CSVtoCSA Certification Exam

Computer Software Assurance Foundations

FORM A | 50 QUESTIONS | 1.0 | 14 September 2026

This assessment covers the ten curriculum modules. Select the single best answer for each question using the facts stated in the scenario. The questions assess interpretation and practical judgment, not a claim that one document template or testing method is universally required.

Candidate details

Name _____

Candidate ID _____

Date _____ Assessor _____

Instructions

- Suggested time: 75 minutes. Standard administration: closed book, with no AI or outside assistance. The assessor may announce an approved accommodation before the session.
- Answer all 50 questions. Each question has four options and one best answer. Record one letter in the answer sheet or clearly circle one option.
- Each correct answer earns one point. Incorrect, blank or multiple answers earn zero. There is no negative marking.
- The proposed pass mark for this form is 40/50, or 80 percent. These are course settings, not regulatory thresholds.
- Use the stated assumptions. Unless a question states otherwise, apply the organization's controlled procedures and consider the defined intended use.
- Do not use the assessor answer key during the examination.

Candidate declaration: I completed this assessment under the stated session conditions.

Signature _____ Date _____

CSVtoCSA educational assessment. A score does not itself approve a system or establish professional licensure or third-party accreditation.

FORM A / MODULE 01 / QUESTIONS 1 TO 5

CSV and CSA Fundamentals

1. Which outcome best demonstrates successful software assurance?

A. The team has replaced all scripted tests with exploratory sessions.
B. The validation package contains the same number of scripts as last year.
C. Evidence supports the defined intended use and addresses relevant failure risks.
D. The supplier has confirmed that its platform is used by regulated customers.

2. An eQMS update changes approval routing and a personal display theme. Only routing controls CAPA closure. What is the most appropriate approach?

A. Exclude both changes because the overall system was validated before go-live.
B. Challenge routing controls rigorously and assess the theme with proportionate checks.
C. Test only the theme because the supplier already tested the workflow engine.
D. Use the same detailed protocol for routing and the personal display theme.

3. A team completes exploratory testing but records only "all passed." What is the principal evidence gap?

A. The record lacks a screenshot for every click performed during the session.
B. The tester must assign a numerical risk score to each mouse action.
C. Exploratory testing is unacceptable unless repeated as a fully scripted protocol.
D. The record does not show the objective, scope, observations, issues and conclusion.

4. A spreadsheet without macros calculates a result used for product acceptance. What should primarily drive its assurance?

A. The absence of macros and the spreadsheet application market share.
B. The software purchase price and the frequency of vendor security patches.
C. The calculation use, failure impact, controls and remaining evidence gaps.
D. The worksheet size and the number of people licensed to edit it.

5. A validated system will be used for a new product-disposition decision. The software version is unchanged. What should happen next?

A. Wait for the next annual review before documenting the new decision process.
B. Assess the new use and obtain evidence for affected functions before relying on it.
C. Repeat every historical test without first identifying the changed use.
D. Extend the existing approval because no software code or version changed.

FORM A / MODULE 02 / QUESTIONS 6 TO 10

Intended Use and GxP Assessment

6. Which element is essential to a useful intended-use statement?

A. The process and decision or record that rely on the software function.
B. The technology brand and a statement that the system is cloud hosted.
C. The complete list of functions advertised on the supplier website.
D. The purchase price and contract renewal date for the application.

7. ComplianceWire records training completions. MES uses those data and enterprise roles to permit manufacturing work. What boundary is appropriate?

A. Limit the assessment to the supplier hosting environment and service agreement.
B. Include completion data, role mapping, the interface and the MES eligibility control.
C. Limit the assessment to the ComplianceWire completion-entry screen.
D. Exclude MES because it receives data instead of assigning the training.

8. An SAP function handles office stationery invoices only. It does not support regulated materials, records or decisions. What is the most defensible GxP conclusion?

A. Exempt every SAP function because this one is limited to office purchases.
B. Classify the function as GxP because payment failures are commercially important.
C. Classify the function as GxP because SAP is enterprise resource planning software.
D. Document a non-GxP rationale for this defined use and its exclusions.

9. An SFDC dashboard formerly used for workload planning becomes the sole basis for complaint escalation decisions. What should change?

A. Reassess its intended use, data dependencies and controls for the new reliance.
B. Classify every SFDC feature as equally critical to complaint decisions.
C. Rely on the source-system assessment without evaluating dashboard calculations.
D. Retain the original assessment because the dashboard code did not change.

10. Agile PLM controls GxP Quality documents and change approvals. What is the appropriate next step for Part 11 screening?

A. Declare all Part 11 provisions applicable solely because the system is GxP.
B. Exclude Part 11 because an approval page can be printed to paper.
C. Identify applicable predicate records, electronic reliance and signature use separately.
D. Assess signature controls only if the supplier describes the product as compliant.

FORM A / MODULE 03 / QUESTIONS 11 TO 15

Requirements and Traceability

11. Which requirement is sufficiently specific to support a meaningful test?

A. Block CAPA closure until the required Quality approval is complete.
B. The CAPA workflow should be easy for Quality users to operate.
C. The system must be compliant and perform reliably for all users.
D. The application should support appropriate CAPA management functionality.

12. A requirement says, "The system supports approvals." What clarification most directly addresses unauthorized approval risk?

A. Specify the approval-screen color and the preferred default window size.
B. Require a screenshot of the home page for each approver account.
C. Define authorized roles, approval prerequisites and prohibited approval paths.
D. Reference the supplier brochure as the full acceptance criterion.

13. A test passes, but its referenced requirement was replaced after a configuration change. What should the reviewer do?

A. Delete the old requirement so the test appears to reference the remaining record.
B. Resolve the version linkage and assess whether evidence covers the current requirement.
C. Keep the pass result because test execution occurred after the original approval.
D. Accept the result if the tester remembers the intended requirement verbally.

14. LIMS sends a numeric result to ERP. The initial requirement defines the value but omits units and batch identity. What is missing?

A. A requirement that every message must be reviewed by the software supplier.
B. A requirement that both applications use identical database technologies.
C. A requirement that network bandwidth exceeds all supplier recommendations.
D. Requirements for meaning, mapping and association with the correct regulated record.

15. An RTM lists tests for every critical requirement, but two tests failed and deviations remain unresolved. What conclusion is justified?

A. The failed tests can be removed because the other requirements passed.
B. A high overall pass percentage is sufficient to close the two deviations.
C. Traceability is complete, so the intended use is automatically acceptable.
D. Coverage is visible, but acceptable performance and release readiness remain unproven.

FORM A / MODULE 04 / QUESTIONS 16 TO 20

Functional Risk Assessment

16. Which is the most useful functional-risk statement?

A. The application has many users and is difficult to administer.
B. The MES is a high-risk system because manufacturing depends on it.
C. Wrong role mapping permits an unqualified operator to start a manufacturing step.
D. The software might fail and therefore requires extensive validation.

17. A workflow blocks closure without approval; a later review checks the change history. How should these controls be classified?

A. Both controls are preventive because they are documented in procedures.
B. Neither is a control unless it removes the need for software testing.
C. The closure block is preventive; the later history review is detective.
D. The closure block is detective; the later history review is preventive.

18. A calculation error is said to be low risk because a person reviews the output. What evidence matters most before crediting that control?

A. The reviewer can independently detect representative errors before the decision is used.
B. The reviewer has an account and has clicked the training acknowledgement.
C. The system displays the calculated value in a second location on screen.
D. The review procedure contains the words independent verification.

19. A critical failure receives a low risk score because the team estimates it is unlikely, but no supporting data exist. What is the best response?

A. Record the uncertainty, challenge the estimate and select justified controls and evidence.
B. Accept the low score because a completed risk matrix is objective evidence.
C. Remove the failure from scope because its frequency cannot be calculated.
D. Lower severity until the score fits the planned testing budget.

20. An interface may silently drop approved batch results; a dashboard preference may reset. How should additional assurance be prioritized?

A. Prioritize the preference because users will notice it more frequently.
B. Test only the interface transport connection and ignore record completeness.
C. Prioritize transfer integrity and reconciliation while assessing the preference proportionately.
D. Apply identical testing solely because both functions are in the same system.

FORM A / MODULE 05 / QUESTIONS 21 TO 25

Risk Based Testing

21. Which statement correctly describes exploratory testing?

A. It combines learning and investigation with a defined objective and recorded evidence.
B. It consists of random actions whose results do not need to be retained.
C. It can replace every deterministic challenge for a critical permission control.
D. It is acceptable only after every action has been written as a fixed script.

22. An approved rule accepts values less than or equal to 10.0 mg. Inputs have one decimal place and no rounding is applied. Which set directly challenges the boundary?

A. 10.0 mg, 20.0 mg and 30.0 mg, expecting all three to be rejected.
B. 9.9 mg, 10.0 mg and 10.1 mg, expecting accept, accept and reject.
C. 0.0 mg, 5.0 mg and 15.0 mg, without specifying expected results.
D. 1.0 mg, 5.0 mg and 9.0 mg, expecting all three to be accepted.

23. Only Quality Approvers may close a CAPA. Which test most directly challenges the permission requirement?

A. Check that a supplier administrator can log into its own test environment.
B. Attempt closure as an unauthorized role and verify denial with the record unchanged.
C. Verify that the closure button uses the configured company color.
D. Confirm that a Quality Approver can open the application home page.

24. An automated regression run is green, but it used an older approval configuration. What should the team do?

A. Assess applicability and run or obtain evidence for the changed configuration and risks.
B. Accept the green status because automated evidence is inherently reliable.
C. Discard all automated testing and repeat every check manually from the beginning.
D. Change the report label to the new configuration without repeating any checks.

25. A SaaS release changes shared identity-role mapping. Which regression scope is most appropriate?

A. Assess dependent permissions, approvals, signatures and interfaces using the changed mapping.
B. Exclude approval workflows because their screen layouts have not changed.
C. Test only a new user account and assume existing role assignments are unaffected.
D. Test only the identity settings page named in the release notes.

FORM A / MODULE 06 / QUESTIONS 26 TO 30

Supplier Assessment and Existing Evidence

26. What is the key distinction between supplier qualification and customer validation?

A. Qualification is performed only for on-premises software; validation only for SaaS.
B. Qualification assesses supplier capability; validation addresses the customer intended use.
C. Qualification replaces the need to evaluate local configurations and interfaces.
D. Qualification and validation are interchangeable once a supplier is widely used.

27. A SaaS supplier provides a current SOC report and ISO certificate but no evidence for the customer CAPA routing. What do these documents establish?

A. No useful information because only locally executed tests can support assurance.
B. Proof that electronic records automatically meet all Part 11 provisions.
C. Proof that the customer CAPA workflow meets every approved requirement.
D. Evidence within their stated scope, with local workflow assurance still to be addressed.

28. Supplier regression evidence covers the standard workflow engine on the deployed version. What is the best next step?

A. Ignore the evidence because the tests were executed outside the customer site.
B. Map it to relevant claims and identify gaps in local routing, permissions and interfaces.
C. Repeat all supplier tests before considering the customer configuration.
D. Adopt the supplier test summary as the complete local release decision.

29. The supplier backs up a SaaS database, while the customer owns retention rules and record retrieval. What should the agreement and assurance plan clarify?

A. That a supplier backup-success message is the final customer recovery acceptance.
B. Recovery scope, responsibilities, evidence access and verification of usable required records.
C. That all retention responsibility transfers to the supplier after contract signature.
D. That customer retrieval checks are unnecessary when the service meets uptime targets.

30. A supplier will not provide detailed test records for a critical locally configured function. What is the strongest response?

A. Assume the function is low risk because evidence cannot be obtained.
B. Record the supplier statement as equivalent to detailed objective evidence.
C. Remove the function from intended use while continuing to rely on it operationally.
D. Document the limitation, assess alternatives and perform justified local assurance for the gap.

FORM A / MODULE 07 / QUESTIONS 31 TO 35

Data Integrity and Electronic Records and Signatures

31. Which statement is correct when screening Part 11 electronic records and signatures?

A. A password-protected login does not by itself establish an electronic-signature act.
B. Printing an electronic record always removes it from Part 11 consideration.
C. Every GxP application automatically uses electronic signatures whenever users log in.
D. Supplier marketing statements determine which predicate records apply to a customer.

32. A user changes a CAPA criticality from High to Low. What evidence best supports the change-history control?

A. A screenshot of the new Low value without identifying the prior value or user.
B. Authorized access and retained user, time, old and new values, plus required reason.
C. A server uptime report covering the day on which the record was modified.
D. A policy stating that users should avoid changing criticality after creation.

33. A signed approval record is exported. Which behavior should be verified for its signature representation?

A. The signer, signing date and time, and meaning remain associated with the record.
B. The exported record shows a login timestamp in place of the signing event.
C. Only the image of a handwritten signature is retained in the exported file.
D. The signer information can be copied independently to another approval record.

34. A migration preserves final report PDFs but omits original data and metadata needed to reconstruct regulated results. What is the principal concern?

A. Only the number of PDF files matters when demonstrating successful retention.
B. The retained package may be incomplete for the regulated record and its intended use.
C. The records are acceptable because PDFs are always equivalent to source records.
D. The migration is acceptable if the filenames match the original report titles.

35. Several Quality reviewers share one account for approving controlled changes. What risk most directly follows?

A. Approval attribution and accountability cannot reliably identify the individual reviewer.
B. The system can no longer produce any electronic record in a readable format.
C. The shared account necessarily changes the calculation algorithm used by the system.
D. The shared account prevents supplier infrastructure backups from completing.

FORM A / MODULE 08 / QUESTIONS 36 TO 40

SaaS Interfaces and Data Migration

36. Why is matching the source and target record count insufficient to verify a migration?

A. Record counts are irrelevant and should never be included in migration evidence.
B. Equal counts prove completeness, accuracy, readability and signature linkage.
C. Migration verification is required only when the target uses a different supplier.
D. Equal counts can conceal wrong values, missing metadata, duplicates and broken relationships.

37. A LIMS-to-ERP transfer sends 0.5 g as 0.5 mg for the correct batch. The transport reports success. What failed?

A. The transport connection failed because its success status must be incorrect.
B. Nothing failed because the numeric value and batch identity were transferred.
C. The interface failed to preserve the result meaning through unit mapping or conversion.
D. Only the display font failed because the result digits are unchanged.

38. An interface retries after a timeout even though ERP received the original message. Which behavior should the test verify?

A. The repeated message is detected and handled without an unintended duplicate transaction.
B. A successful connection is treated as proof that no duplicate can exist.
C. The interface discards every later message after any network timeout occurs.
D. The retry always creates a new transaction to guarantee that data are not lost.

39. A result message fails validation and is placed in an error queue. What completes an effective exception process?

A. Automatic deletion of the queue after the interface service restarts successfully.
B. A dashboard total that combines successful and failed messages without distinction.
C. Assigned review, controlled correction or retry, reconciliation and retained disposition evidence.
D. A permanent unread queue because the failed message has been technically stored.

40. Release notes mention a changed export format used by the customer ERP interface. What is most appropriate before accepting the release for that use?

A. Exclude the interface because the customer did not modify its integration code.
B. Assess mapping and downstream impact, then verify affected transfers and exceptions.
C. Accept the release because supplier regression passed for the export function.
D. Test only that the export file downloads and has the expected filename.

FORM A / MODULE 09 / QUESTIONS 41 TO 45

Maintaining the Validated State

41. What does maintaining the validated state require?

A. Retaining the final report while allowing operational changes without assessment.
B. Repeating the entire initial qualification protocol on a fixed monthly schedule.
C. Reusing the original validation conclusion without considering later changes.
D. Continuing assessment of changes, incidents, controls and evidence against the approved use.

42. Nightly backups are green, but a restore omits CAPA attachments and approval history. What conclusion is justified?

A. Recovery is acceptable because the database service restarted without an error.
B. A new backup-success report is enough to close the failed recovery observation.
C. The missing content can be ignored if the number of CAPA records is unchanged.
D. Backup execution succeeded, but recovery of the required record was not demonstrated.

43. After release, a defect is found that may associate a laboratory result with the wrong batch. What action is most appropriate?

A. Contain reliance, investigate affected records and decisions, and assess corrective action and retesting.
B. Correct future mapping only and assume earlier released batches were unaffected.
C. Close the incident when the interface connection test returns a success message.
D. Wait for the annual review because the system passed its original validation.

44. An employee has moved out of Quality but retains approval rights. What should an access review trigger?

A. Accept the access because the employee remains employed by the organization.
B. Change the account display name and leave the underlying permissions unchanged.
C. Remove inappropriate rights and assess approvals or activity performed after the role change.
D. Keep the rights until the employee password expires at the next scheduled interval.

45. An old regulated system will be retired while its records remain within retention. What must the retirement plan address?

A. Archiving record counts without verifying access to the underlying record content.
B. Continued readable retrieval of complete required records, history and signature associations.
C. Deletion of the source database immediately after the new platform goes live.
D. Retention of a login screenshot and the original software purchase invoice.

FORM A / MODULE 10 / QUESTIONS 46 TO 50

AI Enabled GxP Systems

46. Why must AI intended use distinguish drafting, recommending, deciding and executing?

A. A human reviewer automatically makes every role low risk without further evidence.
B. Drafting systems are always outside GxP regardless of how outputs are used.
C. The distinction determines whether the software can be called artificial intelligence.
D. These roles create different reliance, consequences, controls and evidence needs.

47. An AI protocol reviewer flags many issues. Which evaluation best supports a usefulness and safety conclusion for the defined task?

A. Count all findings and assume a larger number means better review performance.
B. Measure only response speed on a set of documents selected because they passed.
C. Compare with qualified reference findings and examine critical misses, false alarms and dispositions.
D. Ask the model whether its own findings are correct and accept its explanation.

48. A reference set contains 100 genuine critical issues. The AI detects 92 and misses 8. A prespecified criterion permits no critical misses. What is the result?

A. Specificity is 100 percent because every detected critical issue was correct.
B. Overall accuracy is 92 percent, so the system passes any reasonable criterion.
C. The false-positive rate is 8 percent, so the stated criterion is met.
D. Critical-issue sensitivity is 92 percent, and the stated acceptance criterion is not met.

49. AI suggestions are reviewed by a person before approval. How should the combined workflow be challenged?

A. Accept reviewer job titles as sufficient evidence of effective review performance.
B. Count review acknowledgements without examining whether the reviewers detect errors.
C. Test only the AI response because human review is outside the system boundary.
D. Seed plausible errors and omissions and verify detection, source checking and appropriate disposition.

50. The provider changes a model version and the customer changes its prompt template. What should happen before continued use for regulated review?

A. Continue use because the application interface and user roles have not changed.
B. Approve the change if one familiar document produces a fluent and plausible answer.
C. Assess both changes and relevant dependencies, then evaluate against controlled references and criteria.
D. Evaluate only the prompt because supplier model changes are outside customer responsibility.

Candidate answer sheet

Name _____ Candidate ID _____

Enter one letter A, B, C or D per question. Clearly erase or strike through any changed response so only one final answer remains.

Question	Answer	Question	Answer
1		26	
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Assessor use: Correct _____ / 50 Percentage _____ Result _____

Assessor _____ Date _____