

21 CFR Part 11

Pricing Under Compliance Constraints

Quick Guide

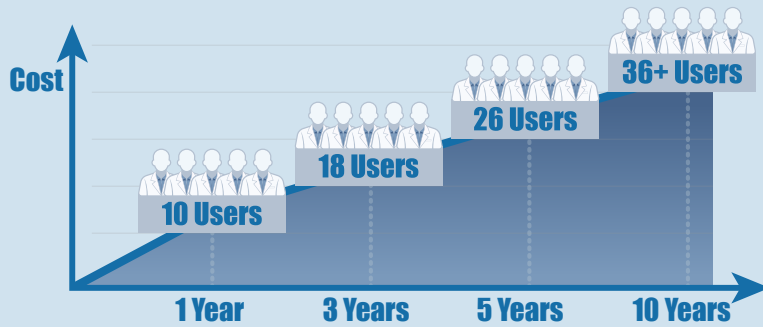
The Problem **The compounded cost of compliance**

In regulated labs, 21 CFR Part 11 requirements make user-linked history and audit trails long-lived. If licensing is tied to user seats, costs can rise over time even when day-to-day headcount stays flat.

Why this happens

21 CFR Part 11 changes the meaning of a user. Records must remain attributable: who did the work, when, and what changed. When people leave, the records stay - and many systems keep inactive accounts to preserve auditability.

The Cost Over Time: Per-Seat Licensing Growth








The Pain Point for Laboratories

Inactive users can become an ongoing cost driver. Per-seat vendors may still bill for users who haven't logged in for years because their identity and history must remain accessible for audits.

Turnover becomes a licensing multiplier.



Common questions (use in sales calls)



-  How many unique people have touched the system in the last 3-5 years (including interns/contractors)?
-  When someone leaves, can you disable them while keeping attribution intact? Are they still billable?
-  Do renewals creep up year-over-year even when your active team size is stable?

-  Do you ever restrict access because licenses are expensive (vs. security policy)?
-  If an auditor asked 'who did this' on a record from 4 years ago, could you show it instantly?



Customer evaluation

-  Are disabled/inactive users counted as paid seats?
-  What defines a 'user' - named, concurrent, role, site, instrument? Do historical identities count?

-  Model total cost over 5-10 years under realistic turnover.
-  How is audit trail readability preserved after offboarding without paid licenses?

Rudolph Advantage

Rudolph offers a **ONE-TIME** 21 CFR Part 11 compliance charge and does not charge per seat. Labs keep full auditability and user-linked history without ongoing seat growth - resulting in predictable, stable total cost of ownership across long instrument lifecycles.

