CSVtoCSA Certification Study Handbook

Computer Software Assurance Foundations

1.0 | 14 September 2026

This handbook prepares Quality, Validation, CSV, CSA and IT Quality practitioners to explain and apply software assurance decisions. It covers ten modules, from intended use and GxP assessment through requirements, functional risk, testing, supplier evidence, regulated records, lifecycle controls and AI-enabled use.

Use the handbook with the supplied module documents. Each module provides focused concepts, a worked example and an application exercise. The aim is to explain why a particular control and body of evidence support the defined use, rather than memorize a preferred document format.

How to study

- Read the modules in order and write your own intended-use statement for one familiar system.
- Work through each example by connecting function, failure, impact, controls and evidence.
- Complete the application prompt before reading its worked response.
- Use the final capstone to assemble a coherent assurance approach, then take Form A.

Assessment format

Form A contains 50 single-best-answer questions: five per module, with one point per correct answer. The proposed course standard is 40/50 or 80 percent. Suggested administration is 75 minutes, closed book. These are CSVtoCSA course settings, not regulatory requirements.

Scope of the learning outcome

This is an educational assessment of the curriculum. It does not itself establish job qualification, approve a regulated system or represent third-party accreditation. Apply governing requirements and your organization's procedures to real decisions. All worked cases are fictional teaching examples.

Learning map

Plan approximately 45 to 60 minutes per module, plus time for the capstone and revision. Actual study time depends on experience. The original ten module files are included in the learner pack for further reading.

Module	Topic	Handbook pages
1	CSV and CSA Fundamentals	3 to 4
2	Intended Use and GxP Assessment	5 to 6
3	Requirements and Traceability	7 to 8
4	Functional Risk Assessment	9 to 10
5	Risk Based Testing	11 to 12
6	Supplier Assessment and Existing Evidence	13 to 14
7	Data Integrity and Electronic Records and Signatures	15 to 16
8	SaaS Interfaces and Data Migration	17 to 18
9	Maintaining the Validated State	19 to 20
10	AI Enabled GxP Systems	21 to 22

A reusable decision sequence

Intended use → Function → Failure → Impact → Controls → Evidence gap → Assurance activity → Conclusion → Lifecycle review

At each step, write a specific claim and the facts that support it. State unknowns. Identify who owns decisions and actions. Keep the electronic-record and signature assessment distinct from the decision that a use is GxP-relevant.

What to retain from your study

- One clear intended-use statement and a boundary that includes relevant dependencies.
- One traceable example linking a requirement, failure, test and evidence.
- One explanation of why supplier evidence applies and what local gaps remain.
- One lifecycle trigger that would make you reassess the conclusion.

MODULE 01 / CONCEPTS

CSV and CSA Fundamentals

By the end of this module, you should be able to:

- Explain the validation objective and the scope of FDA CSA guidance.
- Select assurance from function-level failures rather than document volume.
- Recognize evidence and lifecycle conditions needed for a defensible conclusion.

Purpose and scope

CSV establishes documented confidence that a computerized system is suitable for its intended use. CSA emphasizes critical thinking about the use, failure consequences, controls and evidence. The objective is not a smaller documentation package or a preferred test method. FDA issued its current CSA guidance on 3 February 2026 for medical-device production and quality management system software. It supersedes the September 2025 version and Section 6 of the 2002 software-validation guidance. Broader pharmaceutical and clinical examples in this course are practitioner applications; their own governing requirements still apply. [R1, R2]

From system to function

A system can contain a critical approval rule and a low-impact display preference. Assess the function and credible failure, including dependent services. A software brand, cloud deployment or lack of macros is not a risk conclusion. Business criticality, GxP applicability and process risk answer different questions. FDA uses high process risk and not high process risk in its guidance; any company high, medium and low scheme needs defined criteria and should not be presented as an FDA classification. [R1]

Choose evidence that resolves uncertainty

Review requirements, configuration, supplier testing, existing automated checks and operational evidence before adding work. Use predefined challenges where precise expected behavior matters, and exploration where investigation can reveal important exception paths. A screenshot shows only what it captures. Evidence must connect a particular version, environment, scope and result to the claim being made. Unscripted testing still needs an objective, responsible tester, observations, issues and conclusion.

A conclusion has conditions

A release conclusion explains why the use is supported, which evidence was accepted, how deviations were resolved, what limitations remain and which changes trigger reassessment. It belongs within the organization's Quality and system governance. Passing a course or a software test does not approve a regulated system. After release, configuration changes, new uses, incidents and supplier releases may change the basis for confidence.

MODULE 01 / APPLICATION

Apply the reasoning

A configurable eQMS routes CAPA approvals, stores signatures and sends reminders. The supplier tested the standard engine, while the customer configured routing. A successful supplier run supports relevant engine behavior. It does not establish the customer role matrix, closure prerequisites or exception handling. If reminders are only a convenience and a monitored task list is the relied-upon control, they warrant a different testing depth from a closure block.

Function or focus	Failure or claim	Useful evidence
Closure rule	CAPA closes before approval	Challenge required and missing approvals; retain record state.
Signature authority	Wrong person approves	Challenge authorized and unauthorized roles and attribution.
Reminder email	Reminder arrives late	Check the supporting use and the effectiveness of the task-list control.

Application exercise

For a spreadsheet used in product acceptance, identify one failure that matters even when the workbook has no macros. Propose an observable check and the evidence you would retain.

Worked response

A wrong formula or rounding rule can change acceptance. Compare calculations with independently derived values, challenge the acceptance boundary and formula protection, and retain the controlled workbook version, inputs, expected and actual outcomes, issues and disposition. A second reviewer is useful only if the review can detect the relevant error.

What to remember

Begin with intended use; distinguish failures; use relevant evidence; document a supported conclusion; maintain that basis through the lifecycle.

Your application notes

Study references: R1, R2; supplied Module 1 sections 1 to 10.

MODULE 02 / CONCEPTS

Intended Use and GxP Assessment

By the end of this module, you should be able to:

- Write an intended use that identifies actual reliance.
- Separate GxP relevance from business importance and Part 11 screening.
- Set a boundary around the complete regulated decision.

Describe the actual reliance

State the process, what the software does, who relies on it, and the decision, record or control supported. Add the important input and downstream dependency. "The LMS manages training" is too broad. A useful statement says that the LMS records required training and supplies status used to determine eligibility for specified manufacturing work. An intended use establishes scope; detailed behavior belongs in requirements.

Determine GxP relevance

Ask whether the use controls a regulated activity, performs a relevant calculation, creates or maintains a required record, or supplies information relied upon for a regulated decision. Document the applicable process and rationale. An SAP stationery-payment function and an SAP batch-release function need different assessments. Do not expand a conclusion about one use to the entire platform. A high purchase price or operational dependence is not, by itself, a GxP connection.

Include the decision chain

Follow data from origin through mapping, transformation, transfer and downstream action. Include identity, role services, interfaces and manual controls that can change the outcome. Name the official record, the system making the decision and the treatment of stale or unavailable data. Supplier ownership does not remove a dependency from the assessment. Define exclusions and why they cannot affect the assessed use.

Screen records and signatures separately

GxP relevance and Part 11 applicability are related but distinct. Identify records required by applicable FDA predicate rules, their electronic form and actual reliance, then assess electronic-signature use separately. A login is authentication, not automatically a signature. A printout does not settle whether the electronic record remains the relied-upon record. Document uncertainty and the facts needed to resolve it. [R3, R4]

Reassess changes in use

A read-only dashboard may still affect a regulated decision. If it becomes the only basis for escalation, filtering and timeliness can become significant even if no code changes. Human decision authority is part of intended use, not a reason to presume no GxP impact. Confirm what the human reviews and whether independent source checks actually occur.

MODULE 02 / APPLICATION

Apply the reasoning

ComplianceWire supplies training status to MES. The eligibility decision also uses enterprise role data. A learner has completed a course, but a role-mapping error assigns a different manufacturing qualification. Validating only the LMS completion screen would miss the failure. The assessment must cover the combined decision and the interlock that permits or prevents work.

Function or focus	Failure or claim	Useful evidence
Training record	Wrong completion status	Confirm current required curriculum and identity.
Role and interface	Wrong or stale eligibility	Challenge role mapping, transfer failures and stale data.
MES interlock	Unqualified work permitted	Verify authorized work and denial of ineligible work.

Application exercise

Write an intended-use statement for Agile PLM used for GxP Quality documents and change approvals. Identify one electronic record question and one boundary dependency.

Worked response

Agile PLM maintains controlled Quality documents, routes designated change approvals and restricts effective-document release until required approval is complete. Confirm which records and signatures fulfill applicable obligations. Include identity and role management, document versions, signature linkage and any downstream distribution or training interface relied upon.

What to remember

The assessment follows what the organization relies on, including its records, decisions and dependencies.

Your application notes

Study references: R1, R3, R4; supplied Module 2 sections 2.1 to 2.10.

MODULE 03 / CONCEPTS

Requirements and Traceability

By the end of this module, you should be able to:

- Translate intended use into observable behavior.
- Write requirements for control paths, configuration and interfaces.
- Use traceability to evaluate evidence coverage and unresolved gaps.

Requirements remain necessary

A risk-based approach still needs a definition of intended behavior. Requirements can be recorded in a URS, controlled configuration specification, acceptance criteria or another governed form appropriate to the organization. The format does not replace the content. State the rule, actor, relevant preconditions and expected result clearly enough that independent reviewers can agree on what satisfactory performance means.

Make the behavior observable

Replace "supports compliant approval" with "block CAPA closure until required Quality approval is complete." Identify who may approve, which prerequisites apply and how rejection, withdrawal or reassignment should behave. Avoid mixing several unrelated rules into one requirement. Where timing, precision or performance matters, define justified criteria. Include the negative condition as well as successful operation.

Detail follows risk and dependencies

Critical calculations need rules for inputs, units, rounding, missing values and acceptance boundaries. Interface requirements need record identity, field meaning, transformations, duplicate handling and reconciliation. Configured workflows need role and state-transition rules. Cosmetic preferences can use simpler criteria when their use and failure impact justify it. More detail is useful where ambiguity could conceal a consequential error.

Trace the current claim

Link intended use to function, failure risk, requirement, assurance activity and evidence. Include supplier or automated evidence when it supports the requirement, with scope and limitations recorded. Maintain identifiers and version relationships when requirements or configuration change. A traceability matrix is one useful representation, not the only acceptable format. Links should be reviewable without relying on someone's memory.

Coverage is not acceptance

A test listed against a requirement may have failed, used the wrong configuration or addressed only the positive path. Review the actual outcome and unresolved deviations. A release summary should distinguish covered-and-supported requirements from gaps, limitations and failures. A high percentage of passed tests does not make an important unresolved failure acceptable.

MODULE 03 / APPLICATION

Apply the reasoning

CAPA-REQ-07 requires Quality approval before closure. Risk FRA-03 describes closure without required oversight. TEST-12 challenges complete approval; TEST-13 attempts closure with a missing approval and an unauthorized role. A supplier engine report supports standard state handling, but the local results support the configured rule. If TEST-13 fails, a complete row in the RTM cannot justify release.

Function or focus	Failure or claim	Useful evidence
Requirement	Defined closure rule	Controlled requirement and role/configuration version.
Assurance	Positive and forbidden paths	Test results, actual state, relevant history and issues.
Conclusion	Current use supported	Resolved deviation, retest and reviewer disposition.

Application exercise

Improve "The interface transfers laboratory results accurately." Add three testable elements that protect the business meaning of the result.

Worked response

Define the batch/material association, required units and conversion/precision rule, and behavior for missing or duplicate messages. Acceptance evidence should compare source and target content, verify the defined mapping and show that failed transfers are detected and resolved without unintended business action.

What to remember

Traceability connects a current, explicit requirement to evidence and its disposition; a link alone is not proof.

Your application notes

Study references: R1; supplied Module 3 topics 3.1 to 3.5.

MODULE 04 / CONCEPTS

Functional Risk Assessment

By the end of this module, you should be able to:

- Describe credible failures and their consequences.
- Distinguish preventive and detective controls.
- Use uncertainty and control evidence to prioritize assurance.

Start with a function and failure

Assess a meaningful unit of behavior, such as approving a change, calculating a result or transferring status. "The system fails" is too vague. A better statement is "wrong role mapping allows an unqualified operator to start a manufacturing step." State the mechanism and consequence without assuming every possible failure has equal impact. Review dependent services and shared controls that can produce the same outcome.

Explain the consequence

Link the failure to product quality, patient safety, data integrity, a regulated record or a required decision. Separate the severity of the credible consequence from the likelihood estimate and the ability to detect the event. A commercial outage may matter greatly without being the same as a product-quality failure. Conversely, a small spreadsheet can influence a consequential disposition decision.

Credit controls with evidence

A preventive control blocks an event, such as a role-based closure restriction. A detective control finds an event, such as reconciliation or history review. Describe who operates the control, when it acts and what follows detection. A written procedure does not establish effectiveness by itself. An independent review must be able to detect the relevant error in time; a second display of the same wrong value is not independent verification.

Expose uncertainty rather than hiding it

A numerical score can summarize reasoning but cannot create evidence. Record unknown frequency, untested controls, incomplete supplier evidence or novel behavior. Avoid reducing severity or likelihood merely to fit the testing budget. Choose additional evidence that addresses the uncertainty and explain the basis for the conclusion. ICH Q9(R1) supports scientific, proportionate quality-risk decisions; a universal scoring formula is not prescribed. [R5]

Translate risk into action

Determine the rigor, method and evidence needed for each important failure. Deterministic consequential controls often need explicit challenge cases. Exploratory work can investigate combinations and exceptions; supplier or automated evidence may cover established behavior. Preserve end-to-end coverage even when individual functions are assessed separately. The owner of residual-risk acceptance must follow the organization's governance.

MODULE 04 / APPLICATION

Apply the reasoning

An eQMS supplier changes its workflow engine. Local routing remains configured by the customer. One failure bypasses a required approver; another resets a display preference. The same supplier release affects both, but their consequences differ. Assess the changed engine, customer rule execution, role mapping and exception states before selecting targeted assurance.

Function or focus	Failure or claim	Useful evidence
Approval bypass	Required oversight omitted	Predefined negative and state-transition challenges.
Shared role mapping	Wrong authority assigned	Permission matrix and dependent workflow tests.
Display preference	Personal setting lost	Focused functional check with a documented use rationale.

Application exercise

A risk assessment says "Low risk because a trained reviewer checks the result." What three facts would you seek before accepting that justification?

Worked response

Confirm what the reviewer independently compares, evidence of detecting representative consequential errors, and whether review occurs before the regulated decision is used. Also define action on discrepancies, workload limitations and the maintained qualification needed for the control to remain effective.

What to remember

Use Function to Failure to Impact to Control to Evidence to Decision. Keep uncertainty and assumptions visible.

Your application notes

Study references: R1, R5; supplied Module 4 topics 4.1 to 4.5.

MODULE 05 / CONCEPTS

Risk Based Testing

By the end of this module, you should be able to:

- Select complementary testing methods for the failure being assessed.
- Define positive, negative and boundary scenarios.
- Evaluate automated results and regression scope for relevance.

Scripted and positive testing

Predefine steps and expected outcomes when precision, reproducibility or important deterministic controls warrant that rigor. A positive test demonstrates permitted behavior under satisfied prerequisites. It does not establish that forbidden behavior is blocked. Include the relevant configuration, test data, environment, role and expected final state. The method should produce evidence for the claim, not simply satisfy a script-count target.

Negative and boundary challenges

A negative test attempts an invalid input, unauthorized action or prohibited transition and checks the intended safe response. Verify that denial did not still change a record. Boundary testing examines behavior below, at and above a decision threshold using valid precision and defined rounding. State whether a limit is inclusive. For an input limited to one decimal place and an inclusive 12.0 limit, 11.9, 12.0 and 12.1 challenge the decision boundary.

Exploration with an objective

An exploratory charter sets a target, scope, roles, data and risks to investigate while allowing the tester to adapt. For example, investigate returned approvals, reassignment and interrupted sessions to find inconsistent record states. Record the build, tester, activities, observations, issues and conclusion. Unscripted is a broader term; exploratory work is one purposeful approach, not a permission to omit documentation.

Automated and supplier results

A green result is meaningful only if the assertions, test data, environment and version support the intended claim. Review whether tests genuinely detect the failure and whether relevant coverage passed. Understand failures, skipped checks and limitations. Reuse reliable evidence where it applies, but obtain additional evidence for changed customer configuration, interfaces or unsupported cases.

Regression follows impact

Identify changes and their dependencies before choosing regression. Shared identity, libraries, schemas, configuration and interfaces can affect functions whose screens are unchanged. Consider prior defects and failure paths as well as successful operation. A narrow release-note label does not prove a narrow business impact. Document inclusion and exclusion rationale and disposition failed or uncertain results before the release conclusion.

MODULE 05 / APPLICATION

Apply the reasoning

A controlled workbook calculates an acceptance value. The requirement specifies inputs to one decimal place, no intermediate rounding and acceptance at or below 12.0 units. Normal inputs can show the formula works in the middle of the range, but cannot establish threshold behavior, protection from overwrites or appropriate handling of blanks and text.

Function or focus	Failure or claim	Useful evidence
Positive	Valid value well within limit	Independent calculation and expected accepted state.
Boundary	11.9, 12.0 and 12.1	Accept, accept, reject under the stated rule.
Negative	Text input or overwritten formula	Defined rejection or protection; no unintended result.

Application exercise

Write a short exploratory charter for an approval workflow. Include the objective, two exception paths and what you will retain as evidence.

Worked response

Investigate whether CAPA state and authority remain consistent during rejection and reassignment. Use approved test roles and records on the controlled build, try relevant action sequences and retain activities, observations, state/history evidence, defects and a conclusion. Add explicit scripted challenges for critical permissions where needed.

What to remember

The failure and evidence gap determine the testing mix. Positive, negative, boundary and exploratory work answer different questions.

Your application notes

Study references: R1; supplied Module 5 topics 5.1 to 5.6.

MODULE 06 / CONCEPTS

Supplier Assessment and Existing Evidence

By the end of this module, you should be able to:

- Distinguish supplier capability from local fitness for use.
- Evaluate evidence scope, relevance, reliability and limitations.
- Define the customer and supplier responsibility split.

Supplier capability

Assess the supplier in relation to the service and its significance: development and change processes, quality practices, defect handling, release communication, security, continuity and support. Select assessment depth from the intended use and risk. A questionnaire, audit, performance history or independent report can contribute evidence, but none should be treated as a universal substitute for understanding the supplied service.

Qualification and local validation

Supplier qualification supports confidence in capability. Customer validation addresses whether the implemented configuration, data, workflows, interfaces and operating controls support the customer intended use. The supplier can demonstrate standard behavior without testing the local role matrix or business rule. Make the boundary between supplier evidence and customer responsibility explicit so neither assumes the other covered a consequential gap.

Review evidence before reuse

Check the product and version, configuration, environment, tested scope, expected behavior, actual outcomes, unresolved defects and provenance. Map evidence to relevant requirements or claims. Automated tests and previous local results need the same applicability reasoning. A limitation does not make an entire package useless; identify what it supports and what remains unproven. Record why the evidence can be relied upon and what additional work is justified.

SOC and ISO limits

An independent report or certificate can inform the controls within its stated scope and period. Review the covered service, exclusions, exceptions and any customer responsibilities. Such evidence does not, by itself, prove a local approval workflow, record-retention configuration or Part 11 determination. Likewise, customer references and supplier marketing language are not executed evidence of the customer intended use.

Responsibilities throughout service life

Clarify release notification, incident communication, data ownership, retention, backup scope, restoration, evidence availability and exit support. A backup service may exclude attachments or customer-held keys. Define how usable records will be verified. If necessary evidence is unavailable, record the gap and consider alternatives, targeted local verification, stronger controls or limits on the proposed use. The local conclusion must address what remains uncertain.

MODULE 06 / APPLICATION

Apply the reasoning

A supplier regression package covers the standard CAPA workflow engine on the deployed version. The customer changed routing and uses an ERP interface. A SOC report covers hosting controls, but does not test those local paths. The evidence plan should use each source for the claim it actually supports and add local checks for the customer-specific behavior.

Function or focus	Failure or claim	Useful evidence
Standard engine	Supplier regression	Confirm version, scope, outcomes and relevant exceptions.
Customer routing	Local configuration tests	Challenge approval prerequisites and role paths.
ERP transfer	End-to-end evidence	Verify mapping, failures, retry and reconciliation.

Application exercise

The supplier cannot provide detailed results for a critical function. Describe an appropriate response without treating either the supplier assertion or repeated testing as an automatic answer.

Worked response

Document exactly which claim lacks evidence. Assess alternative trustworthy material and its limitations, then define targeted local challenges or other justified controls. Escalate unresolved consequential gaps through the release process; do not relabel the function as low risk simply because evidence is unavailable.

What to remember

Reuse evidence for supported claims and make the remaining local responsibility visible.

Your application notes

Study references: R1; supplied Module 6 topics 6.1 to 6.6.

MODULE 07 / CONCEPTS

Data Integrity and Electronic Records and Signatures

By the end of this module, you should be able to:

- Identify required record content across the lifecycle.
- Explain attribution, history, access and signature controls.
- Separate GxP, electronic-record and electronic-signature determinations.

The record is more than the final report

Follow creation, processing, review, use, transfer, retention and retrieval. Determine what data, metadata, attachments and relationships are needed to understand and reconstruct the regulated activity. A readable PDF may be useful but may not preserve all required source content or history. ALCOA and related completeness, consistency, endurance and availability principles provide practical prompts; their use must reflect the actual records and applicable obligations. [R6]

History and its review

For relevant record changes, determine how the system preserves who changed what and when, the prior and new values, and a reason where required by the process. Protect history from inappropriate alteration. Define who reviews relevant events, with what frequency or trigger and what action follows a discrepancy. A trail that exists but is never reviewed when review is needed is an incomplete detective process.

Access and attribution

Give users permissions appropriate to their current responsibilities, govern privileged access and remove rights when the role changes. Shared approval accounts weaken individual attribution. Verify both the allowed and forbidden paths, including whether a denied action nevertheless changes a record. Consider service identities, emergency access and administrative actions separately from ordinary user approval rights.

Signing is a distinct act

A login authenticates access; it does not automatically mean that the user has signed every subsequent action. Where applicable electronic signatures are used, assess identity, authority, the meaning of the act and its association with the record. Verify signature information such as signer name, signing date/time and meaning, including its representation in relevant copies, and linkage that prevents ordinary removal or transfer to falsify another record. [R3]

Applicability and retention

Identify the FDA predicate requirement and actual electronic reliance before determining Part 11 scope. Separately identify signature use and applicable controls. Do not infer compliance from a supplier badge or from the ability to print. Required records must remain complete, protected and retrievable through their applicable retention period, including after migration or retirement. Other jurisdictions or processes can impose obligations independently of Part 11. [R3, R4]

MODULE 07 / APPLICATION

Apply the reasoning

A CAPA criticality is changed from High to Low. The intended control requires authorized changes, retained prior and new values, user, time and a reason. A reviewer must understand the history before relying on the new status. Testing only that Low appears on screen cannot establish authorization, history protection or the review process.

Function or focus	Failure or claim	Useful evidence
Authorization	Unauthorized downgrade	Attempt the change under permitted and forbidden roles.
Change history	Prior state is lost	Verify old/new values, actor, time and required reason.
Retention and use	History becomes unreadable	Retrieve the record and relevant history in normal review/export.

Application exercise

A signed record is archived as a file showing only a handwritten-signature image. What further evidence is needed to understand whether the retained approval remains meaningful?

Worked response

Determine the actual required record and signature method, then verify signer identity, the signing event and meaning, linkage to the specific record, and preservation of required content and history. An image by itself does not establish attribution, authority or a valid association with the approval.

What to remember

Protect the complete record, its meaning and its attribution across the lifecycle.

Your application notes

Study references: R3, R4, R6; supplied Module 7 topics 7.1 to 7.6.

MODULE 08 / CONCEPTS

SaaS Interfaces and Data Migration

By the end of this module, you should be able to:

- Assess SaaS changes through local dependencies.
- Verify transfer meaning, exception handling and reconciliation.
- Evaluate migration beyond record counts.

SaaS release assessment

A supplier release can change a shared service, permission rule, API, export or data schema without changing the customer interface code. Assess the release against customer use and configuration. Use supplier evidence within its scope and define targeted regression for affected business paths. Agree how releases, urgent fixes and incidents will be communicated, and record the evidence and conditions supporting continued use.

Preserve business meaning

Define source and target fields, identities, units, conversions, rounding, status and relationships. Technical receipt of a message is not proof that the correct result reached the correct batch. Verify representative mappings and consequential edge cases. Reconcile the actual business record rather than only network acknowledgements. Where data age matters, define how stale or unavailable data affect the downstream decision.

Handle partial failure and retry

A timeout can occur after the receiver accepted a message, leaving the sender uncertain. Define message identity, duplicate handling and controlled retries so the same event does not create an unintended second transaction. Test rejection, interruption, ordering and recovery conditions relevant to the interface. A retry design should support consistent business outcomes, not merely a green service indicator.

Complete the exception process

Missing or rejected records should be detectable and assigned to someone for resolution. Define alerting, queue handling, controlled correction, reconciliation and escalation. Retain what failed, what action was taken and the final disposition. A growing unread error queue is not successful control simply because the system stored the messages. Detection must connect to a timely operational response.

Migrate records and context

Approve mapping and transformation rules before executing a controlled migration. Compare counts as one check, then verify values, relationships, metadata, attachments, histories, signature associations and retrieval as applicable. Use risk-based sampling or full checks with a justified method for the different data types. Equal counts can hide duplicates offset by missing records. Resolve exceptions and verify the retained record before retiring the source.

MODULE 08 / APPLICATION

Apply the reasoning

LIMS transfers 0.5 g to ERP, but a field mapping labels the unchanged numeric value as mg. The correct batch identity and a transport success code do not make this a correct transfer. A separate retry after a lost acknowledgement can also create duplicates. The test strategy must cover semantic correctness and behavior under uncertain delivery.

Function or focus	Failure or claim	Useful evidence
Mapping	Wrong unit or association	Compare source and target values, units and batch identities.
Retry	Duplicate business action	Simulate uncertain delivery and verify duplicate handling.
Migration	Missing record context	Reconcile content, history, links and usable retrieval.

Application exercise

A migration report shows 10,000 records in each system. Identify three additional checks needed before drawing a suitability conclusion.

Worked response

Verify selected or fully reconciled critical fields and transformations; confirm required attachments, metadata and relationships; and demonstrate readable retrieval with applicable histories and signatures. Investigate exceptions and ensure the counting method can identify missing and duplicate records rather than offsetting them.

What to remember

Verify the intended business outcome across the data flow, including failures and recovery.

Your application notes

Study references: R1, R6; supplied Module 8 topics 8.1 to 8.6.

MODULE 09 / CONCEPTS

Maintaining the Validated State

By the end of this module, you should be able to:

- Use lifecycle controls to maintain the original assurance basis.
- Distinguish technical recovery from usable record recovery.
- Plan controlled retirement without losing required records.

Change control maintains the basis

Assess changed intended use, configuration, roles, interfaces, infrastructure and supplier components against affected requirements and risks. Determine what existing evidence remains relevant and what additional work is necessary. Record authorization, implementation, verification and the resulting conclusion. Emergency changes need a controlled route with suitable impact assessment and follow-up; urgency does not make consequences disappear.

Incidents can affect prior decisions

A defect discovered after release may affect records or product decisions already made. Contain inappropriate reliance, establish the affected period and population, and evaluate relevant business consequences. Investigate cause, correct the issue and obtain evidence that the correction works. A connection restart or a passing technical check does not, by itself, settle the impact on past regulated records.

Access and periodic review

Review rights against current duties, including transferred staff, privileged users and service identities. Investigate relevant activity when inappropriate rights are discovered. Periodic review brings together changes, incidents, recurring defects, supplier performance, recovery results, record retention and outstanding commitments. Its depth and timing should follow approved procedures and risk, rather than an assumed universal annual interval.

Backup is not demonstrated recovery

A backup-success message shows that a defined job completed. Recovery evidence should show that required content can be restored, read and used, including relevant attachments, history, permissions and signature associations. Consider dependencies such as software versions, keys and external stores. Where recovery-time and recovery-point objectives are used, define and verify the justified targets. Availability and complete usable recovery are different claims.

Retire under a retention plan

Before decommissioning, identify records still subject to retention and the future owner, retrieval method, access control and supporting dependencies. Verify archived or migrated content, including relevant context and history. Retain the evidence of the retirement decision and handle unresolved exceptions. Do not destroy the source simply because the replacement application is live; the retained record must remain usable for the required period.

MODULE 09 / APPLICATION

Apply the reasoning

Nightly SaaS backups show success. During a recovery exercise, CAPA records restore but attachments and approval history are missing. The database and service are available, yet the regulated record is incomplete for its intended use. The recovery claim remains unproven until the omitted dependencies and their business impact are addressed.

Function or focus	Failure or claim	Useful evidence
Change	New disposition use	Assess scope, risks and evidence before relying on it.
Incident	Wrong batch association	Contain, investigate past impact, correct and verify.
Recovery	Incomplete restored record	Verify required content and retrieval after restoration.

Application exercise

A former Quality approver has retained approval rights after a transfer. Define a response that addresses both present access and the past exposure.

Worked response

Remove or adjust inappropriate rights through the access process, establish when the role changed and review relevant approval activity during the exposure period. Assess record and decision impact, document disposition and address the process weakness that allowed the rights to persist.

What to remember

The validated state is a maintained body of justified confidence, not a permanent status granted at go-live.

Your application notes

Study references: R1, R6; supplied Module 9 topics 9.1 to 9.6.

MODULE 10 / CONCEPTS

AI Enabled GxP Systems

By the end of this module, you should be able to:

- Define AI reliance and decision authority.
- Evaluate errors against controlled reference information.
- Demonstrate human review and manage behavioral changes.

Define the AI role

Specify whether the AI drafts text, recommends findings, supports review, decides or executes an action. Identify input documents, allowed outputs, users, human authority and prohibited uses. Drafting can still be GxP-relevant when reviewers rely on the content. A human in the workflow is not automatic proof that an AI failure cannot matter. Evaluate the combined process in the specific regulated use.

Use qualified reference information

Evaluate representative documents or cases against independently established, qualified reference findings. Define what counts as a true issue, a correct finding, a missed issue and an unsupported flag. Include difficult and consequential cases, realistic document quality and relevant subgroups. Control dataset versions and separate development examples from the held-out evaluation where appropriate. Resolve disagreements through documented adjudication, not the AI's self-assessment.

Measure the failures that matter

A false negative is a real issue that was missed; a false positive is an issue flagged where the reference does not support it. Sensitivity is detected true issues divided by all reference true issues. Precision concerns how many flagged issues are correct. Define the evaluation unit and denominators. High overall accuracy can hide rare but important misses. Prespecify justified criteria for critical misses, false alarms and workflow performance; this course does not prescribe universal thresholds.

Verify human review

Test whether qualified reviewers detect plausible errors and omissions, inspect supporting sources and record suitable dispositions under realistic time and workload conditions. A reviewer title, training acknowledgement or accept button alone is weak evidence. Measure the combined workflow, including whether unnecessary flags create fatigue or hide critical findings. Define escalation and a safe response when the output or source support is uncertain.

Control changes and monitor use

Models, prompts, retrieval content, parsers, tools and provider behavior can change outputs. Record the relevant versions and assess changes against the intended use and failure modes. Repeat justified evaluations using controlled references before continued reliance. Monitor critical misses, unsupported findings, reviewer overrides and unexpected input patterns, with owners and response triggers. These are practitioner assurance measures; product-specific AI rules require separate applicability assessment.

MODULE 10 / APPLICATION

Apply the reasoning

An AI document reviewer identifies missing validation controls for a Quality reviewer to disposition. In a teaching evaluation, 50 genuine critical issues are present and the AI detects 45. Critical-issue sensitivity is 90 percent. This does not establish overall accuracy or suitability. A prespecified zero-critical-miss criterion would fail because five issues were missed; the criterion must be justified for the particular use.

Function or focus	Failure or claim	Useful evidence
Output quality	Critical omission	Compare with qualified reference findings and defined criteria.
Human review	Plausible error accepted	Seed errors and verify detection, source review and disposition.
Change control	Behavior shifts after update	Assess model/prompt dependencies and targeted re-evaluation.

Application exercise

A model upgrade produces fluent answers on three familiar documents. Identify what is still missing from an acceptance case for regulated document review.

Worked response

Fluency on familiar examples does not show representative performance. Use controlled and appropriately independent reference cases, critical failure challenges, error metrics with denominators and prespecified criteria, plus evidence that human review detects and dispositions failures. Assess the changed version and define monitoring and escalation.

What to remember

Assess what the AI is relied upon to do, its errors and the effectiveness of the combined human and software workflow.

Your application notes

Study references: Supplied Module 10 topics 10.1 to 10.7; practitioner methods linked to Modules 2, 4, 5 and 9.

Capstone exercise

Agile PLM maintains GxP Quality documents and routes change approvals. The organization configures document types, status rules and approval roles. The supplier provides standard regression results. An interface distributes effective-document status to an LMS. Quality approves changes before the new document becomes effective.

A release changes the shared workflow engine and the document export schema. Audit-trail export behavior is not yet confirmed. The supplier backup description mentions database records but does not explicitly address attachments. The team wants to support the revised use without repeating irrelevant tests.

Prepare your assurance recommendation

- Write the intended use and name the relied-upon records and decision authority.
- Screen GxP and Part 11 separately; record the facts still needed.
- Identify three consequential functions and one lower-impact supporting function.
- Write one testable requirement and a linked failure scenario for each consequential function.
- Select positive, negative, boundary or exploratory challenges where relevant.
- Define how supplier evidence applies and what local verification remains.
- Specify evidence for interface reconciliation and usable recovery.
- State open issues, the decision owner and change or incident triggers for reassessment.

Working record

Intended use and boundary

_____

_____

Principal failure and consequence

_____

_____

Evidence gap and additional assurance

_____

_____

Conditions for a supported conclusion

_____

_____

Capstone worked approach

The intended use is controlled maintenance, approval and distribution of GxP Quality documents and changes. The boundary includes PLM configuration, individual identity and authority, signatures where used, attachments and history, the export/interface and the LMS action that relies on current document status.

Function	Credible failure	Assurance and expected evidence
Approval and effectivity	Document becomes effective without required approval.	Challenge approved and incomplete paths and forbidden roles; retain state, role, version and history evidence.
Record and signature history	Approval attribution or change history is missing from the retained record.	Verify the applicable record/signature controls and retrieval or export of required content and linkage.
PLM to LMS transfer	Wrong document version or status is distributed.	Compare identity/version/status, test missing or duplicate transfers, and retain exception and reconciliation results.
Supporting display	Personal preference resets without changing decisions.	Confirm the defined supporting use and perform a focused check proportionate to that consequence.

The evidence decision

Review supplier results against the deployed engine and their scope. Use relevant evidence for standard behavior and locally verify configured approval rules and the changed export dependency. An example requirement is that effectivity must remain blocked until the designated approval is complete. Link it to a bypass risk, positive and negative tests, actual outcomes and any deviation disposition.

Resolve the open questions

Confirm the applicable predicate records, electronic reliance and signature use; do not infer all Part 11 controls solely from GxP relevance. Resolve audit-trail export and attachment-recovery coverage. A backup job report does not settle usable restoration. Quality and the system owner should receive the evidence, limitations and unresolved consequences required for their governed release decision.

Continue after release

Define review triggers for changed roles, workflow rules, schema, new regulated uses, transfer failures and record-recovery incidents. Monitor the controls actually relied upon, with owners and actions for exceptions. The capstone is a reasoning exercise and is not part of the 50-question score.

Terms for revision

Term	Meaning in this curriculum
Intended use	What the organization relies on a system or function to do.
GxP assessment	Determination of the connection between the defined use and regulated processes, records or decisions.
Predicate rule	Underlying applicable FDA requirement for the record or signature being assessed.
Functional risk	Risk assessed through a specific function, credible failure and consequence.
Preventive control	A measure intended to stop an unwanted event.
Detective control	A measure intended to identify an event, with a defined response.
Traceability	Reviewable links among intended use, function, risk, requirement, assurance and evidence.
Objective evidence	Information relevant to a claim, with identifiable scope, results and limitations.
Reconciliation	Comparison that establishes and resolves differences between expected and actual data or business outcomes.
Residual risk	Risk remaining after the controls considered in the assessment.
Sensitivity	True issues detected divided by all true issues in the defined reference set.
False positive	A flagged issue that the qualified reference does not support.
False negative	A genuine reference issue that is missed.

Distinctions to keep clear

GxP relevance is not the same as Part 11 applicability. Authentication is not the same as signing. A traceability link is not a passing result. Supplier qualification is not local validation. A backup job is not proven recovery. Fluent AI output is not demonstrated correctness.

Source notes and further reading

The supplied CSVtoCSA Modules 1 to 10 establish the curriculum and examples. This handbook adds focused teaching notes, exercises and assessment preparation. References below identify primary regulatory context; practitioner examples and course settings are not additional regulatory requirements. Source status was checked on 14 September 2026.

R1 FDA Computer Software Assurance for Production and Quality Management System Software

Final guidance issued 3 February 2026. Medical-device production and quality management system scope.

Open the primary source

R2 FDA Quality Management System Regulation

QMSR became effective 2 February 2026 and incorporates ISO 13485 2016 by reference.

Open the primary source

R3 Electronic Records and Electronic Signatures

21 CFR Part 11, particularly scope, closed-system controls, signature manifestations and record linkage.

Open the primary source

R4 FDA Part 11 Scope and Application

August 2003 guidance on the scope and application of Part 11.

Open the primary source

R5 ICH Q9 R1 Quality Risk Management

Step 4 guideline adopted 18 January 2023; current document records a 15 January 2025 typographical correction.

Open the primary source

R6 FDA Data Integrity and Compliance With Drug CGMP

December 2018 questions and answers; pharmaceutical CGMP scope.

Open the primary source