Issue 2: Designing Enterprise MDR Governance: From Functional Silos to Integrated Decision Councils

Why Governance, Not Headcount, Is the Constraint

Most large MedTech organizations did not enter EU MDR with weak talent; they entered with governance designed for a lighter, less integrated regulatory era.
Regulatory, clinical, quality, and commercial teams each work hard — but they do not always decide together on the same facts, at the same time. As MDR transition, surveillance and evidence expectations intensify, this is becoming the primary bottleneck.

In a 2026 landscape of evolving MDR revisions, EUDAMED transparency, and Notified Body pressure, this fragmented model is no longer viable.
Enterprise leaders need a governance system that turns cross-functional complexity into clear, time-bound decisions.

---

1. The Symptoms of Weak MDR Governance

Long before anyone says "we have a governance problem," the symptoms are visible:

- **Fragmented risk picture.** Each function has its own dashboard; nobody owns the integrated view of certificates, evidence health, quality exposure, and revenue.
- **Surprise escalations.** Certificate cliffs, NB findings, or PMS signals surface late at executive level, framed as emergencies rather than options.
- **Duplicated effort.** Multiple MDR "projects" chase similar data because accountabilities and decision rights are unclear.
- **Inconsistent decisions**. Similar products get treated differently in different BUs or regions because there is no shared framework for triage or investment.

These are not primarily resourcing issues. They are decision-architecture issues.

---

2. Principles of Enterprise-Grade MDR Governance

Effective MDR governance in a multinational MedTech is built on four simple principles:

1. **Single Source of Truth**
   Critical MDR information — certificates, evidence status, PMS signals, QMS exposure, revenue — is curated into shared portfolio views, not scattered across slide decks and trackers.
2. **Clear Decision Rights**
   It is explicit who recommends, who decides, and who executes for key MDR decisions (e.g., evidence spend, SKU exits, NB strategy) at global, regional, and BU levels.

3. **Predictable Cadence**
   Regular forums (monthly / quarterly) with defined inputs and outputs replace ad-hoc crises. MDR decisions become part of the operating rhythm, not one-off events.

4. **Structured Escalation Paths**
   Pre-agreed rules determine when issues move from product team to portfolio, and from portfolio to executive committee or board, so escalation is a feature of the system, not a sign of failure.

Governance is not about creating more meetings; it is about ensuring the same information **consistently produces the same type of decision**, regardless of who is in the room.

---

3. From Functional Committees to Integrated Decision Councils

Many organizations already have separate Regulatory Committees, Clinical Councils, and Quality Forums. Under MDR, those structures need to evolve into **integrated MDR Decision Councils** that cut across functions.

A practical enterprise design typically includes:

a) Portfolio & Certificates Council

- **Mandate:** Own the MDR portfolio heatmap; set certificate strategy and renewal waves; oversee NB relationships for key product families.
- **Inputs:** Portfolio heatmaps, transition timelines, NB feedback, commercial exposure.
- **Outputs:** Protect / Transform / Release decisions; prioritization of remediation and redesign; NB engagement plans.

b) Evidence & PMS Council

- **Mandate:** Own the clinical-evidence architecture — CER, PMS, PMCF, PSUR — and its alignment with market access and pricing strategy.
- **Inputs:** CER status, PMS/PMCF data, HTA requirements, RWE opportunities.
- **Outputs:** Evidence priorities, PMCF design, integration of RWE, and value-narrative decisions.

c) Quality & Operations Council

- **Mandate:** Ensure QMS, supplier governance, and manufacturing operations are aligned with MDR risk and evidence needs.
- **Inputs:** Audit and inspection results, CAPA trends, supplier performance and documentation status.
- **Outputs:** Systemic CAPAs, supplier-risk strategies, site-level readiness plans.

d) Executive MDR Steering Group

- **Mandate:** Integrate recommendations from the three councils into portfolio and capital-allocation decisions; own MDR narrative at board level.
- **Inputs:** Council summaries, financial impact, strategic scenarios.
- **Outputs:** Approved portfolio strategy, funding, and risk appetite.

Each council has a concise charter, defined membership, and explicit decision rights. Together they form the **MDR governance operating system**.

---

4. Global, Regional, and Local: Getting the Interfaces Right

Enterprise MedTechs cannot centralize every decision. Effective MDR governance clarifies what is decided where:

- Global level
    - MDR policy and standards, core templates, global evidence strategy, portfolio heatmaps, NB portfolio strategy.
- Regional level
    - Adaptation to specific NB expectations, language requirements, and local HTA / reimbursement realities; oversight of regional economic operators and distributors.
- Local / Site level
    - Day-to-day QMS execution, vigilance operations, CAPA management, supplier qualification and monitoring.

Strong governance gives regional and site teams real decision authority within clear global guardrails, rather than routing every question back to HQ.

---

5. Metrics That Signal Governance Maturity

You can't manage what you don't measure. Useful MDR governance metrics are less about volume ("# of projects") and more about decision quality and timing:

- Percentage of MDR-relevant issues first identified at portfolio level vs during NB review.
- Time from PMS signal or NB concern to documented cross-functional decision.
- Proportion of MDR evidence / remediation spend aligned to agreed Protect / Transform / Release clusters.
- Frequency and completion rate of MDR portfolio reviews at executive level.

- Alignment of MDR risk themes between internal audits, NB reports, and board discussions.

When governance is working, these metrics trend towards earlier detection, faster decisions, and fewer surprises.

---

6. How SHOTUNE Designs and Implements MDR Governance

SHOTUNE's work on MDR governance typically follows a structured path:

1. **Map the reality.**
   Interview teams and trace a few recent MDR decisions end-to-end: who was involved, what information they had, how long it took, what trade-offs were considered.
2. **Design the councils and charters.**
   Define Portfolio & Certificates, Evidence & PMS, and Quality & Operations Councils, plus the Executive Steering Group — including membership, inputs, outputs, and escalation rules.
3. **Integrate portfolio and evidence tools.**
   Embed MDR portfolio heatmaps and evidence dashboards as the standard inputs to council discussions, so decisions are made on shared facts rather than competing slides.
4. **Pilot the cadence.**
   Run several cycles of council meetings focusing on real decisions (not theory): a certificate cliff, a PMCF redesign, a supplier issue that touches evidence and supply.
5. **Codify and hand over.**
   Document the MDR governance model as a living "playbook" and help leadership weave it into existing portfolio management, risk, and board routines.

The objective is not to add bureaucracy.
It is to ensure that MDR — and the evidence, quality, and commercial decisions it demands — are handled with the same discipline as any other strategic investment decision.

When governance is designed this way, MDR stops being a slow-moving compliance storm. It becomes a structured lens through which boards, BU leaders, and investors can see risk early, choose their battles, and protect enterprise value on purpose.

Respectfully,

Shola Sulaimon, DVM, MSc, PhD
Founder & CEO
SHOTUNE Medical Consulting Group