

AI in MedTech

MedTech

What changes for the MedTech company as AI enters its industry

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01 How many submissions can you run in parallel?

02 What does a single RA departure cost?

03 Is your market access capability institutional or personal?



What changes for the MedTech company as AI enters its industry

A mid-market MedTech company competes against the same regulatory complexity as organizations ten times its size. MDR compliance, notified body interactions, post-market surveillance, clinical evidence architecture. The difference is that the large-cap firm spreads this knowledge across a department of forty specialists. The mid-market firm concentrates it in one or two regulatory affairs professionals whose departure would delay a CE mark submission by twelve to eighteen months.

That concentration of expertise is the structural vulnerability AI exposes. Not because AI replaces regulatory judgment. It does not, and suggesting otherwise triggers an immediate compliance objection. The vulnerability is that AI makes it possible to encode the accumulated understanding behind regulatory submissions into institutional infrastructure. The firms that do this first make their expertise survivable. The firms that do not remain one resignation letter away from a missed market window worth millions in delayed revenue.

At the same time, a second front is opening. Hospital procurement across Europe is shifting from clinical champion adoption to evidence-based evaluation. EU HTA is extending to high-risk medical devices in 2026. Commercial teams built on clinical relationships over the past twenty years do not have health economics capability. The companies that build this evidence infrastructure while competitors are still relying on physician relationships capture procurement cycles their competitors cannot enter.

For the CEO, these two forces converge on the same question. Revenue depends on regulatory speed and market access capability. Profit depends on whether the cost of building institutional knowledge infrastructure is offset by the elimination of single-point-of-failure risk and the compression of submission timelines. Valuation depends on whether an acquirer or investor sees a company whose market access capability is institutional or personal.

This briefing is about what it takes to convert personal regulatory and commercial expertise into institutional capability before the competitive window closes.

The knowledge bottleneck is now the growth bottleneck.

MedTech has always been a knowledge-intensive industry. MDR is prescriptive, but the methodology for navigating it is not. How a firm interprets notified body expectations, structures clinical evidence packages, sequences submissions across markets, and manages post-market surveillance depends on accumulated judgment that takes years to develop. That judgment lives almost entirely in individual regulatory affairs professionals.

The sector-wide shortage of regulatory talent has turned this from a quality problem into a growth constraint. Mid-market firms cannot recruit fast enough to staff parallel submissions. They cannot retain experienced RA directors against offers from larger firms with deeper pockets. And they cannot train replacements quickly enough because the knowledge that matters is tacit: how to read a notified body's feedback, which clinical evidence architecture works for which device class, what to prioritize in a pre-submission meeting.

Nobody is suggesting AI in the submission. The question is whether the accumulated understanding that makes submissions possible exists in institutional systems or in the head of one person who could leave tomorrow.

AI does not solve the regulatory judgment problem. What it solves is the knowledge infrastructure problem around the judgment. Monitoring regulatory changes across markets, assembling documentation from precedent, tracking notified body interpretation patterns, surfacing relevant clinical evidence. These are the tasks that consume sixty percent of a senior RA professional's time and prevent them from doing the judgment work that only they can do. The shift is from regulatory expertise as a scarce personal asset to regulatory expertise as an institutional capability that scales with the organization.

THREE QUESTIONS

Revenue. Profit. Valuation.

Under the old model these three questions had three different answers. AI ties them together. Build the knowledge infrastructure and you move all three at the same time.

01 · REVENUE

How many submissions can you run in parallel?

Revenue in MedTech is gated by regulatory speed. Every month a CE mark is delayed is a month of lost market access. When regulatory capacity is concentrated in one or two people, the number of parallel submissions is capped by their bandwidth. A competitor who builds institutional regulatory infrastructure runs three submissions while you run one.

02 · PROFIT

What does a single RA departure cost?

A senior regulatory affairs director's departure delays submissions by twelve to eighteen months. At typical device revenue trajectories, that delay costs millions in market timing. The retention cost of a single specialist is a fraction of the revenue at risk. The profit question is whether knowledge infrastructure can eliminate this single-point-of-failure before it materializes.

03 · VALUATION

Is your market access capability institutional or personal?

An acquirer or investor evaluating a MedTech company prices regulatory capability. Personal expertise in two heads is a risk discount. Institutional knowledge infrastructure encoded into systems, precedent databases, and structured submission processes is a premium. Same pipeline, same revenue. Different multiples depending on whether the capability survives a leadership transition.

Two columns. The whole industry sorts itself between them.

The pattern is consistent across every function in a MedTech company. Standard documentation, monitoring, and compilation tasks are compressing toward commodity. The work that appreciates is the judgment that depends on years of regulatory experience, clinical interpretation depth, and commercial creativity. The further a function sits from this judgment, the more pressure it is under.

DEPRECIATING

- Standard GSPR assembly and documentation
- Regulatory change monitoring across markets
- Post-market surveillance report compilation
- Clinical literature screening and summaries
- Procurement response boilerplate

APPRECIATING

- Notified body relationship management and interpretation
- Novel submission strategy for ambiguous requirements
- Health economics argumentation and evidence design
- Clinical evidence architecture for new device classes
- Creative market access and pricing strategies

Whichever column the management team trains the organization into over the next three years is the company it becomes. The decision is not whether AI affects regulatory operations. It is which side of the line the leadership deliberately moves the organization toward.

Two paths. Same technology. Opposite outcomes.

The same AI technology, deployed into the same MedTech company, produces opposite outcomes depending on what the company chooses to build.

THE DEFAULT PATH

Rely on individual experts

Regulatory knowledge stays personal. Two people carry a decade of submission context. Every departure is a capability crisis.

React to evidence demands

Hospital procurement shifts to HTA evaluation. The commercial team scrambles. Health economics capability is hired reactively at premium cost.

Cap submissions at specialist bandwidth

One RA director means one submission stream. Growth is throttled by a single person's capacity. Parallel markets wait.

Accept the risk discount

Investors and acquirers see personal expertise concentration. Valuation reflects the fragility. Every board meeting revisits key-person risk.

THE REPOSITIONING PATH

Build knowledge infrastructure

Encode submission history, notified body precedent, and clinical evidence architecture. Make the capability institutional before the person leaves.

Build evidence capability proactively

Structure health economics data, build comparative effectiveness arguments, train commercial teams. Arrive at procurement cycles prepared.

Scale regulatory throughput

AI handles monitoring, documentation, and precedent research. Specialists focus on judgment. Three parallel submissions instead of one.

Earn the institutional premium

Regulatory and commercial capability encoded into infrastructure. The same pipeline and revenue, priced at a different multiple.

Same technology. Opposite outcomes. The difference is whether you build institutional capability or continue to depend on individual expertise.

The growth levers that compound when used together

Repositioning is not a single decision. It is four levers, each available to the company right now, that compound when pulled together. Used in isolation, any one produces a modest gain. Used together, they convert personal expertise into institutional advantage.

1

Encode regulatory knowledge before specialists leave

Not the GSPR template. The reasoning. Why this notified body interprets this requirement differently from the published guidance. Which clinical evidence architecture works for Class III versus Class IIb. What to prioritize in a pre-submission meeting based on ten years of interaction history. Make it institutional. This is the lever that converts personal regulatory capability into permanent organizational capability.

2

Build health economics evidence infrastructure now

EU HTA extends to high-risk devices in 2026. Hospital procurement is already shifting to evidence-based evaluation across Northern Europe. The commercial teams that built their entire approach on clinical champion relationships need a fundamentally different capability. Building it before the procurement cycles demand it means arriving prepared while competitors are still scrambling.

3

Free specialist capacity from documentation to judgment

Senior RA professionals spend the majority of their time on tasks AI can handle: regulatory monitoring, documentation assembly, literature screening, surveillance reporting. Reclaiming that time does not replace their judgment. It multiplies their capacity for the work only they can do. One specialist running three submission streams instead of one. Same person, three times the regulatory throughput.

4

Convert the submission history into a compounding asset

Every regulatory submission, every notified body interaction, every clinical evidence package is organizational learning. Most MedTech companies let it sit in filing cabinets and personal folders. Structured and encoded, it becomes a precedent database that makes every future submission faster and more precise. The knowledge compounds with every interaction. The competitor starting fresh cannot replicate a decade of accumulated institutional learning.

Business first. Technology second.

GRAIL is an AI-native management consultancy. We help European mid-market leadership teams figure out the one or two things that fundamentally change about their business as AI enters their industry, and then build the capability to act on it before competitors do. For MedTech specifically, GRAIL does not advise on MDR submissions or clinical evidence design. We address the organizational knowledge infrastructure that makes regulatory and commercial capability institutional rather than personal. The entry point is the management team, not the regulatory affairs department.

The market offers two things: vendor lock-in dressed as transformation, and consulting reports dressed as strategy. GRAIL delivers a third option: working AI capability that you own.

WHAT YOU GET

Senior advisory direct to the CEO and GMT

Working AI capability you own from day one

Custom agents built around your business logic

Outcomes in weeks, not quarters

No lock-in at any phase of the engagement

WHY IT MATTERS

Founded by operators, not technologists

Business-first strategy, technology second

Context architecture, change management, workflow design

Results before you commit to scale

Each next step earned, never assumed

Three sessions with your management team. No IT involvement. Working tools from week one.

GRAIL starts with the management team because organizational transformation cannot outrun the leadership team's personal understanding of what is possible. Three workshops. Each delivers standalone value. Each earns the right to the next.

WORKSHOP 01

How to think

The strategic foundation. Where AI creates real value in MedTech and where it is noise. The knowledge infrastructure thesis. The regulatory compliance boundary: what AI touches and what it does not. Your leadership team leaves with a shared frame for the rest of the work, and with the first working agent built live in the room.

WORKSHOP 02

Your AI team

A half-day activation. Each member of the management team receives a personal suite of five to ten custom agents trained on their workflow, their decisions, their competitive landscape. Regulatory monitoring. Clinical evidence screening. Health economics evidence builder. Competitive device intelligence. Working tools from week one, not slides about tools.

WORKSHOP 03

Competitive edge

Refinement from real usage. Agents upgraded based on how the team actually used them. The knowledge infrastructure roadmap. The commercial capability development plan. The recommendation for what comes next, earned by what just shipped.

Three weeks. No IT involvement. No board approval needed to start. The sharpest strategic conversation your leadership team will have this year, backed by working tools they are already using.

What to ask in your next leadership meeting

The questions where the room cannot agree on an answer are the ones worth a longer conversation. Ask these honestly. The point is not the polished response. The point is whether the answer would survive contact with a major client three months from now.

If your regulatory affairs director accepted a competitor's offer tomorrow, how many months before your next CE mark submission could proceed at the same quality?

What fraction of your regulatory submission knowledge is encoded in institutional systems versus held in the heads of one or two specialists?

When hospital procurement asks for health economics evidence on your next device, does your commercial team have the capability to respond, or are you hiring it reactively?

How many regulatory submissions can you run in parallel right now, and how many could you run if your specialists spent their time on judgment instead of documentation?

If an acquirer evaluated your company next quarter, would they price your regulatory capability as institutional infrastructure or as key-person risk?

If any of these questions land somewhere uncomfortable, that is the conversation worth having.

IN THIS SERIES

There's a version of this briefing for every seat at the table.

GRAIL has produced industry briefings calibrated to the specific reality of each C-suite role.

CEO

▶ YOU ARE READING

Revenue. Margin. Valuation.

Three numbers your board reads. AI is rewriting all three in your industry.

CFO

Capital. Forecast. Story.

What you allocate this year is the story your board reads next year.

COO

Cheaper. Better. Faster.

The triple threat that used to be a tradeoff is now table stakes.

CHRO

Capacity. Capability. Promise.

The biggest talent transition of a career. Compete on capacity, not headcount.

CPTO

Moat. Speed. Allocation.

The platform moat that survives 2028 is being chosen this year.

CCO

Margin. Pace. Position.

The whole GTM playbook is being rewritten in real time, across every commercial team at once.

Visit grail.works for the full series.

GRAIL

An AI-native management consultancy helping European mid-market leadership teams figure out what fundamentally changes about their business as AI enters their industry.

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