

What's Changing in How You Get to Market

MedTech

You have seen this on your submissions calendar

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01

How many submissions can our RA team run at once, and what is stopping us from running more?

02

What happens to our first-pass acceptance rate when our most experienced RA or clinical specialist leaves?

03

What is our average time from submission to approval, and what would it take to cut that by three months?



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Every Chief Operating Officer at a mid-sized European medtech company has had a version of the same Monday morning. A deficiency letter arrived on Friday from the notified body on the Class IIb submission. Three questions about the clinical evidence architecture. The only person who can answer all three is your Head of Regulatory Affairs, flying back from a notified-body meeting in Cologne, available at 2 PM. The response is due by end of week. Separately, your market access team has flagged that the JCA submission window for the new device opens in six weeks. They have never done a Joint Clinical Assessment before. At 10 AM you have a quarterly review with the CFO, who wants to understand why the MDR compliance programme has added two full-time equivalents without compressing the CE mark cycle. You have a correct answer. It does not satisfy him.

Something changed. The MDR compliance surface expanded without proportional headcount growth. Your CE mark cycles have not shortened. The JCA process is new territory for a market access team that has not built health economics infrastructure. And you can name the two or three regulatory specialists whose departure would pause your pipeline for a year.

The regulatory expertise gap and the market access evidence gap are not two separate problems. They are one. Most medtech COOs treat them separately. The ones who see them as a single operations problem, and build accordingly, are the ones whose pipelines flow when competitors' pipelines stall.

This briefing covers what is happening in your sector, what it means inside your regulatory and clinical operations, and the three questions your team should answer before the next board cycle.

Medtech just ran into a compliance surface it was not built to carry

Every regulatory shift your sector absorbed in the past twenty years added complexity that mid-market firms managed by adding specialists. MDD to MDR expanded the technical documentation burden, and firms hired more regulatory affairs staff. Post-market surveillance requirements deepened, and clinical teams grew. The sector adapted by scaling headcount alongside compliance surface. The model worked because headcount could scale.

Two things have happened simultaneously that break that model. First, the MDR compliance burden is now structurally disproportionate for mid-market firms. Over ninety percent of European medtech companies are small or medium enterprises. The same technical documentation requirements, post-market surveillance obligations, and notified body scrutiny that a large-cap firm manages with a regulatory department of forty is landing on a team of six. The certification bottlenecks are not temporary. They are built into the regulation.

Your mid-market competitors face the same MDR surface with the same small teams. The ones pulling ahead are not doing it by adding more people. They are doing it by making fewer people carry more.

Second, EU HTA is extending to medical devices. High-risk devices entering JCA scope in 2026 means the evidence burden your commercial team has never managed before is arriving this year, not next. The hospital procurement that your commercial teams built on clinical champion relationships for two decades is shifting to evidence-based evaluation with health economics data, real-world evidence, and formal comparative effectiveness assessments. The firms that begin building this infrastructure now will be the ones whose HTA dossiers land on time when the window opens. The ones that start when the window opens will still be building when the window closes.

Your regulatory and clinical operations are feeling it every week

Your regulatory affairs team. Your RA specialists are the rate-limiting constraint on how many submissions you can run simultaneously. The documentation burden per submission has grown without a corresponding growth in specialist time. The routine work — assembling GSPR checklists, drafting post-market surveillance reports, monitoring regulatory updates across thirty-plus markets — is consuming the same specialist hours that notified body strategy and novel pathway interpretation require. Your team is talented enough. The architecture around them has not changed since MDR landed.

Your clinical affairs function. Your clinical lead knows which study designs your notified body will accept. They know which real-world evidence sources the HTA body will find credible and which they will question. That knowledge took a decade to build and has never been written down. It resides in their judgment on every clinical strategy call, every KOL relationship, every study report that gets reviewed before it goes out. When they rotate or leave, the next clinical specialist runs the same learning curve at the cost of one or two submission cycles.

Your quality and compliance function. Your quality leads are carrying CAPA cycles, complaint processing, and audit preparation on top of the MDR post-market surveillance requirements. The judgment work — root cause analysis, systemic pattern recognition, deciding which trend warrants escalation before the notified body asks — is the part only they can do. The documentation work is consuming the same hours. Every week your best quality specialists spend four hours on compliance documentation is four hours they are not spending on the judgment calls that prevent the next quality incident.

Your market access and field service teams. Your market access team is preparing for HTA evidence demands that require a different kind of commercial knowledge than the clinical champion relationships that carried your sales for twenty years. And your field service engineers carry ten years of product-specific troubleshooting knowledge in their heads. When one of them takes a competing offer, the next engineer assigned to that account starts from the beginning.

The firms pulling ahead are building one piece of infrastructure

Your sector is compressing from the regulatory side because the MDR compliance surface grew without proportional headcount. Your commercial pipeline is compressing from the market access side because hospital procurement now demands evidence your commercial team was not built to produce. But there is a third pressure that most medtech COOs have not named yet, and it is the one that ties the others together.

You do not have three problems. You have one. The regulatory and clinical knowledge that makes your submissions credible, your CE mark cycles short, and your HTA dossiers strong has never been separated from the specialists who carry it. Every throughput problem, every quality risk, every market access delay is a symptom of that single unsolved thing. Your submissions pipeline is as resilient as your most irreplaceable regulatory specialist.

Look at the firms in your segment who are moving their submission cycles from eighteen months toward twelve. Their RA teams are not larger. Their specialists are not working harder. The accumulated judgment their senior RA directors have built about what a specific notified body expects, what clinical evidence architecture survives scrutiny, what pre-submission meeting notes reveal about review priorities. That judgment lives in infrastructure their next specialist inherits from day one. The record, not the person who wrote it, carries the capability forward. The RA director does not become less valuable. They become more valuable, because they spend their time on the judgment that only they can provide rather than on documentation the infrastructure now carries.

The regulatory function is not a compliance cost. It is the commercial pipeline. The COO who builds infrastructure to carry accumulated submission knowledge controls the pipeline independent of who is in the seat next year.

You have a window. The firms that build this infrastructure in 2026 will be the ones whose pipelines do not pause when a senior specialist leaves, whose HTA dossiers are ready when the JCA window opens, and whose CE mark cycles have moved when the CFO asks again next year.

What most medtech firms are doing. What the winners are doing instead.

Every medtech COO has had the regulatory infrastructure conversation. Most are making the same four decisions. A smaller group is making different ones. The difference is architecture.

THE DEFAULT PATH

Hire more RA specialists when the pipeline slows

Each new hire takes twelve months to reach full effectiveness. The bottleneck moves, it does not shrink.

Treat senior RA departures as a transition problem

Mentoring sessions and overlap periods. One in three transitions pauses the submissions calendar.

Deploy AI tools on top of existing workflows

Throughput rises slightly. CE mark cycles do not move because the workflow architecture is unchanged.

Prepare HTA evidence project by project

Each JCA submission starts from scratch. Evidence gaps found at submission time cost months.

THE WINNERS' PATH

Build infrastructure that multiplies specialist capacity

The same team manages more simultaneous submissions. New hires inherit accumulated knowledge on day one.

Extract knowledge as a side-effect of active submissions

Every technical file and deficiency response builds the record while paid work proceeds.

Rebuild workflows around the new capacity

Specialist time concentrates on notified body judgment. Documentation moves to infrastructure. Cycle compresses.

Build HTA evidence infrastructure ahead of the window

Real-world evidence and health economics framework assembled systematically before each submission window.

Same regulatory team. Same eighteen months. Opposite pipeline outcomes. The difference is whether the knowledge lives in the person or in the infrastructure they leave behind.

THREE QUESTIONS

Regulatory Throughput. Dossier Quality. Market Access Speed.

Three questions every medtech COO is tracking. All three have the same answer underneath them.

01 · REGULATORY THROUGHPUT

How many submissions can our RA team run at once, and what is stopping us from running more?

Your RA specialists' time is the constraint. The MDR compliance surface has grown without proportional growth in specialist capacity. The routine documentation work — GSPR assembly, post-market surveillance reporting, regulatory update monitoring — is consuming the same hours that notified body strategy requires. The team is not under-resourced. The time allocation within each specialist's week is the question.

02 · DOSSIER QUALITY

What happens to our first-pass acceptance rate when our most experienced RA or clinical specialist leaves?

Your notified body acceptance rate depends on the judgment of two or three specialists who know what language survives scrutiny, what evidence architecture works, and what the pre-submission meeting revealed about review priorities. That knowledge took years to build. It has never been systematically captured. When it leaves, the deficiency rate rises before anyone can name the cause.

03 · MARKET ACCESS SPEED

What is our average time from submission to approval, and what would it take to cut that by three months?

Every month the CE mark cycle compresses is a month of commercial runway the firm captures before a competitor files a comparable device. The firms compressing cycle time in 2026 are not doing it by working faster. They are doing it by building infrastructure that carries the preparation and assembly work that previously consumed most of a specialist's calendar, concentrating their time on the decisions that determine how quickly the notified body responds.

What the firms winning this play are actually doing

Four concrete moves any medtech COO can start this quarter. Each touches one part of the operations function. Together, they become one architecture.

1 **Regulatory affairs: extract submission knowledge as a side-effect of active work, not as a separate project**

Extract from the artefacts your RA team already produces: technical files, deficiency response letters, pre-submission meeting notes. The accumulated reasoning patterns build into institutional infrastructure as paid submissions proceed. Your Head of RA is not asked to explain themselves. Their role becomes the escalation layer above the record they have built. The knowledge stays when they go.

2 **Clinical affairs: concentrate clinical specialist time on strategy and KOL relationships, not evidence assembly**

Literature search, evidence compilation, and study report preparation now compress with the infrastructure that exists. Free your clinical specialists for what only they can do: the study design decisions and KOL relationships that determine whether the clinical data package survives scrutiny at submission.

3 **Quality and compliance: move quality leads from documentation assembly to systemic judgment**

Route CAPA documentation, complaint processing, and audit-preparation boilerplate to infrastructure. Quality leads spend their time on what matters: deciding what the notified body will ask about next quarter before it asks, and catching the trend that becomes a CAPA cycle before it becomes a recall.

4 **Market access and field service: build HTA evidence infrastructure before the window, not during it**

Begin now: real-world evidence architecture, health economics framework, comparative effectiveness data library, and field service knowledge capture for each product family. Nine weeks of HTA dossier preparation instead of eighteen wins the first commercial quarter in every reimbursement-gated market.

The only firm that joins regulatory operations to working infrastructure

The medtech COO has four places to go. None of them can do what we do, and each for a specific reason.

The major strategy and life-sciences consulting firms produce thorough operating-model documents and cannot put working regulatory knowledge infrastructure in your RA team's workflow in three months. Their delivery model is built on the architecture they would tell you to change.

The regulatory-affairs and QMS platform vendors sell a system for filing documents with metadata and workflow routing. Your submission knowledge does not live in a form field. The judgment behind fifteen years of notified-body responses cannot be captured by tagging a document.

The CRO and regulatory outsourcing firms take the work away rather than building capability in-house. The knowledge of how your notified body responds to your products accumulates at the CRO, not at your firm.

Your internal IT function and enterprise AI rollouts build search tools and chatbots. IT does not sit close enough to how your Head of RA reasons through a novel product pathway to build the infrastructure that carries that judgment forward.

The market offers four things you have already considered. GRAIL is the fifth option.

WHAT YOU GET

Senior advisory that speaks regulatory operations, not strategy decks

Working infrastructure your RA and clinical teams use the same week

Custom agents built on your submissions, your products, your notified body history

The start of a knowledge infrastructure your best specialists feed

No vendor lock-in at any phase of the engagement

WHY IT MATTERS

Built by practitioners who understand regulated knowledge operations

Business first, technology second

Three weeks from first meeting to working infrastructure

Your teams keep the infrastructure, you own the IP

Every next step earned by what just shipped, never assumed

Three sessions with your operations leadership. Working infrastructure from week one.

We start with your operations leadership because the change cannot outrun the team's understanding of what is possible. Three workshops. Each delivers standalone value. Each earns the right to the next.

WORKSHOP 01

How to think

Walk through what is happening in medtech operations and your regulatory function. Build the first piece of infrastructure in the room: a submission-knowledge agent for one of your active product lines, extracted from the technical files you already hold. Your team leaves with a shared view and the first piece of working infrastructure in hand.

WORKSHOP 02

Your regulatory infrastructure

A half-day build. Your Head of RA, Head of Clinical Affairs, Head of Quality, and Head of Market Access each leave with five to ten pieces of working infrastructure tuned to their function: submission knowledge capture, clinical evidence assembly, CAPA preparation, HTA evidence framework. Used the same week, not decks about infrastructure.

WORKSHOP 03

Ready to run

Refined infrastructure from real use. The rollout plan for your wider regulatory and clinical organisation. The knowledge-extraction plan for senior RA and clinical specialists. The HTA evidence architecture for your next JCA window. The CFO conversation with numbers they can check: submissions per specialist, CE mark cycle, retention exposure.

Three weeks. No IT project. No board approval needed to start. The infrastructure your regulatory operations are already running on when we finish.

For your next operations review

Where your operations team cannot agree on the answer is where the conversation is worth an hour.

If your Head of Regulatory Affairs left next month, how long before your current submissions calendar could proceed at the same quality? Who would answer the next deficiency letter from your notified body, and what would they not know?

What percentage of your RA and clinical specialists' time last quarter went to documentation assembly, literature search, and compliance reporting versus the judgment work that determines submission outcome? What would it take to cut the first category in half?

What is your current average time from design-freeze to submission-ready, and from submission to first commercial sale? Which part of that cycle has not moved in three years?

When your most experienced regulatory or clinical specialist makes a decision that your notified body accepts, does that reasoning exist anywhere outside their head? If they joined a competitor tomorrow, what would your next submission not know?

Does your market access team have the health economics and real-world evidence infrastructure to support a JCA submission today? If not, when do you start building it, and what does the next six weeks look like before that window opens?

If any of these produces a disagreement in your operations team, that is the conversation worth having before the board asks about the pipeline.

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