

CLIENT CASE STUDY

Maximum Pressure. No Margin for Error.

How the Commercial Operating System™ Delivered Early FDA Clearance for a First-in-Category Product

The Accountable Operator | Alexander Jamison™ Commercial Operating System™

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| Organization | Mid-size publicly traded medtech company — specialty device portfolio in a high-growth chronic disease category |
| The Situation | Commercial-stage organization managing a multi-hundred-million dollar franchise across three products at different lifecycle stages: a mature platform, an advanced next-generation system, and a first-in-category product approaching regulatory submission |
| Role | Senior Director, Global Product Marketing → Interim Vice President, Franchise Lead (9 months of VP-level accountability) |
| Engagement Model | Internal operating leadership — directly analogous to a Commercial Operating System Design & Activation engagement |
| Timeline | Multi-year engagement (approx. 2.5 years); Interim VP designation for 9 months within that period |
| Commercial Operating System™ Domains Deployed | Decision Velocity Framework™ · Commercial Operating Model Blueprint™ · Enterprise Visibility Architecture™ · Strategic Asset Governance Model™ |

THE SITUATION

When the interim VP designation was made, the franchise was managing compounding complexity across three concurrent product lifecycles — a mature platform, an advanced next-generation system, and a first-in-category launch product approaching regulatory submission with no commercial precedent in the company's history. A cross-functional team of 50+ spanned the full commercial and operational ecosystem — including marketing, sales, market access, medical affairs, customer support, training, human factors, and product operations.

What made the situation more complex was that the new product was not owned by a dedicated team. It was effectively being managed as a secondary responsibility — layered on top of full-time roles, with limited budget and no protected time. The strategy existed at a high level. But the execution details did not. The organization believed it was moving toward launch readiness. In reality, critical decisions had not yet been made — and no system existed to ensure they would be made in time.

The stakes: A multi-hundred-million dollar franchise and a first-in-category product launch were both on the line. Miss the regulatory window and the commercial buildout stalls. Lose alignment across 50+ people mid-submission and the launch timeline slips — publicly, with a board and investors watching. There was no version of “we’ll fix governance after the launch.” The operating system had to be built while the machine was already running.

The governance infrastructure had not scaled with the portfolio complexity. Four problems were present simultaneously:

Launch readiness uncertainty

The organization was approaching regulatory submission for a first-in-category product with no precedent in the company's commercial history. Alignment on whether the commercial organization was truly ready had not been formally established.

Decision re-litigation

Cross-functional decisions were not holding. Decisions reached in one forum were re-opened in the next — often at a higher level. By late stage, most decisions were escalating to the Chief Medical Officer and Chief Technology Officer — not because they should, but because the organization had no defined decision boundaries. Cycle time increased. Confidence decreased. And the organization began to lose trust in its own ability to execute.

Organizational structure gaps

The commercial org structure was not explicitly mapped to the demands of a three-product franchise at different lifecycle stages. Role clarity, reporting lines, and cross-functional ownership were informal rather than designed.

Board and investor visibility

As a publicly traded company with significant investor scrutiny on the commercial buildout, leadership needed board-ready performance visibility that the existing reporting infrastructure could not reliably produce.

"The Accountable Operator's reality: four governance problems active at once, a first-in-category product approaching FDA submission, a board watching every commercial signal, and no time to pause and redesign the system before execution had to continue."

WHAT WAS BUILT

Rather than addressing each problem in isolation, the work focused on building governance architecture that resolved all four simultaneously — over the course of the full engagement, not in a single intervention. The shift was gradual and deliberate: each structural change created the conditions for the next.

| BEFORE | AFTER |
|--|--|
| Decisions re-opened across forums | → Decisions resolved at the defined level |
| No clear accountability across the franchise | → Explicit decision rights mapped across 50+ person team |
| Fragmented reporting — no board-ready signal | → Board-ready KPI system with real-time franchise visibility |
| Commercial org structure informal and unmapped | → Salesforce & org architecture aligned to three-product franchise |

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| <p>1 — Enterprise Decision Rights Architecture (EDRA)</p> <p>Mapped explicit decision rights across the 50+ person cross-functional team. Defined which decisions resided at the functional level, which required franchise-level alignment, and which required VP escalation. Eliminated the pattern of decisions being re-opened at each successive forum. And therefore: the submission stayed on timeline because the decisions that could have stalled it were resolved at the right level — without consuming executive bandwidth or triggering CMO/CTO escalation.</p> | <p>2 — Franchise Governance System Design</p> <p>Redesigned meeting cadence and forum purpose across the franchise. Each forum was given a defined scope, decision authority, and membership. Eliminated redundant escalation meetings and reduced the executive time burden of managing alignment noise. And therefore: the organization stopped solving the same problems twice — freeing leadership attention for the decisions that actually required it.</p> |
| <p>3 — KPI Framework & Board Visibility</p> <p>Built the KPI framework and board-ready reporting structure for the franchise. Translated operational complexity — customer starts, pipeline performance, payer access, salesforce productivity — into the executive-ready signal the board and investor relations function required. And therefore: leadership could walk into every board conversation with a coherent, defensible story about commercial performance — not a reactive scramble.</p> | <p>4 — Commercial Org & Salesforce Architecture</p> <p>Designed and piloted a primary care district sales model and co-developed a five-year salesforce expansion plan. Aligned the org structure to the demands of a three-product franchise, with clear accountability across all lifecycle stages. And therefore: the commercial organization could scale into new markets with a model already stress-tested — not improvised under launch pressure.</p> |

HOW THE COMMERCIAL OPERATING SYSTEM™ SHOWED UP IN THIS ENGAGEMENT

The **Commercial Operating System™** is not a methodology applied after the fact. It is the architecture that governs how a commercial organization makes decisions, structures itself, reports performance, and scales. Every element of the work described in this engagement maps directly to a specific domain of the system — and each domain solved a distinct problem the organization could not solve on its own.

| COS™ Domain | The Problem It Solved | What Was Deployed | What It Unlocked |
|---|---|--|---|
| I — Decision Velocity Framework™ | Decisions were re-litigating across every forum. Without defined decision rights, everything escalated to the CMO and CTO — creating bottlenecks, eroding confidence, and threatening the launch timeline. | Enterprise Decision Rights Architecture (EDRA) — explicit ownership at functional, franchise, and VP levels across a 50+ person team | On-time regulatory submission and early FDA clearance — with zero executive re-litigation at the finish line |
| II — Commercial Operating Model Blueprint™ | The org structure was not mapped to a three-product franchise. Shared functions had no franchise-specific accountability. Role clarity was informal, and the new asset had no dedicated team — just secondary responsibilities layered on top of full-time roles. | Primary care district sales model, five-year salesforce expansion plan, org structure redesigned to the demands of each lifecycle stage | 15K+ new customer starts across all lifecycle stages; commercial organization scaled into primary care with a model already stress-tested |
| IV — Strategic Asset Governance Model™ | The first-in-category asset was being managed as a pet project — no dedicated team, no protected resources, no formal launch readiness framework. The organization believed it was ready. The execution details said otherwise. | Franchise governance structure built from scratch — defined launch readiness criteria, cross-functional accountability, and execution milestones with no commercial precedent to reference | First-in-category product cleared on time — the only measurable definition of success for an asset with no commercial precedent in the company's history |
| V — Enterprise Visibility Architecture™ | As a publicly traded company under significant investor scrutiny, leadership needed board-ready performance visibility the existing infrastructure could not produce. Reporting was fragmented, reactive, and not designed for executive consumption. | Full KPI framework and board-ready reporting structure — customer starts, pipeline, payer access, salesforce productivity — delivered to leadership every Monday | Leadership walked into every board conversation with a coherent, defensible commercial story — not a reactive scramble |

THE OUTCOMES

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| <p>Early Clearance</p> <p>On-time regulatory submission & early clearance for the first-in-category product — on timeline, no executive re-litigation</p> | <p>15K+</p> <p>New customer starts driven across the franchise at all lifecycle stages</p> | <p>7-Figures</p> <p>Revenue generated via primary care pilot — lean team model, pre-full commercialization</p> | <p>50+</p> <p>Cross-functional team operating with aligned governance architecture by close of engagement</p> |
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The regulatory clearance outcome is the headline — but it is not the whole story. Early clearance for the first-in-category product was the result of a commercial organization that had built the governance infrastructure to execute without losing velocity. The submission stayed on timeline because decisions that could have stalled it were resolved at the right level, with the right people, without requiring executive re-litigation at each turn.

"The most important outcome wasn't a single metric. It was that by the close of the engagement, the organization had a commercial operating system it could run — not just a launch it had survived."

WHAT THIS LOOKS LIKE AS AN ALEXANDER JAMISON ENGAGEMENT

This case study describes work done from inside an organization. When Alexander Jamison delivers the **Commercial Operating System™** as an external advisor, the dynamic is different — and in several ways, more powerful.

| Working Inside the Org (as in this case) | Alexander Jamison External Advisory |
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| Subject to internal politics, hierarchy, and career considerations | No internal politics. Position-taking without career risk. |
| Governance redesign competes with daily execution demands | Dedicated engagement scope — governance architecture is the whole mandate |
| Perspective shaped by what the organization already sees | Pattern recognition from 17+ launches — sees what insiders can't |
| Timeline determined by organizational bandwidth | Time-bound engagement — 12–16 weeks for full system design and activation |
| Departure creates dependency unless capability is institutionalized | Every engagement designed so the organization runs the system independently when AJA exits |

WHEN THIS STARTS TO FEEL FAMILIAR

Is your commercial organization facing a similar inflection point?

Most organizations that need this don't recognize it until a launch is already at risk. By that point, the cost of closing the gap compounds — across timelines, resources, and credibility.

The **Commercial Operating System™ Diagnostic** is designed to surface those gaps before they become visible.

A focused, three-week engagement that delivers a scored assessment across all five governance domains — and a clear path to building the infrastructure required to execute at scale.

Michelle Alexander | michelle@alexanderjamison.com | alexanderjamison.com