VENDOR EVALUATION · GUIDE

eSignature Tool Validation Guide

10 questions to ask your vendor before you commit

PART A Quality system & validation approach

1 Initial validation package

What specific validation documentation do you provide? Are there any additional fees for this documentation or for hands-on validation support?

RED FLAG ANSWER

Treating the validation package as a costly, separate professional service instead of including it as standard.

2 Ongoing validation & change control

How are system updates managed? What re-validation evidence do you provide to help us maintain our validated state?

RED FLAG ANSWER

Lacking a formal change control process that provides advance notification of updates. This forces you into a reactive state and puts your system's validated status at constant risk.

PART B Core compliance & functionality

3 Compliance traceability

Can you provide a requirements traceability matrix that maps each requirement of 21 CFR Part 11 and Annex 11 to specific system functions and their validation tests?

RED FLAG ANSWER

High-level materials as opposed to detailed mapping of each regulation to specific, tested functions.

4 Workflow integrity

Please describe the exact workflow for signing a document. Is the document ever required to leave the validated source system?

RED FLAG ANSWER

A workflow that requires downloading documents from your source system and re-uploading them after signing.

5 Unified audit trail

How does your system produce a single, unified audit trail for a document, especially one signed by both internal and external users? How are the audit trails protected from modification?

RED FLAG ANSWER

Creating two separate audit trails (one in the signature tool, one in your QMS) that require manual reconciliation.

6 Signature linking

How do you technically ensure the signature is "inextricably linked" to the record and cannot be copied, falsified, or moved?

RED FLAG ANSWER

Vague, high-level explanations. Your vendor should be able to explain the technical capabilities of the system.

7 Data invalidation

Describe the system's behavior if a signed document is altered. How is the signature visibly invalidated to prevent reliance on an altered record?

RED FLAG ANSWER

Any process that places the burden of control entirely on internal user procedures, not on technical controls, which is a weaker compliance stance.

PART C User experience & total cost

8 External partner experience

What is the process for external collaborators to sign documents? Do they need to purchase a license or create an account on your platform?

RED FLAG ANSWER

Requiring your partners to buy software or go through a complex registration process, which creates friction in your critical business workflows.

9 User authentication

What mechanisms ensure the person signing is who they claim to be at the moment of signing?

RED FLAG ANSWER

A lack of two distinct identification components per signee. This signifies the signature is not 21 CFR Part 11 compliant.

10 Total cost of ownership

Beyond licenses, what other costs should we anticipate? (e.g., per-signature fees, validation packages, implementation, training, API access).

RED FLAG ANSWER

Hidden fees for implementation, validation, or revalidation. This makes the true total cost of ownership unclear.

ZENSIGN

The right partner has these answers ready

At ZenQMS, our entire platform is built on a foundation of quality and compliance. Our eSignature feature, ZenSign, is fully integrated into our pre-validated eQMS, which means:

No hidden fees
Our validation package is included.

No disconnected workflows
The signature process is a seamless, closed loop.

No compliance gaps
We have the documentation and expertise to be your trusted partner.

Ready for a preview of ZenQMS? Get more info here.