IFUcare
SAFEGUARDING YOUR eIFU SINCE 2008

Build vs. Buy: a decision framework for international eIFU systems

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The wrong eIFU decision will cost you a decade

Build vs. buy

Regulatory risk

MDR, IVDR, FDA 21 CFR Part 11. Compliance requirements don't stand still. Neither can your documentation platform.

Operational burden

Validation, hosting, paper-on-request, SOPs. This isn't a project you finish. It's a function you staff, maintain, and defend indefinitely.

Security exposure

Global uptime, ISO 27001:2022, GDPR. Cloud infrastructure is a starting point, not a security program. The gap between the two is your liability.

Innovation velocity

The medical device industry moves fast. Internal builds typically stall after year four, leaving you behind the regulatory curve precisely when it matters most.

Buying is faster, safer, and significantly cheaper. The numbers make the case.

Build vs. buy

Buy

- **Low risk:** the vendor absorbs regulatory and security liability under contract. You don't.
- **Fast:** 4 to 8 weeks to first device family in production. No hiring, no scoping, no delays.
- **Scalable:** multilingual delivery, global CDN, and paper-on-request, all built in and validated.
- **Future-proof:** continuous innovation funded across dozens of manufacturers. Your roadmap benefits from every customer.
- **Predictable cost:** $1M to $3.5M over 5 years, fully loaded.

Build

- **High control:** internal team owns architecture and roadmap
- **High cost:** $4.2M to $11M over 5 years
- **High maintenance:** re-validation, security, and paper-on-request all fall to your team
- **Obsolescence risk:** replatforming pressure hits at year 5 to 7
- **Continuous burden:** this never becomes a finished project

Twelve dimensions decide the build-versus-buy outcome

Build vs. buy

Most teams evaluate three or four. The remaining eight are where build economics break down.

01 Compliance & validation	**02** Global regulatory coverage	**03** Security	**04** Paper-on-request	**05** SOPs & documentation	**06** Speed to deploy
07 Multilingual access	**08** Integrations	**09** Innovation velocity	**10** Total cost of ownership	**11** Risk exposure	**12** Scalability

Decision matrix (1 of 2): regulatory, security, operations

Build vs. buy

Dimension	Buy	Build
Regulatory compliance	Audit-ready, 21 CFR Part 11 capable	Full internal responsibility
Validation	Complete validation pack included	Build and re-validate every release
Security	ISO 27001:2022 controls, GDPR-aligned	Build global security program
Paper-on-request	Turnkey toll-free + fulfillment	Build, staff, document, audit
SOPs & documentation	Templates and controlled processes	Author and maintain all SOPs
Global regulatory coverage	Continuous multi-jurisdiction updates	Manufacturer-staffed regulatory intelligence

Decision matrix (2 of 2): technical, financial, strategic

Build vs. buy

Dimension	Buy	Build
Speed to deploy	4 to 8 weeks	12 to 24 months
Multilingual access	Built-in global support	Build workflows and hosting
Integrations	API and pre-built connectors	Custom development
Innovation velocity	Network effects across customers	Bounded by internal budget
5-year TCO	$1M to $3.5M (for larger companies)	$4.2M to $11M
Risk exposure	Vendor absorbs major risks	Manufacturer absorbs all risks

Security is the most underestimated build-versus-buy factor

Build vs. buy

WHAT AN EIFU SECURITY PROGRAM REQUIRES

- Global uptime and redundancy
- Penetration testing (annual + remediation)
- Encryption at rest and in transit
- 24/7 monitoring
- ISO 27001:2022 controls + audit
- GDPR-aligned data handling
- Disaster recovery + geo-disparate hosting
- Vulnerability management program

BUILD VS. BUY VERDICT

BUY — IFUCARE

Security is included. Not an add-on.

ISO 27001:2022, SOC 2 Type II posture, and third-party attestations delivered annually as part of the platform. Zero internal overhead.

BUILD — IN-HOUSE

Security must be engineered, staffed, and maintained.

Implement, monitor, and document every control. Run annual pen tests. Stand up and sustain a full audit program. This never becomes a finished project.

ISO 27001:2022 on internal eIFU: $150k–$400k upfront · $80k–$150k per year

Paper-on-request: a regulatory requirement that is operationally heavy to build

Build vs. buy

EU Regulation 2021/2226 Article 5: paper IFU on demand, in-language, free, within 7 calendar days.

01 Toll-free access	02 Inbound handling	03 Request capture	04 Fulfillment	05 Audit trail	06 SLA reporting
Provided across geographies	Multilingual operators, 24/7	Logged in vendor system	Vendor-operated print & ship	Vendor-maintained	7-day SLA per EU 2021/2226 Art. 5
Acquire ITFS lines per jurisdiction	Staff or outsource call center	Build logging + QMS integration	Build fulfillment workflow	Manufacturer-maintained	Manufacturer reports vs. SLA

⟶ Build adds $50k–$150k per year — before peak handling, audit prep, and re-validation costs

A compliant eIFU system requires an extensive controlled-document stack

Build vs. buy

What compliance requires (you own these)

- Content publishing procedures
- Version control procedures
- Paper-on-request workflow
- Validation pack (URS, FRS, IQ, OQ, PQ, VSR)
- Change-control procedures
- Training records
- Supplier qualification (if outsourced)
- Incident response plans

Build vs. Buy: The Verdict

BUY: IFUcare provides guidance and reference documents.

- You still own your SOPs under your QMS. IFUcare gives you the guidance, templates, and reference material so you do not start from a blank page.

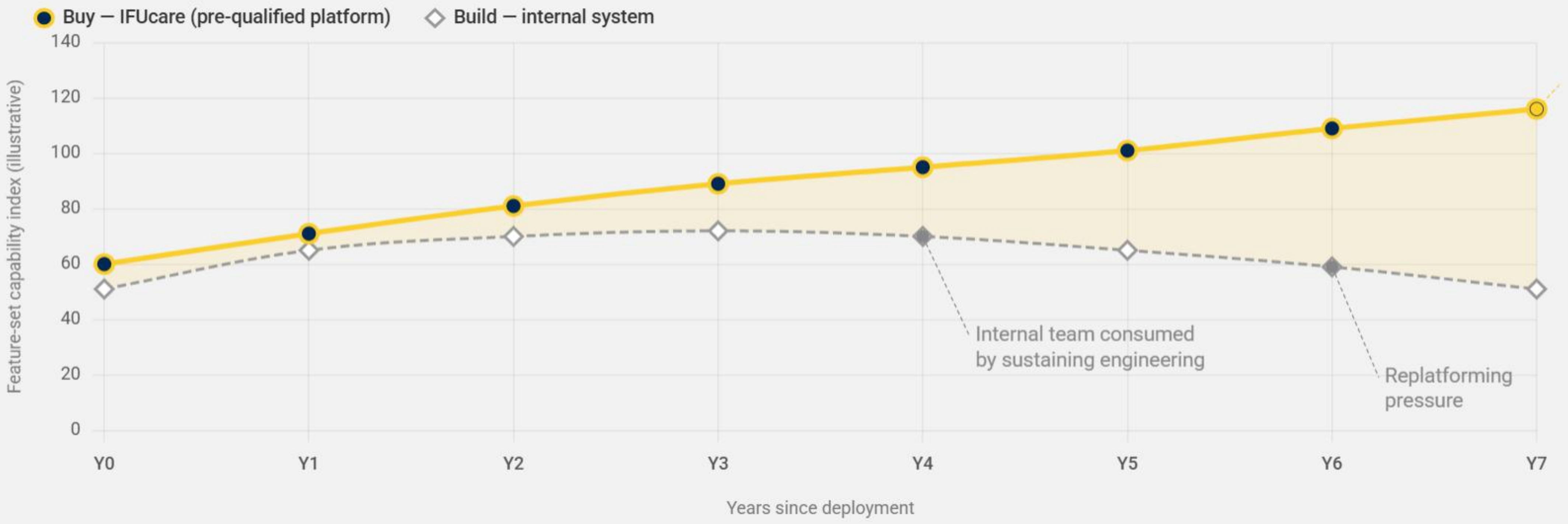
BUILD: full internal authorship and maintenance.

- Every system change cascades into procedure updates, training, and re-validation, with no external reference to start from.

Shared innovation is the structural advantage of buying

Build vs. buy

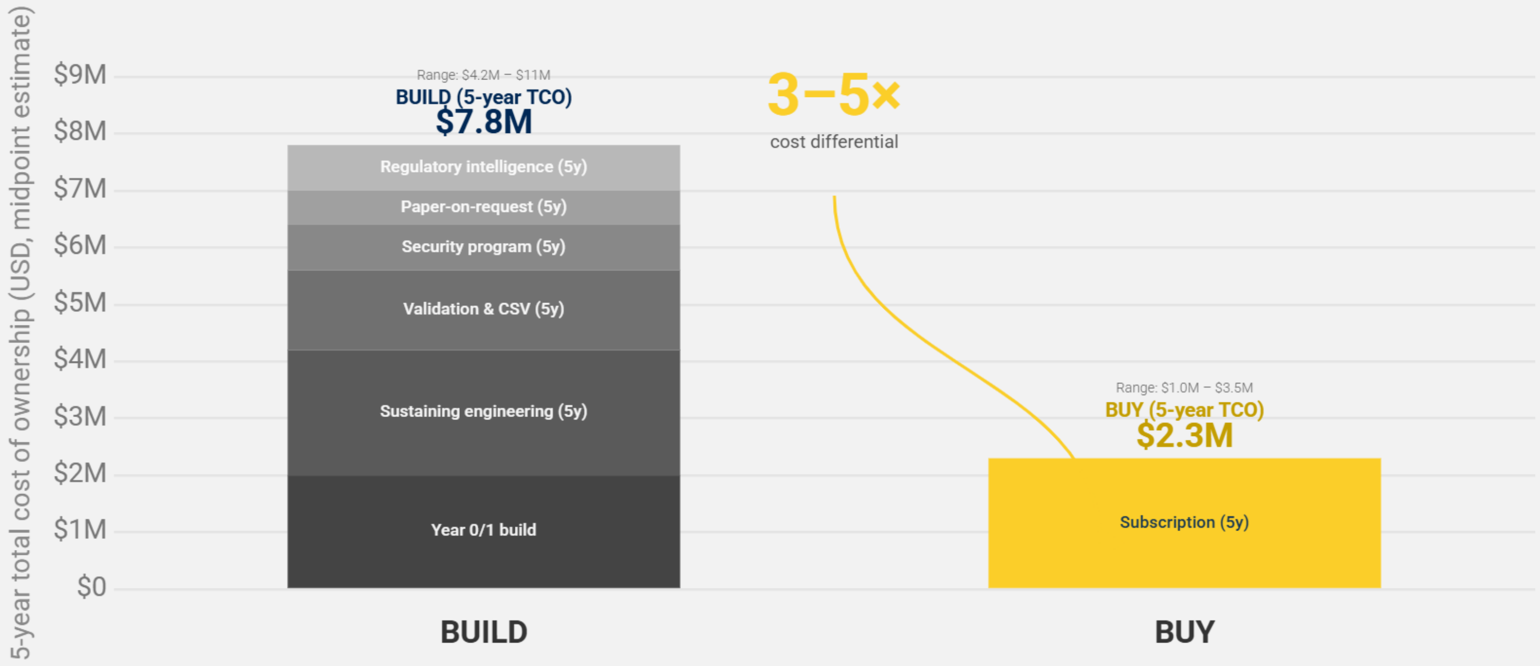
Most internal eIFU systems fail silently at year 4 to 5, when stagnation becomes irreversible.



Internal builds frequently cost 3 to 5x more over 5 years than anticipated

Build vs. buy

Internal estimates capture build cost accurately and underestimate sustaining ops, validation, security, and paper-on-request.



When buying wins, when building wins

Build vs. buy

BUY when

- Compliance risk is high
- Regulatory timelines are tight
- Distribution is global and multilingual
- Security and uptime matter
- Predictable OPEX is preferred
- Innovation velocity is important
- Paper-on-request is required
- Internal regulatory IT capacity is constrained

BUILD when

- Internal digital infrastructure team is large and dedicated
- Device portfolio is extremely large and stable
- Strategic mandate to own digital labeling end to end
- Leadership commits to permanent sustaining investment
- In all other scenarios, buy.

Recommendation: license IFUcare. Pause internal build scoping

Build vs. buy

Avoid sunk cost

- **$4.2M to $11M** 5-year build path — before replatforming
- Permanent **sustaining function**, not a one-time project
- **Replatforming pressure** hits at year 5 to 7

Accelerate value

- **4 to 8 weeks** to validated production
- Multilingual, paper-on-request, **ISO 27001:2022** included
- **Vendor-managed** regulatory intelligence, continuously updated

Decision needed

- Approve a **30-day evaluation** of IFUcare
- **Pause** internal build scoping
- **Reallocate** engineering capacity to core product

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SAFEGUARDING YOUR eIFU SINCE 2008

Not sure whether to build or buy your eIFU system?

Most manufacturers underestimate the lifecycle cost of building by 3 to 5 times. Get the full picture before you decide.

Learn more on ifucare.io/build-or-buy