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FDA AEMS E2B(R3) Cutover: 2026 Migration Runbook

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Executive Summary

As of **September 19, 2026**, the operating date remains **October 1, 2026**: **postmarketing individual case safety reports** (ICSRs) sent through the U.S. Food and Drug Administration (FDA) Electronic Submissions Gateway Next Generation (ESG NextGen) must reach the FDA Adverse Event Monitoring System (AEMS) in **E2B(R3)** format. FDA will accept the older E2B(R2) standard only through **September 30, 2026** ([federalregister.gov](https://www.federalregister.gov)). The notice covers human drugs, biological products, and drug-led or biologic-led combination products ([federalregister.gov](https://www.federalregister.gov)). It applies only to ICSRs and attachments delivered through ESG NextGen ([federalregister.gov](https://www.federalregister.gov)), so an SRP-only workflow is outside this specific gateway cutover.

The most consequential operating constraint is FDA's expectation that, after a company starts R3, **all of its ICSR submissions use R3** ([federalregister.gov](https://www.federalregister.gov)). This makes the production event a company-wide transition, not a report-by-report pilot. A credible go decision therefore requires a drained R2 queue, mapped follow-ups, an **FDA-approved Message Sender Identifier** before FAERS submissions, working endpoint and certificates, current terminology, validated transformations, and end-to-end positive acknowledgements. The highest-risk conversions are case-level R2 seriousness into event-level R3 seriousness (database.ich.org), repeatable reaction and dosage structures, and the shift to attachments embedded in the XML with B64 representation for binary data (database.ich.org).

Readiness should be evidenced, not asserted. A mature electronic-reporting test model obtains a positive acknowledgement for every test (ema.europa.eu). The evidence package should connect user requirements to mappings, code lists, test cases, defects, approvals, and deployment records. This is consistent with **21 CFR 11.10**, which calls for **validation supporting accuracy, reliability, and consistent intended performance** ([ecfr.gov](https://www.ecfr.gov)), and with EU Annex 11's expectation that user requirements remain traceable through the system life cycle (health.ec.europa.eu).

The recommended control is a **one-way, evidence-gated cutover**. Release only after every transmitted unique case can be reconciled to gateway and application acknowledgements, with duplicates, rejections, and unresolved cases counted separately. No public source establishes an FDA benchmark for acceptance rate or a permitted R2 rollback after the first R3 production submission. Organizations should therefore set their own zero-unresolved threshold, pre-authorize failure owners, and treat rollback as restoration of the R3 service, not resumption of R2.

Introduction and Background

The FDA AEMS E2B(R3) cutover is the last-mile operational change in a longer regulatory sequence. The **2014 final rule** established the binding baseline that mandatory postmarketing safety reports be delivered electronically in a form FDA can process, review, and archive ([federalregister.gov](https://www.federalregister.gov)). The corresponding current regulation applies that electronic-format requirement to safety reports, ICSRs, attachments, and periodic-report information ([ecfr.gov](https://www.ecfr.gov)). The April 2026 notice then fixed the R3 operating boundary for postmarketing traffic on ESG NextGen.

The date itself has already moved once. FDA says the current announcement extended the earlier implementation period by **six months** ([fda.gov](https://www.fda.gov)). This report found no later official extension as of the publication date. A plan that assumes another deferral is therefore not a compliant operating assumption.

E2B(R3) is not simply a new XML envelope. ICH identifies **ISO/HL7 27953-2:2011** as the underlying ICSR standard (admin.ich.org), and the implementation package includes schemas needed by software that creates and reads ICSR messages (admin.ich.org). FDA then layers regional requirements onto that core, a pattern ICH expressly anticipates through regional implementation guides (admin.ich.org).

The intended audience needs a release decision, not a standards tutorial. The sections below convert the regulatory boundary into scope rules, mapping controls, gateway checks, validation evidence, cutover steps, and post-release metrics.

Key Changes

A fixed FDA boundary and a company-wide transition

The production rule is clear: **Beginning October 1, 2026**, postmarketing ICSRs must use R3 for AEMS ([federalregister.gov](https://www.federalregister.gov)). FDA's one-way expectation means a sponsor should select a single enterprise cutover point after its last planned R2 transmission. The wording is an agency expectation in the notice, while the broader duty to submit in an FDA-processable electronic format comes from binding regulation. FDA's regional guide likewise states that the guide does not independently bind FDA or the public ([fda.gov](https://www.fda.gov)).

The practical effect is that a mixed R2/R3 production strategy after the first R3 case is not a defensible default. The cutover inventory must include initial cases, follow-ups, nullifications, periodic non-expedited cases, literature cases, partner cases, and attachments. A follow-up crossing the boundary needs a tested continuity rule because the most-recent-information date changes when follow-up data arrive (database.ich.org), while identifiers received with a case must be retransmitted (database.ich.org).

Scope varies by report class and channel

The deadline does not make every FDA safety-reporting population identical. Commercial investigational new drug (IND) sponsors already faced an **April 1, 2026** R3 requirement for applicable premarketing ICSRs ([fda.gov](https://www.fda.gov)). Noncommercial INDs are exempt from the section 745A(a) electronic-submission requirement ([fda.gov](https://www.fda.gov)). IND-exempt bioavailability and bioequivalence (BA/BE) safety reports remain required, but electronic ICSR submission is a voluntary option ([fda.gov](https://www.fda.gov)). The FDA regional guide also excludes postmarketing vaccine safety reports from its stated scope ([fda.gov](https://www.fda.gov)).

Table 1 turns those distinctions into a routing decision.

Population or report	Channel and status at September 19, 2026	Cutover action
Postmarketing human drugs, biologics, and drug-led or biologic-led combination products	ESG NextGen to AEMS; R2 accepted only through September 30, then R3 (federalregister.gov)	Include in the enterprise R3 production release.
Existing SRP reporters	SRP is outside the ESG NextGen notice (federalregister.gov)	No gateway migration solely because of October 1; verify local process ownership.
Commercial IND serious and unexpected suspected adverse reactions	Applicable database-to-database R3 requirement has applied since April 1, 2026 (fda.gov)	Treat as an operating R3 flow and regression dependency, not a new October population.
Noncommercial INDs	Exempt from the specified electronic-submission mandate (uscode.house.gov)	Document regulatory pathway and do not infer mandatory gateway conversion.
IND-exempt BA/BE safety reports	Electronic ICSR route is voluntary, despite the underlying reporting duty (fda.gov)	Decide separately and validate the selected channel.

The table's central lesson is that scope should be decided by **product, report type, sender, and channel together**. A company-level R3 release should not silently pull exempt, voluntary, or separately routed populations into the mandatory cutover.

R3 changes the data model and payload

R2 placed seriousness criteria at the safety-report level, while R3 distributes them at the event level (database.ich.org). ICH uses **NI** when the applicable event seriousness information is not present (database.ich.org). Country of occurrence likewise moves from case level to event level (database.ich.org), and dosage information can repeat as necessary for a medicinal product (database.ich.org).

R2 attachments could be sent with or after their ICSR ([fda.gov](https://www.fda.gov)). R3 embeds attachments inside the ICSR XML (database.ich.org). The change affects file size, encoding, virus-scanning boundaries, retry behavior, and the atomicity of case acceptance.

Table 2 identifies transformations that merit explicit requirements and negative tests.

R2 concept	R3 transformation	Principal control and failure risk
Case-level seriousness	Allocate criteria to each reaction or event; represent a nonserious event with the mapped null flavor where required	Test mixed serious and nonserious events. Prevent blanket propagation that overstates every event.
Single country of reaction	Repeat country per reaction	Verify the correct event-country pairing after migration and follow-up.
Single dosage structure per drug	Repeat dosage records per drug	Preserve sequence and units; test multiple regimens and partial dates.

R2 concept	R3 transformation	Principal control and failure risk
Separate attachment transaction	Embed the file inline with Base64 and carry the attachment filename	Compare decoded bytes to the source document; test missing filename, corrupt encoding, and payload limit.
Free or absent values	Use applicable HL7 null flavors, which explain why a valid value is absent (terminology.hl7.org)	Do not substitute a convenient null flavor for a semantically distinct unknown or inapplicable value.
Local dose-form and route terms	Map to EDQM Standard Terms for dose forms and routes (edqm.eu)	Lock the approved mapping set and detect changed or retired terms before export.
Batch and sender fields	Generate a stakeholder-unique batch identifier and use the approved sender identity	Prevent replay and collision; verify the FDA postmarketing receiver identifier is ZZFDA (fda.gov).

These are semantic controls, not just schema checks. An XML document can validate structurally while assigning seriousness to the wrong event or attaching the wrong source document. The test oracle must therefore compare clinically meaningful source and target values, including repeat order, identifiers, terminology version, and decoded attachment hashes.

Safety Database to ESG NextGen to AEMS

The operating architecture

The minimum production chain has five accountable stages: safety database, R3 transformation, outbound gateway adapter, ESG NextGen, and AEMS. ESG NextGen offers a programmatic API that can integrate with internal systems (fda.gov) and an **AS2** system-to-system route (fda.gov). AS2 connections must point to the NextGen endpoint (fda.gov); at the protocol layer, certificate verification must chain to a root (rfc-editor.org).

Each boundary needs its own persistent correlation key. At minimum, retain the safety-report identifier, sender and receiver identifiers, batch message number, ESG Core ID, transport message ID, file hash, transmission time, and every acknowledgement. The AS2 standard adds a Message-ID header specifically to support reconciliation (datatracker.ietf.org). It also defines a warning for an identical document already at the destination (datatracker.ietf.org). That warning is transport evidence, not permission to count the case as accepted.

Acknowledgements are a chain, not one status

ESG's **ACK1** says whether the submission was uploaded; later acknowledgements provide routing and Center responses where applicable (fda.gov). The transport and application layers must remain distinct. AS2 uses Message-ID to reconcile an MDN with the original transmission (rfc-editor.org), while the application acknowledgement reports validation outcome.

The application-level R3 acknowledgement contains both batch and individual-report results (database.ich.org). The broader batch-response pattern also returns an outcome entry for each request entry (hl7.org). The reconciliation state machine should therefore distinguish:

- **Transported:** an AS2 message disposition notification or equivalent API status exists.

- **Gateway received:** ACK1 is positive.
- **Center routed:** applicable ACK2 is positive.
- **Batch processed:** the R3 batch acknowledgement is positive.
- **Case accepted:** the individual message result is positive.
- **Rejected:** a negative application result has an owned corrective action.
- **Duplicate:** the report is linked to its prior transmission and excluded from accepted-unique counts.
- **Unresolved:** the maximum internal acknowledgement age is exceeded, regardless of a transport success.

Oracle's Argus documentation illustrates why payload outcome must be modeled separately: a hard R3 validation failure rejects an incoming message and generates a negative acknowledgement (docs.oracle.com). Its duplicate logic uses the R3 N. 1 . 2 batch message number (docs.oracle.com). Vendor behavior should be verified for the installed release rather than generalized from this example.

Implementation Considerations and Process Changes

Build the evidence package before the release window

Validation should begin with the intended use and regulatory scope, then connect each requirement to configuration, mapping, test, defect, and approval evidence. **21 CFR Part 11** calls for **secure, computer-generated, time-stamped audit trails** in closed systems (ecfr.gov). EU Annex 11 adds a migration-specific expectation that validation check whether data were altered during transfer (health.ec.europa.eu). EMA says the marketing authorization holder remains ultimately responsible for validating pharmacovigilance processes supported by electronic systems (ema.europa.eu).

The **E2B(R3) migration checklist** and evidence package should contain:

- **Scope and intended use:** in-scope companies, products, licenses, report types, channels, affiliates, partners, and vendor components.
- **Regulatory assessment:** binding requirements separated from guidance, FDA expectations, and internal policy.
- **Requirements traceability:** R2-to-R3 mappings, FDA regional rules, controlled terminology, attachments, identifiers, acknowledgements, security, and records retention.
- **Design evidence:** architecture, interface contracts, schema and business-rule versions, configuration baseline, certificates, routing IDs, and monitoring.
- **Data-migration proof:** representative source-to-target comparisons, repeatable structures, hashes for decoded attachments, and preserved identifiers.
- **Test evidence:** positive, negative, boundary, retry, duplicate, follow-up, nullification, multi-event, terminology, attachment, and volume cases.

- **Operational qualification:** successful pre-production transmissions and complete positive acknowledgement chains.
- **Release control:** approved change record, segregation of duties, deployment and backout instructions, training, and quality authorization.
- **Continuity:** manual triage and alternate communication steps, because EMA GVP expects risk-based continuity planning (ema.europa.eu).

Risk management should operate across the computerized-system lifecycle (health.ec.europa.eu). Risk-based testing can be adopted as the method, but the rationale must cite the requirements that actually apply to the pharmacovigilance interface.

Minimum test suite and release gates

Testing must cover requirements, specifications, migration, and the acknowledgement chain. MHRA guidance calls for computer-system testing and assurance of migration completeness and accuracy (mhrainspectorate.blog.gov.uk). EMA's electronic-reporting test model requires a positive acknowledgement for each test (ema.europa.eu). Subsequent system changes should be validated according to risk (database.ich.org).

Table 3 is a compact traceability and go-live matrix. Organizations should add their own requirement IDs, evidence locations, owners, and approved thresholds.

Gate	Minimum test evidence	Release criterion
Scope and mapping	Every in-scope source element mapped to ICH and FDA regional target or justified as not applicable	No unapproved mapping gaps; all report populations have an owner.
Seriousness and repeats	Mixed-event cases, multiple countries, multiple dosages, and nonserious null-flavor paths	Clinical review confirms event-level meaning and repeat association.
Attachments	Zero, one, and multiple files; allowed types; corrupt Base64; missing filename; maximum supported payload	Decoded hash equals source; expected negative cases reject cleanly.
Terminology	Current and previous MedDRA values, EDQM mapping, invalid and retired codes	Use one MedDRA version per ICSR (database.ich.org).
Identity and duplicates	FDA-approved Message Sender Identifier before FAERS submissions, unique batch IDs, replayed batch, replayed case, partner identifier retention	No identifier collision; duplicate classification is explainable and reversible.
Transport and routing	Certificate, endpoint, AS2 MDN or API status, gateway ACKs, batch and case acknowledgement	Complete positive chain for every required pre-production case.
Reconciliation	Missing, delayed, negative, duplicate, and malformed acknowledgements	Every test transmission ends accepted, rejected, duplicate, or formally resolved.
Operations	Monitoring, alert routing, support contacts, manual triage, continuity rehearsal	Named 24-hour hypercare owner and quality-approved escalation paths.

The matrix is intentionally outcome based. A screenshot of a successful XML validator result proves only that one payload passed that tool. It does not prove correct source mapping, production routing, acknowledgement ingestion, or case-level reconciliation.

Freeze, cutover, hypercare, and escalation

No fetched FDA source prescribes a universal freeze duration or queue threshold. Those are internal controls that should be sized from actual throughput and acknowledgement latency. A practical runbook is:

1. **T minus 30 days:** freeze mapping and regional-rule versions; confirm sender identity, receiver ZZFDA, endpoint, certificates, and support contacts; for a net-new ESG NextGen user, complete a test submission before production access only where the applicable Center/Submission Type requires it ([fda.gov](https://www.fda.gov)).
2. **T minus 14 days:** execute the full regression suite, including follow-ups to historical R2 cases and embedded attachments. Obtain quality approval for residual risks.
3. **T minus 7 days:** inventory open outbound work by company, case, due date, report type, and partner. Decide the last permitted R2 batch.
4. **T minus 1 day:** transmit the planned final R2 queue, stop new R2 batch creation, and reconcile every sent case. Do not carry an unexplained R2 transmission into the R3 window.
5. **Cutover:** deploy the approved R3 configuration, verify schema and terminology fingerprints, and, for AS2 connectivity testing, follow FDA's current [ESG NextGen AS2 account set-up instructions](#).
6. **Controlled ramp:** release bounded batches, compare source and outbound counts, and pause on any unexplained duplicate, negative acknowledgement, or missing case result.
7. **Hypercare:** reconcile continuously by unique case and batch, not file count alone. Split transport, gateway, application, and data-quality failures among named owners.
8. **Closure:** obtain quality sign-off only after the R2 queue is zero, all R3 cases have terminal states, audit records are retained, and open issues have approved dispositions.

FDA separates gateway account or transmission support from AEMS reporting-process support ([fda.gov](https://www.fda.gov)). The escalation matrix should mirror that separation: transport failures to the gateway team, invalid R3 payloads to the safety-system and mapping team, unexplained FDA application outcomes to the AEMS coordinator, and potential reporting-timeliness impact to pharmacovigilance operations and quality.

Because the FDA expectation is one-way at company level, a conventional rollback to R2 may conflict with the stated operating model. The recovery plan should restore the approved R3 configuration, fail over its infrastructure, or invoke a pre-assessed continuity process. It should not assume that production can switch back to R2 after the first R3 batch.

Data Analysis and Evidence

The external data provide three useful scale and version signals. First, the ICH Step 4 implementation-guide package is **Version 1.11, published January 2026**, as listed on the [ICH package page](#), which also identifies updated code lists. The separately versioned implementation-guide document is **Version 5.03, dated July 18, 2025** ([database.ich.org](#)). The ICH model leaves acceptable code-system versions to each regional authority ([database.ich.org](#)). Release records should identify the ICH package version and the exact validated component versions, including the implementation guide, code lists and schemas, alongside the FDA regional package versions actually used. A document version alone is not a complete package fingerprint.

Second, terminology is a moving dependency. The MedDRA support site listed **Version 29.1** at the September 2026 anchor ([alt.meddra.org](#)), and MedDRA publishes **two updates each year** ([files.meddra.org](#)). EDQM's Standard Terms database contains **more than 900 terms across 35 languages** ([edqm.eu](#)) and is updated continuously ([edqm.eu](#)). A static test pack without recorded terminology versions cannot be reproduced reliably.

Third, R3 is a global standard with regional operating differences. PMDA states that Japanese safety reporting should follow ICH E2B(R3) ([pmda.go.jp](#)), while Health Canada's ICH status page still described R3 as in implementation at the publication anchor ([canada.ca](#)). A global engine should share the ICH core but keep regional business rules and release dates configurable.

For internal cutover measurement, use unique cases rather than messages:

- **Acceptance ratio:** accepted unique cases divided by transmitted unique cases, multiplied by 100.
- **Duplicate count:** unique transmissions classified as duplicates, shown separately and linked to the accepted original.
- **Rejected count:** unique cases with a negative terminal application result.
- **Unresolved count:** transmitted unique cases without an accepted, rejected, or duplicate terminal state at the reporting cutoff.
- **Control identity:** transmitted unique equals accepted unique plus duplicate plus rejected plus unresolved, after documented exclusions.

There is no public FDA benchmark that makes a ratio below 100% acceptable at cutover. The go-live dashboard should show both the ratio and its component counts. A high percentage can conceal one overdue serious case; a zero-unresolved control is more informative for release governance.

The broader reporting ecosystem illustrates why duplicate controls matter. VigiBase held **more than 40 million reports from over 180 programme members** as of February 2025 ([who-umc.org](#)). Uppsala Monitoring Centre cautions that its algorithm predicts suspected, not confirmed, duplicates ([support.who-umc.org](#)). EMA likewise says every newly received ICSR referring to an individual should be treated as a potential duplicate ([ema.europa.eu](#)). Cutover duplicate logic needs reviewable evidence, not an opaque automatic deletion.

Implications and Future Directions

The immediate implication is organizational. The readiness decision belongs jointly to pharmacovigilance operations, regulatory IT, quality, the gateway team, and vendor owners. No group can prove the full chain alone. Operations owns case completeness and timeliness; IT owns transport and observability; quality owns validated state and residual risk; gateway engineers own certificates and routing; product owners own configuration and vendor evidence.

The second implication is architectural. ICH schemas are necessary but regional schemas and rules must be layered on top (admin.ich.org). Future updates to terminology, regional elements, or acknowledgements should be deployable as controlled configuration rather than one-off code. ICH E6(R3) treats configuration, release, setup, installation, and change control as relevant lifecycle validation subjects (database.ich.org).

The third implication is commercial accountability. Vendor questions should request evidence rather than yes-or-no assurances:

- Which exact ICH, FDA regional, MedDRA, and EDQM versions are installed?
- How are case-level R2 seriousness criteria allocated to event-level R3 fields?
- How are historical R2 follow-ups, sender identifiers, and duplicates preserved?
- What attachment types and decoded sizes have been qualified?
- Which acknowledgement levels are parsed, persisted, and exposed to operations?
- What change would trigger retesting, and what evidence is supplied for each release?
- How are certificate expiry, endpoint health, queue age, and unresolved cases monitored?
- What recovery design restores R3 without assuming an R2 rollback?

IntuitionLabs' first-party description includes data pipelines, integration, warehousing, and business intelligence (intuitionlabs.ai).

Frequently Asked Questions (FAQs)

What exactly changes on October 1, 2026?

Postmarketing ICSRs and their attachments sent to AEMS through ESG NextGen must use E2B(R3). FDA accepts R2 only through September 30, 2026 (federalregister.gov). The 2014 electronic-submission obligation remains the regulatory baseline; the 2026 notice identifies the operative data standard and date.

Can a company pilot a few production R3 cases and keep the rest on R2?

That is inconsistent with FDA's stated expectation that, once a company begins R3, all ICSR submissions use the standard (federalregister.gov). Production confidence should be built in validator and pre-production environments, followed by a controlled company-level release.

Do SRP users need to migrate their gateway interface?

Not solely because of this deadline. The notice applies only to ICSRs and attachments transmitted through ESG NextGen ([federalregister.gov](https://www.federalregister.gov)). Organizations should still confirm whether any other report population uses database-to-database transmission.

What are the highest-risk R2-to-R3 transformations?

They are event-level seriousness, repeatable reaction-country and dosage structures, historical identifiers and follow-ups, null-flavor semantics, controlled terminology, and embedded attachments. ICH describes the batch number as a unique tracking number (database.ich.org); FDA also expects prior approval of the R3 Message Sender Identifier (fda.gov).

Which acknowledgements prove acceptance?

No single transport receipt proves case acceptance. ESG acknowledgements establish upload and routing stages; the R3 application acknowledgement supplies batch and individual-message outcomes. EMA's analogous model describes an acknowledgement as confirming both receipt and validation outcome (ema.europa.eu). The local state model should require the expected application-level result.

What should stop the cutover?

Stop if any in-scope population lacks an owner, an R2 transmission remains unresolved, a required mapping is unapproved, certificates or endpoints are unverified, pre-production evidence is incomplete, or source-to-target semantics differ. These are release criteria, not claims that FDA publishes a universal numeric threshold.

Conclusion

The **FDA AEMS E2B(R3) October 2026 deadline** is a one-way operating transition for applicable postmarketing ICSRs sent through ESG NextGen. The date remains October 1, 2026 as of September 19, and the company-wide R3 expectation makes an informal production pilot inappropriate. Commercial IND R3 reporting, SRP use, noncommercial INDs, IND-exempt BA/BE reports, and excluded vaccine reports must be classified separately rather than forced into one rule.

Readiness turns on four proofs. First, every report population and transmission channel has a documented disposition. Second, R2 semantics, particularly seriousness, repeats, identifiers, terminology, and attachments, survive transformation into the FDA regional R3 model. Third, the transport and application chain produces traceable terminal outcomes for each unique case. Fourth, the validated evidence package connects requirements to configuration, tests, defects, approvals, and retained records.

The go-live decision should therefore be binary and evidence based: either the R2 queue is fully reconciled and the R3 chain is ready, or the organization is not ready to cross the company-wide boundary. Hypercare should measure accepted unique cases against transmitted unique cases while exposing duplicate, rejected, and unresolved counts separately. Recovery should restore R3 service, not presume that FDA will accept a discretionary return to R2. With those controls in place, the October event becomes a governed systems release rather than a deadline-driven format conversion.

Source links

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

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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.

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.

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