

A photograph of two men in a meeting. One man is seen from the back, wearing a light-colored shirt and glasses. The other man is facing him, wearing a dark shirt and glasses. They are in front of a wall with a diamond-shaped pattern. A laptop is visible on a desk to the right.

Build, Buy, or Consolidate

WHITE PAPER

A Decision Framework for Regulated System Replacement That Doesn't Default to 'Buy Something New'

Abstract

When a regulated system reaches end of life, the default instinct in most organizations is to run a vendor selection process and buy its replacement. That instinct skips a step, and the step it skips is expensive to skip. Large IT projects run 45% over budget and deliver 56% less value than predicted on average, and organizations already use only about 54.4% of the software they have already purchased, meaning a meaningful share of any new buy decision adds to a pile of underused licenses rather than solving the underlying problem. Five-year total cost of ownership for both building and buying is routinely underestimated by two to three times the initial projection, and for regulatory-grade capability specifically, internal build projects tend to fail not at launch but roughly eighteen months later, when governance and validation demands exceed what the original roadmap accounted for. The right question is rarely build versus buy in the abstract. It is which specific capability needs which specific answer, and whether the honest answer for a given system is neither: consolidating onto capacity the organization already owns. This white paper draws on established system-consolidation and change-management best practices to lay out a structured build, buy, or consolidate decision process for regulated system replacement.

The Default That Costs More Than It Should

A regulated system reaching end of life triggers a predictable organizational response: assemble requirements, run a vendor evaluation, select a replacement, and migrate. This process treats the decision as settled before it starts, the only real question is which vendor, when build and consolidate were never seriously evaluated as alternatives.

The numbers behind that default should give any organization pause. Large IT projects run 45% over budget on average and deliver 56% less value than predicted, with 17% severe enough to threaten the organization outright. Total cost of ownership over a five-year horizon is routinely underestimated by two to three times the initial projection, for both building and buying. A modest \$200,000 custom tool can grow to roughly \$750,000 over five years once infrastructure, engineering maintenance, and compliance updates are included. An \$80,000 annual subscription can reach a comparable \$700,000 over the same period once implementation and administrative support are counted.¹

Buying is not automatically the safer choice either. Organizations already use only about 54.4% of the software they have licensed, roughly \$19.8 million in average annual waste from idle licenses, and more than three-quarters of IT leaders report encountering unexpected costs after signing a new software contract. A default toward buying without evaluating the alternatives adds to that waste as often as it solves it.

Why Regulated Capability Makes This Decision Harder, Not Easier

For regulated systems specifically, the build-versus-buy calculus carries extra weight that a generic IT decision framework does not capture. Regulatory-grade capability demands accurate, traceable, repeatable outputs with validation and audit trails built into the architecture, not added afterward, and that kind of architectural commitment takes years to develop properly, not a feature sprint.

This is why internal build projects for regulated capability follow a specific, recurring failure pattern: they rarely fail at launch. They fail roughly eighteen months later, when the governance, validation, and audit requirements the initial roadmap did not fully anticipate start to overwhelm the team maintaining the system. One top-ten pharmaceutical company estimated \$5 to \$10 million just to automate clinical study report generation, covering only the first version of the platform, a figure that illustrates how quickly regulated build costs escalate beyond what a simple internal tool comparison suggests.²

None of this means buy always wins for regulated capability. It means the decision needs to be made deliberately, weighing where an organization's own domain expertise creates real strategic differentiation worth building for, against where a specialized vendor's accumulated regulatory knowledge, built over years of ICH guidance and health authority interaction, is not realistically something an internal team can replicate on a reasonable timeline.

Applying Best Practices: A Build, Buy, or Consolidate Framework

A foundational best practice in system consolidation and change management, understanding what a system was actually solving for before deciding what replaces it, is exactly what a genuine build, buy, or consolidate decision requires. The third option, consolidating onto platform capacity the organization already owns, is the one most often skipped entirely because it does not fit neatly into a standard vendor evaluation process.



1. **A Capability Inventory Before a Requirements Document.** Map what the retiring system actually does against capacity that already exists elsewhere in the organization's technology portfolio, before writing requirements for a net-new build or buy decision.
2. **A Strategic Differentiation Test.** Reserve build for capabilities that create genuine competitive differentiation the organization needs to control directly, and default to buy or consolidate for everything else, particularly regulatory-grade infrastructure.
3. **A True Five-Year TCO Model for Every Path.** Model build, buy, and consolidate options against the same multi-year cost horizon, including infrastructure, maintenance, compliance updates, and license utilization, rather than comparing an initial build estimate against a first-year subscription quote.
4. **An Eighteen-Month Governance Stress Test.** For any build option involving regulated capability, explicitly plan for the governance and validation burden that tends to surface roughly eighteen months in, rather than discovering it after the initial build is already sunk cost.

None of this requires a longer decision process for its own sake. It requires making the consolidate option genuinely visible alongside build and buy, since it is the option most consistently skipped in a standard vendor-first replacement process.

What a Structured Framework Buys, and Where It Gets Hard

Advantages

- **Fewer expensive surprises eighteen months in:** explicitly planning for regulated build's governance and validation burden up front avoids the failure pattern that derails internal build projects after launch.
- **Reduced license waste:** seriously evaluating consolidation against existing platform capacity reduces the idle-license waste that a reflexive buy decision tends to compound.
- **More accurate cost expectations:** a true five-year TCO model set against realistic benchmarks prevents the two-to-three-times cost underestimation common to both build and buy paths.
- **Build capacity reserved for real differentiation:** treating build as a deliberate choice rather than a default preserves scarce internal engineering capacity for the capabilities that actually warrant it.

Risks and Barriers

- **Consolidation options are often invisible to the team making the decision:** a system replacement project run within one function may not have visibility into adjacent platform capacity elsewhere in the organization.
- **A structured framework takes longer than a familiar vendor process:** organizations under schedule pressure to replace an end-of-life system may resist a more deliberate evaluation even when it would produce a better outcome.
- **Domain expertise gaps are hard to self-assess honestly:** internal teams can underestimate how much specialized regulatory knowledge a vendor has accumulated that would take years to replicate internally.
- **True TCO modeling requires data organizations do not always track well:** accurately projecting five-year infrastructure, maintenance, and compliance costs requires historical cost data that is not always captured consistently.



Case in Point: The Internal Tool That Solved a Problem the Company Already Owned a Fix For

A mid-size specialty pharmaceutical company's regulatory affairs team needed to replace an aging internal tracking tool for submission timelines and health authority correspondence. Facing a compressed timeline, the team scoped a build project with an internal development group, reasoning that the specific workflow was unique enough to their function that no off-the-shelf product would fit well.

Eighteen months into the build, the project had accumulated exactly the pattern the industry's build-versus-buy literature describes: initial development had gone reasonably well, but ongoing validation documentation, audit trail requirements, and access control governance had grown well beyond the original scope, and the small internal team was now spending most of its time on compliance maintenance rather than the workflow improvements that had motivated the build in the first place.

A late-stage review, prompted by the growing maintenance burden, discovered that the company's quality organization was running a document and correspondence tracking platform with unused capacity that could have handled the regulatory affairs team's core requirements with modest configuration. The company ultimately migrated onto the existing platform, retiring the custom build. The core lesson was not that building had been the wrong instinct. It was that consolidation had never been seriously evaluated as an option before the build decision was made, because the two systems lived in different functions that had not compared notes.

Recommendations for IT and Business Leaders

1. **Inventory existing platform capacity before scoping a replacement.** checking whether an adjacent function already owns a system that could reasonably absorb the retiring system's requirements.
2. **Reserve build decisions for genuine strategic differentiation.** and treat regulatory-grade infrastructure as a strong default toward buy or consolidate rather than build.
3. **Model true five-year total cost of ownership for every path.** including infrastructure, maintenance, compliance updates, and realistic license utilization, before comparing options.
4. **Plan explicitly for the eighteen-month governance inflection point.** on any regulated build decision, rather than treating validation and audit burden as a later problem.
5. **Cross-check consolidation options across functions, not just within the requesting team.** since the platform capacity that solves a problem often sits outside the function that owns the problem.
6. **Revisit license utilization before signing a new buy contract.** to confirm the organization is not adding to an existing pile of underused software.

Measuring Success: KPIs for Build, Buy, or Consolidate Decisions

- **Consolidation options formally evaluated per replacement decision:** tracked to confirm the third option is genuinely considered rather than defaulted past.
- **Five-year TCO accuracy:** actual multi-year cost against the modeled projection for completed build, buy, and consolidate decisions, tracked toward closing the historical two-to-three-times underestimation gap.



- **License utilization rate:** the percentage of purchased software capacity actively in use, tracked toward reducing idle license waste.
 - **Regulated build governance burden at eighteen months:** the share of internal build team capacity consumed by validation and compliance maintenance at the eighteen-month mark, tracked against the original roadmap's assumption.
-

Conclusion

Build versus buy is the wrong question when it is asked in the abstract, and it is an especially incomplete question for regulated systems, where a third option, consolidating onto capacity an organization already owns, is routinely skipped simply because it does not fit a standard vendor evaluation process.

Applying disciplined best practices to build a structured build, buy, or consolidate framework, capability inventory before requirements, a genuine strategic differentiation test, true multi-year cost modeling, and explicit planning for the governance burden that regulated builds accumulate over time, turns a reflexive replacement decision into one an organization can actually defend, in cost terms and in regulatory terms, years after it is made.

About OmniTek & Contact Information

OmniTek Consulting is a trusted partner for organizations seeking to enhance governance, operational agility, and decision-making. We specialize in modernizing business processes with a blend of human-centered design, technology expertise, and hands-on change management.

For IT and business leaders facing a regulated system replacement decision, OmniTek applies proven best practices to build a structured build, buy, or consolidate practice: a capability inventory that surfaces consolidation options, a strategic differentiation test for build decisions, and true multi-year cost modeling across every path. Whether you are scoping your next system replacement or reassessing a build project that has grown beyond its original plan, OmniTek can help you make a decision that holds up years down the road.

Contact us today to explore how OmniTek can support your transformation journey and drive lasting results.



McLean, VA | Serving
clients nationwide



info@omnitekconsulting.com



omnitekconsulting.com

[Click here to book a 15-minute call to see how OmniTek can help your team put these insights into practice.](#)

Endnotes

ⁱ Zylo, "Build vs Buy Software: Pros and Cons, Costs, and How to Decide," citing McKinsey and Oxford large IT project research, software license utilization data, and five-year total cost of ownership modeling, available at <https://zylo.com/blog/build-vs-buy-software-pros-and-cons>

ⁱⁱ Yseop, "The Build-vs-Buy Debate Is the Wrong One for Regulatory-Grade AI," on regulated build project failure patterns and life sciences cost examples, available at <https://yseop.com/blog/the-build-vs-buy-debate-is-the-wrong-one-for-regulatory-grade-ai/>

