Life Sciences AI
ACADEMY
A GxP Frame academy

ENTERPRISE WORKFORCE CAPABILITY

Enterprise AI Training Program Review

15 questions. Five review areas. Evidence and accountable follow-up.

Organization

Review owner / participants

Review date

Systems, processes and learner groups in scope

HOW TO USE THIS WORKSHEET

01 Review each question with the relevant Quality, training, process and system owners.

02 Select an evidence status. Cite the record and describe any gap or scope rationale.

03 Define the action, acceptance criteria, owner and due date. Track closure in your approved action process.

Evidence available: reviewable support. Partial evidence: support is incomplete. Action needed: a gap requires follow-up. Not reviewed: assessment is pending.

Priority actions / action-record reference / next review trigger

Illustrative review aid. Your organization retains applicability, validation, training issuance and work-authorization decisions. Apply local document-control, retention and approval requirements.

REVIEW AREA 01 / 05

Define the scope and accountable owners

Select a status and cite the evidence. Use your controlled action process for follow-up and closure.

01 Have we documented which requirements and internal controls apply to the AI uses in scope?

Evidence: A dated applicability review using current primary sources, with jurisdiction, final or draft status, rationale, reviewer and a review trigger.

- (•) Not reviewed
- ( ) Evidence available
- ( ) Partial evidence
- ( ) Action needed

Evidence reference / gap / scope rationale

Action / acceptance criteria / owner / due date

02 Does our inventory cover the AI used in our work, including embedded features and relevant supplier use?

Evidence: A current register showing system, intended use, process, affected records or decisions, owner and unresolved inventory gaps.

- (•) Not reviewed
- ( ) Evidence available
- ( ) Partial evidence
- ( ) Action needed

Evidence reference / gap / scope rationale

Action / acceptance criteria / owner / due date

03 Are responsibilities and potential GxP consequences clear for each use case?

Evidence: An accountable-owner map, documented provider or deployer responsibilities where relevant, and an impact rationale addressing patient safety, product quality and data integrity.

- (•) Not reviewed
- ( ) Evidence available
- ( ) Partial evidence
- ( ) Action needed

Evidence reference / gap / scope rationale

Action / acceptance criteria / owner / due date

REVIEW AREA 02 / 05

Assign learning to actual work

Select a status and cite the evidence. Use your controlled action process for follow-up and closure.

04 Do learning assignments reflect each person's systems, tasks, access and decision authority?

Evidence: A role-to-system matrix reconciled with access lists and workflow responsibilities, including people who perform multiple roles.

- (•) Not reviewed
- ( ) Evidence available
- ( ) Partial evidence
- ( ) Action needed

Evidence reference / gap / scope rationale

Action / acceptance criteria / owner / due date

05 Have we covered employees, contractors and relevant personnel working on our behalf?

Evidence: Defined learner populations, training responsibilities, onboarding and offboarding controls, and an owner for coverage gaps.

- (•) Not reviewed
- ( ) Evidence available
- ( ) Partial evidence
- ( ) Action needed

Evidence reference / gap / scope rationale

Action / acceptance criteria / owner / due date

06 Are learning outcomes observable, with prerequisites and access decisions defined?

Evidence: Task-specific outcomes, required learning, an assessment method and the company-approved process for access, supervision and task authorization.

- (•) Not reviewed
- ( ) Evidence available
- ( ) Partial evidence
- ( ) Action needed

Evidence reference / gap / scope rationale

Action / acceptance criteria / owner / due date

REVIEW AREA 03 / 05

Develop, deliver and assess the training

Select a status and cite the evidence. Use your controlled action process for follow-up and closure.

07 Does system training explain the approved purpose, limitations, data boundaries and escalation route?

Evidence: Reviewed system-specific materials linked to the applicable procedure, including examples of permitted use, prohibited use and when to stop.

- (•) Not reviewed
- ( ) Evidence available
- ( ) Partial evidence
- ( ) Action needed

Evidence reference / gap / scope rationale

Action / acceptance criteria / owner / due date

08 Are content, delivery responsibilities and training records controlled?

Evidence: Approved material versions, qualified or otherwise approved facilitators under the local process, delivery records and defined retention requirements.

- (•) Not reviewed
- ( ) Evidence available
- ( ) Partial evidence
- ( ) Action needed

Evidence reference / gap / scope rationale

Action / acceptance criteria / owner / due date

09 Can reviewers demonstrate that they detect and handle material AI errors?

Evidence: Known-error practice cases, source-verification exercises, scoring criteria, critical-error rules, remediation and a documented reassessment decision.

- (•) Not reviewed
- ( ) Evidence available
- ( ) Partial evidence
- ( ) Action needed

Evidence reference / gap / scope rationale

Action / acceptance criteria / owner / due date

REVIEW AREA 04 / 05

Maintain performance and supplier oversight

Select a status and cite the evidence. Use your controlled action process for follow-up and closure.

10 Have relevant supplier AI use and training responsibilities been addressed in oversight arrangements?

Evidence: Risk-based supplier questions, evidence requests and applicable contractual or quality-agreement responsibilities, including change notification and subcontractor coverage.

- (•) Not reviewed
- ( ) Evidence available
- ( ) Partial evidence
- ( ) Action needed

Evidence reference / gap / scope rationale

Action / acceptance criteria / owner / due date

11 Do we review whether people apply the training effectively in the actual workflow?

Evidence: An agreed approach to observed practice or sampled work, recurring-error review, reviewer performance, escalation trends and follow-up actions.

- (•) Not reviewed
- ( ) Evidence available
- ( ) Partial evidence
- ( ) Action needed

Evidence reference / gap / scope rationale

Action / acceptance criteria / owner / due date

12 Does change control assess the effect of system and process changes on training?

Evidence: Recorded training-impact decisions for model, feature, intended-use, role and procedure changes, with revised materials and retraining where justified.

- (•) Not reviewed
- ( ) Evidence available
- ( ) Partial evidence
- ( ) Action needed

Evidence reference / gap / scope rationale

Action / acceptance criteria / owner / due date

REVIEW AREA 05 / 05

Make evidence and decisions reviewable

Select a status and cite the evidence. Use your controlled action process for follow-up and closure.

13 Can we distinguish attendance and completion from demonstrated performance and work authorization?

Evidence: Records identifying the learner, material version, assessment scope, result, remediation and the separate company qualification or access decision.

- (•) Not reviewed
- ( ) Evidence available
- ( ) Partial evidence
- ( ) Action needed

Evidence reference / gap / scope rationale

Action / acceptance criteria / owner / due date

14 Can we retrieve a coherent program evidence package within a defined internal target?

Evidence: A retrieval exercise covering the inventory, rationale, assignments, materials, assessments, exceptions and maintenance records, with an owner for missing evidence.

- (•) Not reviewed
- ( ) Evidence available
- ( ) Partial evidence
- ( ) Action needed

Evidence reference / gap / scope rationale

Action / acceptance criteria / owner / due date

15 Does an accountable sponsor review gaps, effectiveness and continued fitness of the program?

Evidence: A documented periodic review, accepted actions with owners and due dates, resource decisions and the next review date or trigger.

- (•) Not reviewed
- ( ) Evidence available
- ( ) Partial evidence
- ( ) Action needed

Evidence reference / gap / scope rationale

Action / acceptance criteria / owner / due date