

Twelve questions before quality AI.

Use this checklist with any supplier before AI touches CAPA, NCR, complaint, audit or other controlled quality work.

01 Which sources may the system use?	02 Can every material claim link to its source?
03 Which decisions are explicitly prohibited?	04 Who must approve the output?
05 What remains the authoritative record?	06 How are user roles and access limited?
07 Are prompts and workflow versions recorded?	08 Can user edits and approvals be reconstructed?
09 How is customer data separated and retained?	10 How are model or workflow changes controlled?
11 What baseline measures success before launch?	12 What happens when evidence is weak or conflicting?

MINIMUM ACCEPTABLE ANSWER

The supplier can demonstrate the control in the working product or agreed operating design - not merely state that the model is secure, compliant or human-in-the-loop.

QAI GOVERNANCE BOUNDARY

QAI may retrieve, compare, structure and draft. Named quality professionals retain authority for root cause, disposition, CAPA closure and product release.

Read the full approach: qaitransformation.com/security