience comprises quality systems leaders, validation directors, commissioning, qualification, and validation (**CQV**) teams, and life-sciences information technology (**IT**) procurement groups. The comparison covers computer system validation (**CSV**), computer software assurance (**CSA**), cleaning, equipment and analytical instruments, and ongoing review. ASTM's current equipment-verification scope includes manufacturing systems, supporting utilities, and associated monitoring and control systems. This helps distinguish equipment assurance from a purely document-centric software purchase. (store.astm.org) (health.ec.europa.eu)

A **quality management system (QMS)** should retain the quality-event ownership, escalation rules, and corrective-action governance assigned to it by the organization. Likewise, document management should retain ownership of controlled policies and procedures where that is the established architecture. The editorial recommendation is to define those boundaries before configuring the validation platform. Veeva's documented unification with QualityDocs and QMS illustrates why boundaries matter even when applications share an environment. (www.veeva.com)

IntuitionLabs' perspective in this comparison is that of an adjacent adviser, not a competing software option. The selection framework below is editorial analysis; product descriptions are attributed vendor documentation, and regulatory statements come from official sources. Public documentation was researched for the publication date. No hands-on product testing or buyer-specific commercial negotiation was performed.

Good practice (GxP) record controls remain part of the operating system of procedures, responsibilities, configuration, and training. The International Society for Pharmaceutical Engineering (**ISPE**) describes Good Automated Manufacturing Practice (**GAMP**) guidance as promoting systems fit for intended use and explicitly says it is not a prescriptive method or standard. A vendor's checklist cannot settle a site's intended-use assessment. (ispe.org) (health.ec.europa.eu)

ValGenesis

Capabilities

The older **Validation Lifecycle Management System (VLMS)** terminology remains visible in ValGenesis material, but its refreshed lifecycle article points to iVal for validation authoring, execution, traceability, and risk-based decisions. The broader **Validation Lifecycle Suite (VLS)** is described as modular and implementable in phases. Procurement should use the current proposed product names and entitlements rather than assume that a historical VLMS description defines the present contract. (www.valgenesis.com)

ValGenesis says customers can configure templates, forms, workflows, and entities. Its iVal page describes parallel review and approval and change-impact assessment identifying affected requirements, specifications, and tests. These claims are relevant to reusable libraries and controlled change, but the demonstration should show what happens to already approved evidence when a shared requirement changes.

(www.valgenesis.com)

The **iClean** application describes version-controlled cleaning data and calculations considering shared surfaces and batch sizes. These are relevant to maximum allowable carryover (**MACO**) and health-based exposure limit workflows. Separately, **iOps** documents offline mobile log-form execution. Its behavior should not be assumed to establish the behavior of an iVal execution session. (www.valgenesis.com)

Adoption

A supplier announcement says Ulrich Medical selected iVal for an enterprise-system CSV program, initially at headquarters with planned expansion. It establishes a named selection and intended rollout, not a measured productivity outcome. Such references are useful for requesting a comparable implementation discussion, with similar intended use and migration complexity. (www.valgenesis.com)

Strengths and Limitations

The editorial reason to shortlist ValGenesis is the documented relationship between core validation and specialist lifecycle applications. The main procurement uncertainty is the precise combination of licenses, interfaces, services, and configuration needed for the buyer's scope. Suite modularity does not by itself answer that commercial question. (www.valgenesis.com)

The iVal datasheet landing page expressly lists offline execution with synchronization. It supplies a stronger public lead than assuming offline capability from mobile access, while leaving conflict resolution and recoverability for testing. (www.valgenesis.com)

- **Challenge authoring:** Change a reusable requirement after a protocol has been approved, then inspect the proposed impact.
- **Challenge execution:** Disconnect the intended device, record results, reconnect, and reconcile concurrent activity.
- **Challenge packaging:** Identify which cleaning, logbook, integration, and archive deliverables appear in the signed scope.

Kneat Gx

Capabilities

Kneat presents **Kneat Gx** as a configurable platform across commissioning, qualification, equipment, and computer-system validation. Its CSV page documents linking requirements, risks, and tests, with an automatically built traceability matrix. This makes requirements reuse and exception handling appropriate demonstration targets rather than assuming that document digitization alone provides lifecycle control. (kneat.com)

A release article describes native **Risk Entities** and reuse of **Data Entities** across instances. Those are specific documented mechanisms worth exploring for enterprise libraries. The buyer should establish who owns a global entity, who may revise it, and how local adaptations affect existing protocols. The article is evidence of those features, not proof of the latest generally available release. (kneat.com)

Kneat's cleaning page describes progression from protocol creation through execution, approval, and revalidation, as well as in-platform cleaning calculations. Its analytical-instrument page separately documents coverage from user requirements to final reports and calibration and requalification tracking. The distinction matters when instrument assurance must connect to recurring maintenance evidence. (kneat.com)

Adoption

The research did not establish a comparable installed-base measure across all contenders. Kneat's implementation offering does document deployment and validation, process design and configuration, and acceptance-testing support. Buyers can use that scope to request an implementation plan and reference matching their own configuration burden, rather than infer adoption speed from a broad customer count. (kneat.com)

Strengths and Limitations

The editorial reason to shortlist Kneat is documented configurability across several validation disciplines, including explicit instrument and cleaning workflows. Its commissioning page describes a risk-based lifecycle approach, which should be tested against the site's equipment-verification method rather than treated as a universal workflow. (kneat.com)

Kneat documents a **Collections** feature for digital audit handover. That does not establish a complete, independently readable archive after contract termination. Similarly, remote parallel or sequential approvals establish connected collaboration, not disconnected execution. Offline operation remained unverified in the researched materials. (kneat.com)

Its current annual filing includes periodic review and revalidation management among platform use cases. This closes a scope question but does not demonstrate review scheduling, record selection, overdue escalation, or the exact licensed configuration. (investors.kneat.com)

- **Challenge reuse:** Revise a shared risk entity and show downstream impact and local approval boundaries.
- **Challenge instruments:** Link qualification evidence with calibration and requalification status.

- **Challenge exit:** Produce a representative Collections handover and compare it with the required retention package.

Veeva Validation Management

Capabilities

Veeva positions **Validation Management** as unified with QualityDocs and QMS, with digital test execution and automatically generated traceability and summary reports. Its public help goes beyond that positioning: it documents placeholder traceability records for requirements that should be tested but have not yet been planned for testing. This is useful evidence for evaluating coverage-gap visibility. (www.veeva.com) (quality.veevavault.help)

The authoring interface permits simultaneous editing of setup and execution steps. Linking a requirement to an execution step updates the traceability matrix. A documented boundary deserves an explicit reuse test: when copying a script to a different validation entity, requirements are not copied and Vault warns the user. The buyer should test the intended reuse pattern rather than assume copied scripts retain every relationship. (quality.veevavault.help)

Execution documentation allows discrepancies to be created from the affected test step and requires an electronic signature for each change to a completed step. Configuration documentation also describes checking that linked requirements are approved before a test becomes pre-approved. These are concrete mechanisms to include in a release-gating demonstration. (quality.veevavault.help)

Adoption

The case for an existing Veeva customer is architectural fit, subject to implementation review: validation can be evaluated alongside documented quality-document and quality-event connections. That is an editorial integration hypothesis, not proof of lower implementation cost or automatic entitlement to adjacent applications. The vendor's unified-product positioning supports the hypothesis but does not price it. (www.veeva.com)

Strengths and Limitations

Veeva documents entity-level periodic reviews, including system, audit-trail, and privileged-user reviews. This provides a specific starting point for ongoing-review demonstrations. Publicly documented scope also includes cleaning and method validation, but the materials reviewed do not establish specialist cleaning-calculation equivalence with the other contenders. (quality.veevavault.help)

The documented attachment download is a **ZIP** containing test-step and discrepancy attachments. It should not be represented as a complete archive of requirements, relationships, signatures, and audit history. Separately, Station Manager's offline quality-document viewing does not establish offline Validation Management execution. (quality.veevavault.help)

- **Challenge reuse:** Copy between validation entities and reconcile requirement links deliberately.

- **Challenge approval:** Attempt pre-approval with an unapproved requirement and inspect the configured gate.
- **Challenge retention:** Compare the attachment ZIP with the complete executed-record and audit-history package.

Feature Comparison

Validation-use-case crosswalk

Table 1 summarizes public documentation, not feature parity or contractual inclusion. “Confirm” means the scoped behavior still needs evidence; it does not mean the product lacks it. A general validation workflow and a specialist scientific calculation workflow should be evaluated separately.

Use case	ValGenesis	Kneat Gx	Veeva Validation Management
CQV and equipment	iVal lifecycle positioning includes CQV. (www.valgenesis.com)	Commissioning and qualification application describes a risk-based lifecycle. (kneat.com)	Documentation includes facilities, equipment, and utilities. (quality.veevavault.help)
CSV and CSA evidence	iVal names CSV and CSA in its core scope. (www.valgenesis.com)	CSV page links requirements, risks, and tests. (kneat.com)	Requirements and test-execution workflows are documented; configure the site's assurance method. (quality.veevavault.help)
Cleaning	iClean documents controlled cleaning data and calculation inputs. (www.valgenesis.com)	Cleaning application documents MACO and exposure-limit calculations. (kneat.com)	Cleaning validation is in documented scope; confirm calculation needs separately. (quality.veevavault.help)
Analytical instruments	iVal describes raw-data and metadata capture from instruments. (www.valgenesis.com)	Dedicated instrument workflow covers requirements through reports. (kneat.com)	Equipment and method scope is documented; confirm the instrument-specific workflow. (quality.veevavault.help)
Ongoing review	Refreshed VLMS material describes periodic-review scheduling; confirm current iVal configuration. (www.valgenesis.com)	Annual filing lists periodic review and revalidation. (investors.kneat.com)	Entity-level system, audit-trail, and privileged-user reviews documented. (quality.veevavault.help)

The crosswalk supports a use-case shortlist, not a ranking. For cleaning, a convincing demonstration must reproduce justified acceptance limits, sampling context, and change impact. The World Health Organization (**WHO**) guidance calls for cleaning acceptance criteria with a rationale for the limits. Merely showing that a platform can host a cleaning protocol does not establish that calculation requirement. (cdn.who.int)

For computer system validation software comparison, risk rationale is equally important. The International Council for Harmonisation (**ICH**) expects quality-risk evaluation to use scientific knowledge and effort proportionate to risk. A reusable template should preserve the reasoning for the assurance approach as well as the resulting test steps. (database.ich.org) (cdn.who.int)

For **ValGenesis vs Kneat Gx**, use the cleaning and instrument rows to choose the harder representative workflow, then test the same evidence chain. For **ValGenesis vs Veeva Validation Management**, compare the proposed modular scope with the proposed connected-quality scope, including each system's record ownership. For **Kneat Gx vs Veeva Validation Management**, prioritize reusable requirements, exceptions, and ongoing reviews before judging interface familiarity. These are editorial demonstration priorities derived from the crosswalk, not measured product rankings.

Integrations and the evidence boundary

Table 2 separates documented integration and export mechanisms from the evidence still required for a production commitment. An application programming interface (**API**), including one using Representational State Transfer (**REST**), permits integration development; it does not establish a supported connector, version compatibility, or a validated interface.

Evidence boundary	ValGenesis	Kneat Gx	Veeva Validation Management
Enterprise connection	Describes prebuilt connectors, REST APIs, webhooks, and import/export; named versions need confirmation. (www.valgenesis.com)	Documents REST import/export of documents, drawings, and data. (kneat.com)	General Vault API supports document and object-record operations; a specific connector was not established. (platform.veevavault.help)
Disconnected work	iVal datasheet lists offline execution with synchronization; test the actual device. (www.valgenesis.com)	Offline execution unverified in researched sources; connected approvals are documented. (kneat.com)	Offline validation execution unverified; separate Station Manager viewing must not be substituted. (quality.veevavault.help)
Evidence handover	Import/export mechanisms documented; full archive acceptance still required. (www.valgenesis.com)	Collections provides digital audit handover; independent readability still needs proof. (kneat.com)	Script and discrepancy attachment ZIP documented; full archive completeness still needs proof. (quality.veevavault.help)

A “native” label should identify what ships in the contracted application. A connector claim should identify the supported source and destination versions, mappings, owner, and release policy. A custom API interface should identify design, monitoring, reconciliation, and maintenance responsibilities. WHO's supplier-management guidance supports making lifecycle responsibilities explicit in contracts. (cdn.who.int)

The integration demonstration should include the actual QMS, asset register, document repository, and identity provider wherever these are in scope:

- **Record identity:** Preserve immutable identifiers and distinguish a reference from a transferred controlled record.
- **Error handling:** Reject an invalid payload, replay a duplicate, and reconcile the final state.
- **Access:** Remove a user's authorization while preserving historic signatory identity.
- **Ownership:** Identify which system owns approval status and which interface may change it. (cdn.who.int)

For single sign-on (**SSO**), National Institute of Standards and Technology (**NIST**) federation guidance provides technical evaluation criteria, including signed assertions and audience checks. Those controls concern authentication; they should be tested alongside application authorization and electronic-signature behavior, not treated as substitutes for them. (pages.nist.gov)

Performance and Benchmarks

What public evidence can establish

No independently controlled head-to-head benchmark was established for these platforms in this research. Vendor descriptions establish advertised workflows, not comparable elapsed time, execution effort, or review quality. A benchmark should therefore use a buyer-controlled protocol, the same source evidence, and agreed acceptance criteria. WHO's computerized-system guidance relates validation effort to risk, complexity, and intended use, providing a defensible basis for choosing representative tasks. (cdn.who.int)

For CQV, ASTM lists **E2500-25** as active, updated **April 1, 2025**. (store.astm.org) Its scope addresses manufacturing systems fit for intended use; the publicly readable listing does not supply the full standard. Buyers should use their applicable approved method when defining demonstration acceptance, rather than score vendors against an assumed universal template. (store.astm.org) (ispe.org)

A traceability stress test

The following is a **Hypothetical Example**, defined by the report for a global procurement exercise as of October 19, 2026. Its identifiers and quantities are test inputs, not observed product performance. Consider requirement **REQ-A**: only an authorized reviewer may approve an executed protocol. Link it to risk **RISK-A**, a test **TEST-A**, a deliberately recorded discrepancy **DISC-A**, and an approved retest. Annex 15 treats the user requirements specification (**URS**) as a lifecycle reference, making this chain a useful selection exercise. (health.ec.europa.eu)

The script should challenge the entire record lifecycle:

- **Author:** Import the approved requirement and risk rationale; version a reusable test.
- **Execute:** Record a passing result, an attachment, an interrupted session, and a deliberately unexpected result.
- **Except:** Open the discrepancy from the affected evidence and retain its disposition and retest link.
- **Trace:** Show the requirement's planned coverage, executed result, discrepancy, retest, and approval.
- **Change:** Amend an approved requirement and identify the affected evidence without rewriting history.
- **Release:** Attempt final approval before all required dispositions are accepted.
- **Review:** Open a periodic-review task and inspect relevant changes, privileges, and audit history.
- **Export:** Deliver the complete package, then reconstruct the chain in the proposed archive.

Record elapsed authoring time, executor effort, reviewer effort, reconciliation effort, and unresolved links separately. Record test environment, product configuration, network conditions, device, and participants' training. (cdn.who.int) These are editorial measurement recommendations, not regulatory time limits or

claimed vendor benchmarks. The assurance approach should remain proportionate to the intended risk, consistent with ICH's treatment of formality as a continuum. (database.ich.org)

Expected evidence package

A useful acceptance package contains the requirement and its version, risk decision, approved test, raw result and attachments, discrepancy history, retest evidence, approvals, and relationship manifest. It should also preserve the audit events needed to interpret changes. (www.ecfr.gov) The Pharmaceutical Inspection Co-operation Scheme (**PIC/S**) guidance calls for original data with relevant metadata and audit trails in a secure, validated process. (picscheme.org)

For United States closed-system records within scope, Title 21 of the Code of Federal Regulations (**21 CFR**), **Part 11**, specifies accurate and complete copies in human-readable and electronic form, while FDA's scope guidance discusses preserving content and meaning. The proposed package should be tested against those needs and the applicable predicate rules, not against whether an export button exists. (www.ecfr.gov) (www.fda.gov)

Data Analysis and Evidence

Pricing comparison and ownership cost

The **ValGenesis, Kneat, and Veeva validation pricing comparison** remains proposal-based: no numeric list price was established from the current official pages researched. This is an evidence limitation, not a claim that every commercial document is confidential. Kneat's current annual filing describes yearly advance subscription charging, pricing proportional to licenses, and typical three-year terms plus renewals. The geographic scope of the filing's commercial description is company-wide, not a country-specific tariff; no currency amount is disclosed for a comparable configuration. (investors.kneat.com)

Request equivalent written scenarios covering production and nonproduction environments, user or license categories, sites, modules, interfaces, retention, and exit services. Compare **total ownership cost** as subscription plus implementation, migration, integration, validation, administration, upgrades, and eventual exit. This is an editorial accounting framework, not an estimated market price. Migration and acceptance-testing responsibilities matter because suppliers can provide services without eliminating the buyer's own intended-use responsibilities. (kneat.com) (health.ec.europa.eu)

What the survey does and does not measure

The historical quantitative source is KPMG and KENX's September 2022 survey of **163 professionals** knowledgeable about or overseeing CSV activities. (kpmg.com) Its unit is people, its geography is unstated, and it is not a 2026 procurement sample. Its validation-tool chart allows multiple responses and provides no item-specific response denominator usable here. Consequently, its vendor bars should not be turned into exclusive market shares or current adoption rankings. (kpmg.com)

This evidence gap makes a controlled buyer demonstration more useful than a synthetic industry league table. Adoption should be evaluated through relevant references, configuration similarity, operating scale, and the ability to reproduce the buyer's evidence package.

Completeness and weighted decisions

For the hypothetical global demonstration above, define **20 required evidence relationships**, of which **18** are verified and **2** remain unresolved. The editorial completeness calculation is $18 / 20 \times 100 = 90\%$. The source of these counts is the report's illustrative test specification dated October 19, 2026; the unit is a verified relationship, and there is no measured geography or vendor result. A critical missing signature-to-record link can still block acceptance despite a high percentage. United States signature-linkage requirements provide a concrete reason to check that relationship explicitly. (www.ecfr.gov)

Table 3 provides proposed weights for three buyer archetypes. All cells are **editorial percentages**, defined on October 19, 2026 for the hypothetical global selection exercise, not survey results or product scores.

Decision criterion	CQV-led manufacturer	CSV/CSA-led enterprise	Existing Veeva quality environment
Use-case depth and scientific calculations	30%	15%	15%
Traceability, exceptions, and release control	25%	30%	25%
Integration and identity fit	15%	20%	30%
Migration and readable retention	20%	20%	20%
Commercial and operating model	10%	15%	10%
Total	100%	100%	100%

The weights express priorities, not a winner. Score demonstrated criteria on an agreed rubric and report **evidence coverage** alongside any weighted score. If a criterion is untested, leave it unknown; do not assign zero or silently redistribute its weight. Risk-based effort should follow the importance of the decision rather than the amount of readily available sales material. (database.ich.org)

- **Source:** Label each input as official requirement, vendor documentation, observed demonstration, or editorial assumption.
- **Date:** Record the product configuration and commercial proposal date.
- **Unit:** Separate elapsed time, labor time, records, relationships, and currency.
- **Coverage:** Show unknown weight explicitly, with critical acceptance gates evaluated separately.
- **Decision:** Document why the observed evidence is sufficient for the intended use.

Implications and Future Directions

Migration should preserve meaning

Before committing, divide the migration inventory into active work, approved evidence, reusable libraries, and legacy archives. These categories are editorial planning recommendations, not product capability claims. For applicable records, United States rules require retention that supports retrieval, while Medicines and

Healthcare products Regulatory Agency (**MHRA**) guidance treats metadata as integral to the original record. The migration plan should preserve context, not merely move files. (www.ecfr.gov) (assets.publishing.service.gov.uk) (picscheme.org)

- **Active protocols:** Choose completion in the source system or controlled re-establishment in the destination, with ownership recorded.
- **Approved evidence:** Preserve the original version, approval context, attachments, and relationship identifiers.
- **Libraries:** Deduplicate deliberately, retaining the history behind approved reusable content. (assets.publishing.service.gov.uk)
- **Archive:** Test retrieval without relying on an active production account or an undocumented conversion. (picscheme.org)
- **Reconciliation:** Compare record inventories, relationship counts, signatures, and representative rendered packages. (www.ecfr.gov)
- **Cutover:** Define write access, responsibility for open discrepancies, rollback conditions, and acceptance approval.

WHO guidance calls for preservation of links involving audit trails and electronic signatures during migration. For Good Laboratory Practice (**GLP**) computerized systems, Organisation for Economic Co-operation and Development (**OECD**) guidance similarly addresses usability, content, and meaning, as well as restoration and readability checks. These are relevant criteria for GLP instrument environments; they should not be presented as universal GMP legal requirements. (cdn.who.int) (www.oecd.org)

A recovery backup is a different deliverable from a readable retention archive. MHRA makes that distinction explicitly. Ask each supplier to demonstrate how the agreed package can be retrieved, interpreted, and checked after a system upgrade or retirement. This should be an acceptance activity with representative evidence rather than an assurance based on file-extension familiarity. (assets.publishing.service.gov.uk) (health.ec.europa.eu)

Ongoing review and change

For European Union Good Manufacturing Practice (**GMP**) computerized systems, Annex 11 calls for periodic evaluation and checks on archived-data accessibility, readability, and integrity. (health.ec.europa.eu) The review program should therefore examine configured functions, changes, open discrepancies, privileges, and relevant operating history. (www.gov.uk) In GLP settings, OECD also relates periodic-review frequency and depth to risk and complexity. (www.oecd.org)

PIC/S places audit-trail review within routine data review and approval. The demonstration should distinguish reviewing individual record events from system-level periodic evaluation. A dashboard or available audit log is useful only if reviewers can identify the relevant event, understand its effect, and record the required disposition. This is a workflow and procedural question as well as a software question. (picscheme.org) (www.ecfr.gov)

The United States signature display and record-linkage requirements supply further concrete checks: preserve signer identity, execution date and time, meaning, and linkage in the retained representation. SSO identity alone does not prove those properties. (www.ecfr.gov) (pages.nist.gov)

Keep regulatory and product roadmaps distinct

FDA's final CSA guidance is dated **February 2026**, superseding its **September 2025** guidance, and addresses medical-device production and quality-management-system software. (www.fda.gov) It supports risk-based assurance with appropriate testing methods, not the removal of evidence obligations from every CSV program. (www.fda.gov) (cdn.who.int)

At the publication-date check, the European Commission's current EudraLex listing still identifies the **January 2011** Annex 11 revision, while the separate consultation material identifies revised guidance as draft. (health.ec.europa.eu) Teams should distinguish operative expectations, consultation proposals, and vendor roadmaps in procurement records. Applicable requirements and intended-use decisions should be confirmed by the organization's quality and regulatory specialists.

Conclusion

Selecting among ValGenesis, Kneat Gx, and Veeva Validation Management requires a comparison of the same evidence lifecycle. The documented differences justify conditional shortlists, but they do not establish a universal winner. ValGenesis warrants examination where a modular validation and cleaning program is central; Kneat where configurable workflows across validation disciplines are central; Veeva where connected quality architecture is central. These are the report's selection hypotheses, to be tested rather than converted into unsupported scores.

The decisive demonstration starts with the buyer's requirement and risk rationale, follows execution and exceptions, challenges release, and ends with a readable, complete retention package. It also establishes who owns connected quality records, how migration preserves meaning, and what remains available after the production contract ends.

Commercial comparison should use equivalent written scopes. A subscription quote without implementation, interfaces, migration, ongoing assurance, and exit provisions is insufficient for the proposed ownership-cost analysis. Likewise, a feature that has not been demonstrated should remain unknown, with its decision weight visible.

The practical outcome is a documented selection whose claims can be traced to official requirements, supplier documentation, and observed acceptance evidence. That approach gives procurement, quality, and validation teams a shared basis for a decision while preserving the distinctions between vendor claims, analyst judgment, and tested performance.

Source links

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

1. <https://www.valgenesis.com/blog/valgenesis-vlms-5.0-next-gen-validation-lifecycle-management>

2. <https://kneat.com/solution>
3. <https://www.veeva.com/products/veeva-validation-management>
4. <https://www.valgenesis.com/application/iclean>
5. <https://kneat.com/application/cleaning-validation>
6. <https://quality.veevavault.help/en/gr/50533904>
7. https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1019-annex3-gmp-validation.pdf?download=true&sfvrsn=9440a5c_0
8. <https://investors.kneat.com/static-files/322654f6-a888-4e1a-8d53-a4c19dd4ba16>
9. <https://kpmg.com/kpmg-us/content/dam/kpmg/pdf/2022/shifting-from-compliance-to-quality.pdf>
10. https://health.ec.europa.eu/document/download/8d305550-dd22-4dad-8463-2ddb4a1345f1_en?filename=annex11_01-2011_en.pdf
11. <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11/subpart-B/section-11.10>
12. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-management-system-software>
13. <https://www.usdm.com/continuous-compliance/validation-lifecycle-management>
14. <https://ispe.org/topics/gamp>
15. <https://store.astm.org/e2500-25.html>
16. https://health.ec.europa.eu/document/download/7c6c5b3c-4902-46ea-b7ab-7608682fb68d_en?filename=2015-10_annex15.pdf
17. <https://www.valgenesis.com/smart-gxp/validation-lifecycle-suite>
18. <https://www.valgenesis.com/news/ulrich-medical-selects-valgenesis-ival-for-sap-driven-csv-upgrade>
19. <https://www.valgenesis.com/download/product-datasheet-ival>
20. <https://kneat.com/article/kneat-gx-95-global-data>
21. <https://kneat.com/implementation>
22. <https://kneat.com/application/commissioning-and-qualification>
23. <https://quality.veevavault.help/en/gr/52308305>
24. <https://quality.veevavault.help/en/gr/50533905>
25. <https://quality.veevavault.help/en/gr/874069>
26. <https://kneat.com/application/computer-system-validation>
27. <https://www.valgenesis.com/application/ival>
28. <https://kneat.com/application/analytical-instrument-validation>
29. https://database.ich.org/sites/default/files/ICH_Q9%28R1%29_Guideline_Step4_2025_0115.pdf
30. <https://www.valgenesis.com/download/product-datasheet-csa-csv-for-medical-devices>
31. <https://platform.veevavault.help/en/gr/18666>
32. <https://quality.veevavault.help/en/gr/34812>
33. <https://pages.nist.gov/800-63-4/sp800-63c/Federation>
34. <https://picscheme.org/layout/document.php?id=714>

35. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application>
36. <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11/subpart-B/section-11.70>
37. https://assets.publishing.service.gov.uk/media/5aa2b9ede5274a3e391e37f3/MHRA_GxP_data_integrity_guide_March_edited_Final.pdf
38. https://www.oecd.org/content/dam/oecd/en/publications/reports/2016/04/application-of-glp-principles-to-computerised-systems_7d05366e/e3c9cda5-en.pdf
39. <https://www.gov.uk/government/publications/guidance-on-gxp-data-integrity>
40. <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11/subpart-B/section-11.50>
41. https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

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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.

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