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FOR MEDICAL DEVICE MANUFACTURERS UNDER MARGIN PRESSURE

Why most medical devices cost 20–40% more than they need to

The hidden engineering decisions that quietly destroy product margins — and the eight levers that give them back.

70–80% of a product's cost is locked in **before purchasing ever sees it** — by engineering decisions, most made quickly, by people who were not thinking about cost.

A 20-minute read · 8 cost levers · 10 myths · 12-question readiness check · decision matrix

HELIXA — HEALTHCARE & LIFE SCIENCES ENGINEERING · BY SOLIDPRO ENGINEERING SERVICES

01 SIX MONTHS, THREE PER CENT

A product team spent **six months** asking suppliers for a 12% reduction.

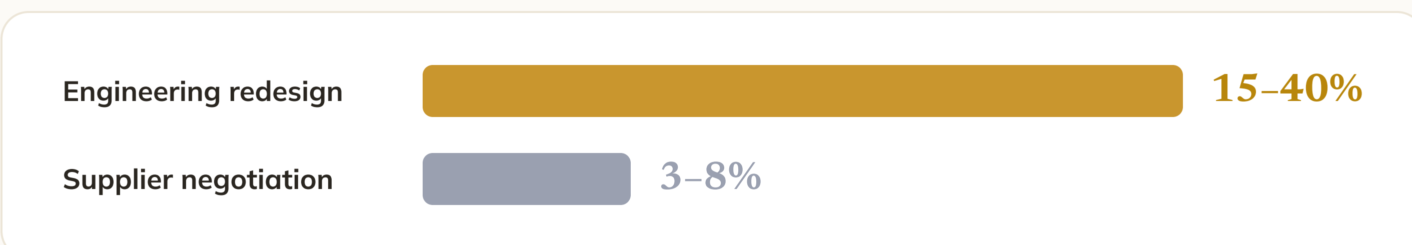
They achieved 3%.

Two weeks later, an engineering teardown found **28%** hidden inside the design.

Nobody in that room was incompetent. They were simply working the wrong lever — the only one they had been given.

Purchasing negotiates inside a cost structure that engineering fixed years earlier. When a CFO asks purchasing to take 15% out of a product, **they are asking the one department that cannot deliver it.**

02 THE COMPARISON NOBODY RUNS



Same product. Same year. One of these conversations happens every quarter; the other almost never happens at all.

The good news is that the structure can be reopened.
That is what a teardown is for.

03 IF YOU READ NOTHING ELSE

The whole guide, in five lines.

1 **Purchasing cannot fix a design problem.** Squeezing suppliers moves 3–8%. Changing the design moves 15–40%.

2 **The biggest cost driver is not a part. It is a requirement.** A tolerance nobody needed, a feature nobody asked for, a spec copied from a competitor.

3 **Cost per function, not cost per part.** A part is expensive relative to *what it does.* The outliers become indefensible.

4 **Should-cost changes every negotiation.** If you know what a part ought to cost, a quotation stops being a fact and becomes an opening position.

5 **Do not cost-optimize a product that should not exist.** A 30% reduction on a product nobody wants is a 30% reduction of nothing.

04 WHERE EVERY ₹100 GOES

The money is upstream of the bill of materials.

Conceptual model, not measured data. The proportions vary by device and volume — what does not vary is the shape: the three largest slices are all engineering decisions, and none of them appear as a line on a BOM.

05 WHY THIS IS A FINANCE CONVERSATION

Why CFOs should care more than engineers do.

Cost engineering is usually presented as a technical project. It is not. It is a margin programme that happens to be executed by engineers — and it moves numbers that appear on both statements.

Margin

A 20% BOM reduction on a device at 40% gross margin moves you to roughly 52% — without selling a single extra unit, and without touching price.

Tender competitiveness

Public-health and hospital tenders are won on landed price. Cost engineering is the only lever that lowers price without lowering margin.

Working capital

Fewer part numbers means less inventory, fewer POs, fewer receipts and fewer supplier audits. The balance-sheet effect outlasts the P&L effect.

Payback

A teardown is a fixed, four-to-six-week cost. On a product at any real volume it typically pays back inside the first quarter of implementation.

Supplier leverage

A should-cost model changes every negotiation you will have for the life of the product — not just the one you are having now.

Risk

Designing out a sole-source component removes a price you do not control and a supply risk you have never priced.

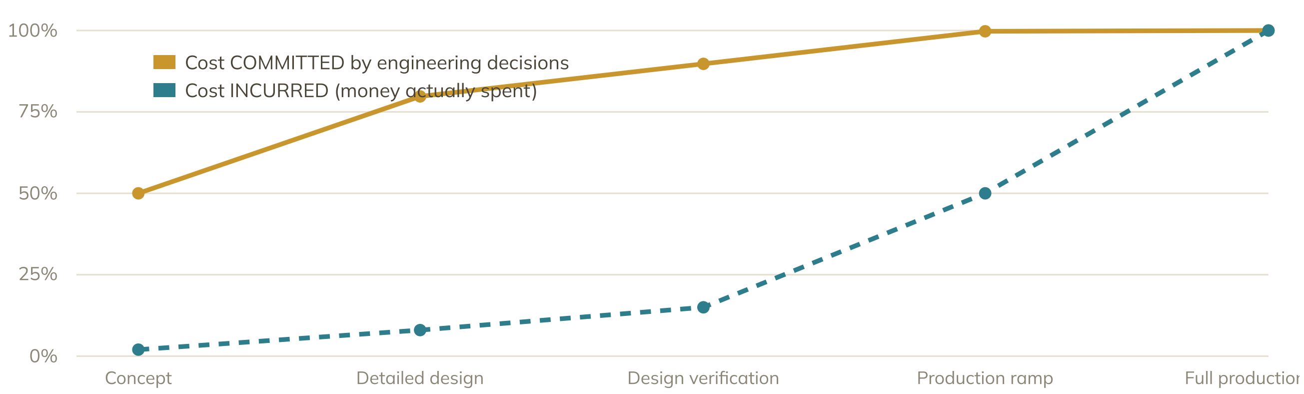
The arithmetic that gets it approved

A device with a ₹7,250 BOM at 8,000 units a year. A teardown identifies ₹3,200 per unit. That is **₹2.56 crore a year** — recurring, from a one-off, four-to-six-week engagement. Every quarter it is deferred costs a quarter of it.

06 THE UNCOMFORTABLE TRUTH ABOUT TIMING

Cost is committed long before it is ever spent.

By the time money leaves the building, almost all of your freedom is gone. This is the single most important chart in the guide.



STAGE	COMMITTED	INCURRED	WHAT IT MEANS
Concept	**~50%**	~2%	Almost no money spent. Half the cost already decided.
Detailed design	**~75%**	~8%	Architecture, tolerances and material choices all locked here.
Design verification	**~85%**	~15%	Changes now cost retest, revalidation and redocumentation.
Production ramp	**~95%**	~50%	You are negotiating pennies inside a structure fixed years ago.
Full production	**100%**	100%	Purchasing fights for 3% because engineering gave away 30%.

07 WHERE THE MONEY ACTUALLY HIDES

Most guides list five levers. Those are the last five.

The first three are where the money is, and they are the ones nobody looks at — because none of them appear on a bill of materials.

1	2	3	4	5	6	7	8
Requirements	Tolerances	Architecture	Materials	Sourcing	Process	Assembly	Packaging
10–25%	5–15%	8–20%	5–15%	5–12%	5–15%	3–10%	2–6%

1 Requirements & over-specification — 10–25%

INVISIBLE ON A BOM

The biggest single lever, and the least used.

Every feature you inherited unexamined is a cost you inherited unexamined. For every requirement ask: who asked for this, and what happens if we do not do it? If nobody can name the customer, the standard or the regulation, you have just found money.

FOR EXAMPLE A capacitive touchscreen the clinician cannot use with gloves. A Wi-Fi module that drags you into cybersecurity regulation for a hospital with no middleware to connect to.

2 Tolerances & specifications — 5–15%

INVISIBLE ON A BOM

A tolerance is a cost. Most tolerances are copied, not calculated.

Tightening a dimension by a factor of two can double the machining cost of that feature. For each critical dimension: what is it interfacing with, and what does that interface actually need? Do the stack-up. Most tolerances loosen once someone does the arithmetic.

FOR EXAMPLE A ±0.02 mm bore mating with a moulded part held to ±0.15 mm. The precision is being thrown away — and paid for.

3 Architecture & part count

8–20%

INVISIBLE ON A BOM

Every part carries a cost far larger than its price.

A part costs you its price, plus purchasing, inspection, inventory, a line in the device master record, a supplier to qualify and audit, and a failure mode to analyse. In a regulated industry the overhead per part number is enormous.

FOR EXAMPLE A bracket, two fasteners and a spacer become one moulded feature. The BOM line disappears. So does the assembly step, the inspection and the supplier.

4 Materials

5–15%

Not cheaper material – *right* material.

Over-specified medical-grade polymer where a lower grade meets the biocompatibility requirement. Metal where a glass-filled polymer is stiffer per rupee. Machined where cast, then finished, is cheaper at your volume.

FOR EXAMPLE A machined aluminium chassis at 5,000 units a year is usually the wrong answer. Sheet metal or a casting almost always wins.

5 Components & sourcing

5–12%

The obvious lever. Real, but smaller than people think.

Consolidate part numbers across products. Design out the sole-source. Qualify a second supplier — the first one's price improves the day you do. And check whether an Indian supplier exists for what you are importing.

FOR EXAMPLE Frequently one does, and nobody has asked them.

6 Manufacturing process

5–15%

The right process for your volume – not for someone else's.

Tooling amortisation changes everything. At 500 units machining wins. At 50,000 injection moulding wins by a mile. Most products are made with a process chosen for a volume they never reached.

7 Assembly & test

3–10%

Design for assembly, and design for test.

Reduce fasteners. Design in self-location so no fixture is needed. If your functional test takes eleven minutes because a technician probes six points by hand, that is a design decision, not a production one.

8 Packaging & logistics

2–6%

Small, but nearly free to fix – and often the fastest win.

For a sterile device, packaging is a regulated, validated system (ISO 11607), not a box. Changing it means revalidation — so change it once, deliberately, and get it right. Volumetric efficiency in the shipper is usually where the easy money is.

Notice the pattern

The three biggest levers — requirements, tolerances and architecture — are all engineering decisions, and **none of them are visible on a bill of materials.** That is precisely why they survive year after year, unexamined and expensive.

08 THE BELIEFS THAT KEEP THE MONEY WHERE IT IS

Ten cost myths, and what they actually cost you.

1 *"A lower supplier price means a lower product cost."*

Wrong. It means a lower *line item.* The part still carries inspection, inventory, a DMR entry and a supplier to audit. Removing the part beats discounting it.

2 *"Cheaper material always saves money."*

Wrong. A cheaper material that needs an extra process, a longer cycle time or a new biocompatibility file costs more. Right material, not cheap material.

3 *"Tighter tolerances improve quality."*

Wrong. Tighter tolerances improve *precision.* Quality is conformance to what the interface actually needs. Precision you throw away is precision you paid for.

4 *"More features increase customer value."*

Wrong. Only features a customer would pay for as an invoice line increase value. The rest increase cost, risk surface and regulatory burden.

5 *"Purchasing owns cost reduction."*

Wrong. Purchasing owns 3–8% of it. Engineering owns the other 15–40%, and locked it in years earlier.

6 ***"We already benchmarked against competitors."***
Wrong. Competitor teardowns tell you what someone else decided. They do not tell you what your own requirements are costing you.

7 ***"Our BOM cost is well understood."***
Wrong. Standard costs are an accounting fiction. Landed cost with real yields, real scrap and real volumes frequently changes the answer before any design work starts.

8 ***"Cost-down means lower quality."***
Wrong. The largest savings usually come from removing things nobody wanted. In the worked example the cheaper interface was the one clinicians preferred.

9 ***"We will do it at the next design refresh."***
Wrong. Every year you wait, you pay the full delta on every unit shipped. On 8,000 units at ₹3,200, a year of waiting costs ₹2.56 crore.

10 ***"A 30% saving is always better than a 9% saving."***
Wrong. Not if the 30% triggers revalidation and the 9% ships next month. Sequence by regulatory impact, not by size.

What every one of these has in common

They all locate cost somewhere it is not. Cost does not live in the supplier's quotation, the material grade or the negotiation. **It lives in decisions made years earlier by people who were solving a different problem.**

09 THE DISCIPLINE THAT CHANGES EVERY NEGOTIATION

A quotation is not a fact. It is an opening position.

Should-cost means building up, from first principles, what a part ***ought*** to cost: material mass × rate, plus machine time × rate, plus setup amortised over the batch, plus scrap, plus a reasonable margin. When you can do that, the conversation changes completely.

WITHOUT SHOULD-COST

"Can you do better than ₹4,200?"

- The supplier decides how much to concede.
- You negotiate against your own budget.
- A 5% saving feels like a win.

WITH SHOULD-COST

"My model says ₹2,600. Walk me through the gap."

- The supplier explains their assumptions.
- You negotiate against physics.
- A 38% gap becomes a conversation about batch size.

What a should-cost build-up actually looks like

ELEMENT	BASIS	VALUE
Material	0.42 kg 316L × ₹620/kg	**₹260**
Machining	11 min × ₹38/min machine rate	**₹418**
Setup	₹3,200 amortised over batch of 250	**₹13**
Scrap	4% of material + process	**₹28**
Overhead + margin	28% on cost	**₹207**
Should-cost	**Quoted: ₹4,200**	**₹926**

The side effect nobody expects

Should-cost models frequently reveal that the supplier is not overcharging at all — you are simply asking for the wrong thing. The tolerance forces a grinding operation. The material forces a specialist. **That is not a negotiation problem. That is a design problem, and it is worth ten times more.**

10 THE IDEA AT THE HEART OF VAVE

Stop asking what a part costs. Start asking what a function costs.

A part is not expensive in isolation. It is expensive relative to what it does. Allocate every rupee of cost to the function it delivers — then stare at the result until it becomes uncomfortable.

FUNCTION	COST TODAY	SHARE OF BOM	REASONABLE?
Deliver fluid at a controlled rate	**₹2,400**	33%	Yes — this is the device
Detect an occlusion	**₹1,100**	15%	**Question it. A route exists at ₹150.**
Recognise the syringe size	**₹320**	4%	Yes
Prevent free-flow	**₹180**	2%	Yes
Look modern (touchscreen)	**₹2,200**	30%	**No. A rotary encoder is ₹1,500, works with gloves, and clinicians prefer it.**

Thirty per cent of the bill of materials is being spent on **looking modern** — and the cheaper alternative is not a compromise, it is better. Gloved hands cannot use capacitive touch reliably. The clinician wanted the knob.

The three questions that do the work

1. What does this function cost me? Allocate every rupee.
2. What is it worth to the customer? Would they pay for it as an invoice line?
3. Is there another way to achieve it? There almost always is.

11 HOW A PROPER TEARDOWN ACTUALLY RUNS

Six steps. Four to six weeks. Not "take it apart and look at it."

1 **Establish the truth**
Complete BOM with landed costs — not standard costs. Real volumes, yields and scrap. This step alone frequently changes the answer.

2 **Decompose into functions**
Map every rupee to the function it delivers. Not to the part — to the function. This is the step people skip, and the one that matters.

3 **Build the should-cost**
From first principles for every significant line: material, process, setup, scrap, margin. Now you know whether gaps are supplier gaps or design gaps.

4 **Challenge every requirement**
For each specification: who asked for it, and what breaks if we relax it? Bring the standard into the room. Bring a clinician if you can.

5 **Generate alternatives**
For every high-cost function, enumerate other engineering routes. Score on cost, risk, lead time, regulatory impact and supply. Never fewer than three.

6 **Quantify and sequence**
Each idea gets a saving, an investment, a payback, a regulatory impact and a risk rating. The ones with no regulatory impact go first.

The step everyone skips — and pays for

In a regulated device a change is not free. A material change may need biocompatibility. A supplier change may need re-qualification. A design change may need re-verification and a technical-file update.

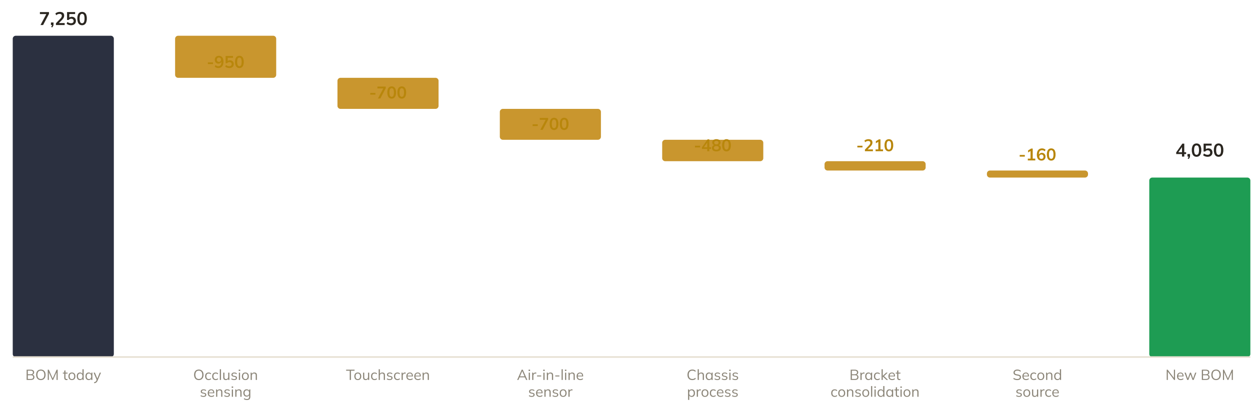
A 20% saving that triggers full revalidation may be worth less than a 9% saving that does not. If your cost-reduction plan does not have a regulatory column, it is not a plan – it is a wish list.

Illustrative worked example. Built from typical engineering economics, not an account of a specific client engagement. It shows the method and the shape of the arithmetic. Numbers are indicative and volume-dependent.

12 A CLASS B DEVICE · 8,000 UNITS A YEAR

₹7,250 → ₹4,050. A 44% reduction.

Margin under pressure from a tender competitor pricing 18% below. The instinct in the room: go back to the suppliers and demand 15%. Here is what the teardown found instead.



FINDING	LEVER	SAVING	REGULATORY IMPACT
Occlusion detection uses a ₹1,100 force sensor. Motor-current sensing meets the same spec.	Architecture	₹950	Verification only
Capacitive touchscreen (₹2,200). Clinicians cannot use it with gloves; a rotary encoder (₹1,500) is preferred.	Requirements	₹700	Usability re-evaluation
Air-in-line sensor fitted (₹700). The applicable standard does not require it for this device type.	Requirements	₹700	Risk file update
Chassis machined from aluminium. At 8,000 units, sheet metal is cheaper and stiff enough.	Process	₹480	None
Three brackets, six fasteners → one moulded feature.	Architecture	₹210	None
Second source qualified for the display driver (currently sole-source).	Sourcing	₹160	Supplier qualification

13 SEQUENCE BY REGULATORY IMPACT, NOT BY SIZE

₹690 of it ships next month. That funds the rest.

A cost-reduction plan without a regulatory column is a wish list. Sorted properly, the findings split into three waves — and the first one needs no regulatory work at all.

₹690
Ships immediately
Chassis process + bracket consolidation. No regulatory impact at all.

₹1,110
After verification
Motor-current sensing + second source qualification.

₹1,400
Needs justification
Touchscreen + air-in-line sensor. Risk-file update required.

Before and after, on the same bill of materials

BEFORE
₹7,250

- Force sensor for occlusion — ₹1,100
- Capacitive touchscreen — ₹2,200
- Air-in-line sensor — ₹700
- Machined aluminium chassis
- 3 brackets + 6 fasteners
- Sole-sourced display driver

→

AFTER
₹4,050

- Motor-current sensing — same spec
- Rotary encoder — clinicians prefer it
- Sensor removed — standard does not require it
- Sheet-metal chassis
- One moulded feature
- Second source qualified

Same function. Same compliance. **₹3,200 less, on every unit, every year.**

The two biggest items were **requirements, not parts.** A screen nobody could use with gloves, and a sensor the standard never asked for. Purchasing could not have found either — no amount of supplier pressure removes a feature you asked for.

13 WHAT TO ATTACK FIRST

The matrix that decides your first ninety days.

Saving alone is the wrong sort order. Sequence by saving ***against*** effort and regulatory impact — because the items with no regulatory consequence can ship while the rest are still in review, and they fund the programme.

OPPORTUNITY	SAVING	EFFORT	REGULATORY	PRIORITY
Requirements & over-spec	**High**	Medium	Low	★★★★★
Architecture & part count	**High**	High	Medium	★★★★☆
Tolerances	**Medium**	Low	Low	★★★★★
Manufacturing process	**Medium**	Medium	Low	★★★★☆
Materials	**Medium**	Medium	High	★★★☆☆
Components & sourcing	**Low**	Low	Medium	★★★☆☆
Assembly & test	**Low**	Medium	Low	★★★☆☆
Packaging & logistics	**Low**	Low	High	★★☆☆☆

Read the top two rows again. Requirements and tolerances are the highest priority not because they save the most in absolute terms, but because they combine real saving with low regulatory drag. They are also the two that no purchasing exercise will ever surface.

TRY IT FREE · BOM MARGIN LEAK MAP

See where recoverable cost typically hides — in your browser

14 THE SECTION THAT COSTS US WORK

Do not run a teardown if any of these are true.

A cost teardown is not always the right project. Sometimes it is an expensive way to avoid a harder conversation. We would rather tell you now than take the engagement.

The volume is not there
A 30% reduction on 400 units a year saves less than the work costs. Fix the market first.

The product is at end of life
You will spend the savings on revalidation and recover nothing.

The problem is price, not cost
If you are losing on brand, service or distribution, a cheaper device loses more cheaply.

The current design is not stable
Optimising an unvalidated product means revalidating twice. Finish, then optimise.

It is really a scale problem
If a competitor has 20× your volume on a commodity, cost engineering narrows the gap but will not close it.

Why we put this in a marketing document

Because the fastest way to lose a technical buyer is to sell them a project that cannot work. If your answer to any of the five above is yes, a teardown is the wrong spend this quarter — and we will say so on the call, for free, before anyone signs anything.

15 ARE YOU READY TO DO THIS?

Twelve questions. Maximum 24.

Score 2 for a confident yes, 1 for partial, 0 for no. Answer with your actual BOM open.

01	**Do you have a complete BOM with landed costs — freight, duty and scrap — not standard costs?** *Standard costs are an accounting fiction. Teardowns run on real numbers.*	0 1 2
02	**Can you allocate every rupee of BOM cost to the function it delivers?** *Cost per part tells you nothing. Cost per function tells you everything.*	0 1 2
03	**Do you know which three functions consume the most cost — and can you defend each one?** *If you cannot defend it, you have found money.*	0 1 2
04	**For each major requirement, can you name who asked for it — a customer, a standard or a regulation?** *The requirements nobody owns are the cheapest ones to remove.*	0 1 2
05	**Have your tolerances been calculated from a stack-up, or copied from a previous product?** *Copied tolerances are almost always tighter than they need to be.*	0 1 2
06	**Do you have a should-cost model for your top ten BOM lines?** *Without one you are negotiating against your own budget, not against physics.*	0 1 2
07	**Is your manufacturing process matched to your actual volume, or the volume you hoped for?** *Machining at 20,000 units, or hard tooling at 500, are both expensive mistakes.*	0 1 2
08	**Do you know your part-number count and the fully-loaded cost of carrying one?** *In a regulated industry the true cost of a part number is far higher than its price.*	0 1 2
09	**Have you identified every sole-source component?** *A sole source is a price you do not control and a risk you have not priced.*	0 1 2
10	**For each cost idea, do you know its regulatory impact?** *A saving that triggers revalidation may be worth less than a smaller one that does not.*	0 1 2
11	**Have you separated ideas that ship immediately from those needing regulatory work?** *The immediate wins fund the rest. Sequence deliberately.*	0 1 2
12	**Is your volume assumption real — based on orders, not a forecast?** *Every cost figure in this guide is volume-dependent. A wrong volume makes every answer wrong.*	0 1 2

16 WHAT YOUR SCORE MEANS

Total your twelve answers.

20–24	**Ready** A teardown will find money quickly, and you will be able to act on it.
13–19	**Foundations there** Fix the BOM and the should-cost model first — a teardown on bad data produces confident nonsense.
7–12	**Start with data** Start with the data, not the design. You cannot optimise what you cannot see.
0–6	**Not yet** Do not start a cost programme yet. Build the cost picture first — that work is itself worth doing.

17 THE NINETY-DAY ROADMAP

WEEK 1–2
Build the truth
Landed-cost BOM with real yields, scrap and volumes.

WEEK 3–4
Function allocation
Every rupee mapped to a function. The outliers surface here.

WEEK 5–6
Challenge & generate
Requirements interrogated. Three routes per high-cost function.

WEEK 7–12
Ship the free wins
Zero-regulatory-impact items implemented while the rest go through review.

Typical payback shape

Q1
Teardown cost incurred

Q2
First free wins ship

Q3
Cumulative saving crosses cost

Q4+
Recurring, every unit, every year

SCORE IT LIVE · GET AN EXECUTIVE REPORT
Cost-down maturity score, priority opportunities and an estimated savings band

HeLiXA
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Somewhere inside your product is a requirement no customer values, a tolerance nobody calculated, or a feature nobody would miss.

The question isn't whether it exists.

The question is how much it has been costing you every year.

01

Do it yourself

Take your BOM. Allocate every rupee to a function, not a part. Free, costs you an afternoon, and frequently changes the conversation entirely.

02

Get your score

Run the twelve questions online. You get a cost-down maturity score, your priority opportunities and an estimated savings band.

03

Commission a teardown

Four to six weeks on one real product. Ranked, costed, regulatory-tagged findings you can act on.

SCAN · GET YOUR EXECUTIVE COST-DOWN REPORT
solidpro-es.com/costdown-report

Three costed opportunities, or the teardown is free.

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