SHOTUNE MEDICAL CONSULTING GROUP

Case Studies

PROTECTING CERTIFICATION, MARKET ACCESS, COMMERCIAL CONTINUITY, AND PORTFOLIO VALUE

MedTech companies rarely lose time, revenue, and credibility because one document is imperfect. They lose momentum when regulatory, clinical, quality, and commercial decisions stop aligning around one defensible evidence position.

THE SHOTUNE DECISION LENS

EXPOSURE	INTERDEPENDENCY	MATERIALITY	DECISION	ACTION
What could affect certification, claims, market access, or continuity?	Which functions, evidence sources, and documents are connected?	What could change timing, investment, revenue, or value?	What must leadership fund, sequence, narrow, escalate, or stop?	Who owns the response, what evidence is required, and by when?

BOOK A CONFIDENTIAL STRATEGY DISCUSSION

Bring one product, one deadline, one open finding, or one portfolio decision. SHOTUNE will help clarify the decision at risk, the evidence dependencies, and the executive action that cannot wait.

Secondary path: *Take the Portfolio Cliff™ Risk Exposure Diagnostic to identify where leadership visibility may be weakest before scheduling a discussion.*

EXPERIENCE DISCLOSURE This *anonymized example is based on Dr. Shola Sulaimon's prior MedTech leadership and advisory experience. Company, product, timing, and operational details have been generalized to protect confidentiality. It illustrates the strategic approach she brings to SHOTUNE and is not represented as a SHOTUNE client engagement unless explicitly stated.*

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CASE STUDY 01 OF 5

PORTFOLIO RISK | EXECUTIVE DECISION-MAKING

Building One Decision Picture Before Staggered EU Market-Access Decisions

DEVICE CLASS EU MDR Class IIb / III (mixed cardiovascular and surgical portfolio)

BUYER MIRROR

Your regulatory, clinical, quality, and commercial teams may all be reporting progress while leadership still cannot answer which products are genuinely supportable — or where investment decisions can no longer wait.

YOU MAY RECOGNIZE THIS SITUATION IF

- Each function has a credible status report, but the reports do not add up to one portfolio-level readiness view.
- Certification, renewal, remediation, and commercial milestones are approaching on different timelines.
- Resources are being allocated using inherited confidence rather than current evidence maturity.
- Commercial commitments are advancing faster than the clinical and regulatory evidence position.

EXECUTIVE STAKES

TIMING	MARKET ACCESS	COMMERCIAL	LEADERSHIP
Staggered certification and remediation milestones	Supportability and continued EU access by product	Commitments moving ahead of evidence maturity	Invest, remediate, sequence, narrow, or stop

THE EXPOSURE

A multi-product cardiovascular and surgical device portfolio had products approaching EU MDR certification, remediation, renewal, and continued market-access decisions on different timelines. Regulatory, clinical, quality, and commercial teams each held part of the picture, but leadership had no consolidated view of evidence maturity, resource capacity, timing, or business exposure. The visible issue was volume of work. The less visible issue was that product-level commitments were being made without a defensible portfolio view of which devices remained supportable.

THE DECISION AT RISK

Leadership needed to determine which products warranted further investment, which required immediate remediation, which could be sequenced through planned work, and where claims or commercial commitments needed to be narrowed or paused until the evidence position was stronger.

WHY IT MATTERED

Without an integrated decision view, the organization could over-invest in lower-value products, under-resource material risks, and discover evidence gaps after timelines were fixed. The consequences would not stay inside regulatory or clinical functions — they could reach certification timing, revenue continuity, resource strain, and the value of keeping a product in the portfolio.

> WHAT DR. SHOLA RECOGNIZES QUICKLY
>
> *The visible problem is often incomplete work. The more consequential problem is that no one has converted fragmented functional evidence into a portfolio-level investment decision.*

THE SHOTUNE DECISION LENS

- Mapped regulatory, clinical, quality, and commercial dependencies across the portfolio, including CER, PMCF, PMS, risk management, claims, and technical documentation.
- Compared evidence maturity against certification and commercial milestones rather than relying on percentage-complete reporting.
- Separated decision-critical exposure from manageable sequencing, capacity, and execution issues.
- Translated technical findings into executive consequences — timing, investment, market access, and portfolio value — and clarified what required leadership escalation.

WHAT CHANGED

- Leadership gained one operating view of portfolio exposure instead of a collection of functional status reports.
- Resourcing and sequencing decisions could be anchored in current evidence maturity rather than inherited confidence.
- Commercial exposure became visible early enough to influence investment, escalation, and market-access planning.

WHEN TO BRING SHOTUNE IN

- Several products are approaching certification, remediation, or market-access decisions at the same time.
- Functions are reporting progress, but leadership cannot compare supportability and exposure across products.
- Leadership needs an independent view before committing additional capital, extending a timeline, or discontinuing a product.

BOOK A CONFIDENTIAL STRATEGY DISCUSSION

Bring your next portfolio review, one high-value product, or one difficult prioritization

decision. SHOTUNE will help clarify where the material exposure sits, which interdependencies matter, and what leadership should decide first.

Secondary path: *Take the Portfolio Cliff™ Risk Exposure Diagnostic to identify where leadership visibility may be weakest before scheduling a discussion.*

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CASE STUDY 02 OF 5

NOTIFIED BODY RESPONSE | EVIDENCE-SYSTEM ALIGNMENT

Closing a Notified Body Deficiency Response Without Creating New Inconsistencies

DEVICE CLASS EU MDR Class III (implantable device — SSCP-applicable)

BUYER MIRROR

Your response may be technically credible in each document while the CER, PMCF, PMS, risk-management file, SSCP, claims, and technical documentation are quietly drifting apart.

YOU MAY RECOGNIZE THIS SITUATION IF

- Findings have been assigned to document owners, but no one owns the evidence narrative across the complete response.
- A proposed correction changes a claim, conclusion, or benefit-risk rationale in more than one controlled document.
- The reviewer is asking repeat questions because the rationale is difficult to trace across the evidence system.
- The response deadline is fixed while regulatory, clinical, quality, and product teams are working in parallel.

EXECUTIVE STAKES

TIMING	MARKET ACCESS	COMMERCIAL	LEADERSHIP
Response deadline and review-cycle predictability	Certification or renewal continuity	Prolonged review and delayed commitments	Isolated correction or integrated closure strategy

THE EXPOSURE

A medical device manufacturer received Notified Body deficiencies spanning clinical evaluation, post-market evidence, risk management, and technical documentation. Functions began preparing responses independently, creating a risk that the CER, PMCF Plan, PMCF Evaluation Report, SSCP, PMS outputs, risk-management file, and technical documentation would no longer tell the same story. No single view showed how one proposed correction could alter connected evidence elsewhere in the file.

THE DECISION AT RISK

Leadership needed to determine whether the findings could be managed as isolated documentation corrections or whether they represented evidence-system issues requiring coordinated ownership, one closure strategy, and cross-functional governance.

WHY IT MATTERED

A response can answer one reviewer question while exposing another inconsistency elsewhere. When the evidence architecture is not aligned, review cycles can extend and certification timing can become less predictable. A rushed response may also lock the organization into

claims other evidence sources cannot support, increasing rework and weakening confidence in the technical documentation.

> **WHAT DR. SHOLA RECOGNIZES QUICKLY**
>
> *The finding is rarely the entire problem. The material risk sits in what the proposed response changes elsewhere — and whether every connected document can still defend the same conclusion.*

THE SHOTUNE DECISION LENS

- Mapped each deficiency to the underlying regulatory, clinical, quality, and evidence expectation.
- Traced the impact of every proposed response across connected evidence sources, claims, and controlled documents.
- Separated documentation gaps from substantive evidence gaps requiring additional analysis or leadership escalation.
- Reconstructed the documentation logic, sequenced foundational decisions before dependent updates, and established one reviewer-facing narrative across functions.

WHAT CHANGED

- The team moved from isolated comment responses to an integrated closure strategy.
- Leadership gained a clearer distinction between document remediation and more consequential evidence-system exposure.
- The response architecture reduced the likelihood of creating new contradictions while addressing the original findings.

WHEN TO BRING SHOTUNE IN

- A Notified Body finding affects more than one document, claim, or evidence source.
- Multiple functions are responding in parallel without one accountable cross-document decision path.
- Leadership needs an independent review before finalizing a high-stakes response package.

BOOK A CONFIDENTIAL STRATEGY DISCUSSION

Bring one open finding and the connected documents. SHOTUNE will help identify where a narrow correction could create a broader inconsistency, which decision must be made first, and how to structure a defensible closure path.

Secondary path: *Take the Portfolio Cliff™ Risk Exposure Diagnostic to identify where leadership visibility may be weakest before scheduling a discussion.*

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CASE STUDY 03 OF 5

COMMERCIALIZATION RISK | EVIDENCE READINESS

Finding Commercialization Risk Hidden Inside a Device's Clinical Evidence Position

DEVICE CLASS EU MDR Class IIb (surgical device)

BUYER MIRROR

The launch plan may look settled, but no one has independently tested whether the current evidence can defend the intended purpose, claims, regulatory pathway, and timing behind the commercial commitment.

YOU MAY RECOGNIZE THIS SITUATION IF

- A launch date has entered the board or operating plan before the evidence position has been pressure-tested.
- Clinical and regulatory documents are progressing, but the intended claims remain broader than the available evidence can comfortably support.
- PMCF or other evidence-generation activities are still open, yet the commercial plan assumes they will not affect timing.
- The internal conversation focuses on document completion rather than whether the evidence position can withstand review.

EXECUTIVE STAKES

TIMING	MARKET ACCESS	COMMERCIAL	LEADERSHIP
Launch and submission milestones	Pathway, claims, and review readiness	Revenue plan and stakeholder confidence	Proceed, resequence, narrow, or invest

THE EXPOSURE

A surgical device team was approaching a planned commercialization milestone, but the clinical evidence position had not been fully pressure-tested against current regulatory expectations, intended purpose, proposed claims, and the applicable market-access pathway. The launch plan assumed the evidence would withstand review. The hidden exposure was the gap between a commercially committed date and the confidence the evidence position had actually earned.

THE DECISION AT RISK

Leadership needed to decide whether to proceed as planned, resequence activities, narrow claims, strengthen the evidence strategy, add resources, or adjust the commercial commitment before the milestone became fixed and more expensive to change.

WHY IT MATTERED

Commercialization risk often begins as evidence risk. When identified late, it can surface as launch delay, claim restriction, market-access uncertainty, revenue interruption, or loss of stakeholder confidence — and the cost can reach manufacturing readiness, sales planning, and investor expectations.

WHAT DR. SHOLA RECOGNIZES QUICKLY

Commercial risk often enters through an evidence assumption that was never formally challenged. A date can be operationally complete and still be clinically or regulatorily indefensible.

THE SHOTUNE DECISION LENS

- Identified the evidence assumptions embedded in the launch timeline, intended purpose, and go-to-market strategy.
- Reviewed whether clinical conclusions, benefit-risk, PMS, PMCF, and risk-management outputs supported the commercial position.
- Assessed unresolved uncertainty and whether planned evidence-generation activities addressed the questions most likely to affect the decision.
- Distinguished likely reviewer scrutiny from confirmed findings and translated evidence limitations into business choices: proceed, narrow, resequence, remediate, or invest.

WHAT CHANGED

- Leadership gained a more realistic view of the factors that could affect timing, claims, and revenue continuity.
- The discussion shifted from whether documents were nearing completion to whether the evidence position could defend the business plan.
- Sequencing, remediation, claims, and resourcing decisions could be addressed before the launch milestone became fixed.

WHEN TO BRING SHOTUNE IN

- A launch date, claim set, or revenue commitment is being finalized before an integrated evidence-readiness review.
- Commercial, regulatory, and clinical teams hold different assumptions about what the current evidence can support.
- Leadership wants an independent challenge before presenting the plan to the board, investors, or launch teams.

BOOK A CONFIDENTIAL STRATEGY DISCUSSION

Bring the proposed claims, launch milestone, and current evidence position. SHOTUNE will test whether the business plan has earned its current confidence — and clarify what leadership should strengthen, narrow, or resequence before the commitment becomes fixed.

Secondary path: *Take the Portfolio Cliff™ Risk Exposure Diagnostic to identify where leadership visibility may be weakest before scheduling a discussion.*

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CASE STUDY 04 OF 5

PMCF STRATEGY | POST-MARKET EVIDENCE

Turning PMCF From a Compliance Activity Into a Portfolio and Commercialization Tool

DEVICE CLASS EU MDR Class IIb / III

BUYER MIRROR

Your PMCF plan may be active and fully scheduled while leadership still cannot name which uncertainty each activity is expected to close — or what decision the result will change.

YOU MAY RECOGNIZE THIS SITUATION IF

- PMCF activities continue because they are in the plan, not because their decision value has been reassessed.
- Reports summarize activity and data but do not clearly answer a defined clinical question.
- CER gaps, PMS signals, residual risks, claims, and PMCF objectives are not visibly connected.
- The organization is investing in post-market evidence without a clear escalation, modification, or stop rule.

EXECUTIVE STAKES

TIMING	MARKET ACCESS	COMMERCIAL	LEADERSHIP
Future certification and evidence updates	Residual uncertainty and reviewer confidence	Claims, continuity, and evidence investment	Continue, redesign, escalate, or stop

THE EXPOSURE

A manufacturer had a PMCF Plan in place, but the program was being managed primarily as a recurring obligation and schedule of activities. Studies and data-collection efforts were described, yet the connection to residual clinical uncertainty, CER limitations, benefit-risk conclusions, and future certification decisions was not sufficiently clear. Activity created the appearance of progress, but leadership could not readily see which uncertainty each effort was intended to reduce.

THE DECISION AT RISK

Leadership needed to determine which PMCF activities were materially reducing uncertainty, which required redesign, which could be narrowed or stopped, and where unresolved evidence exposure should be escalated rather than carried forward.

WHY IT MATTERED

Generic PMCF programs can create false confidence. An activity may satisfy a template while leaving clinical uncertainty, benefit-risk questions, and market-access exposure unresolved — spending time and capital on data that cannot change the certification strategy. The result is

activity without closure, and a gap that becomes more expensive as the next review approaches.

> **WHAT DR. SHOLA RECOGNIZES QUICKLY**
>
> *The right PMCF question is not "Are we collecting data?" It is "Which uncertainty will this evidence reduce, and what will leadership do differently when the result arrives?"*

THE SHOTUNE DECISION LENS

- Identified the clinical uncertainties that mattered most for the device, its claims, and its benefit-risk conclusions.
- Linked PMCF objectives directly to CER gaps, PMS signals, risk-management needs, and future certification decisions.
- Tested whether each method, endpoint, and data source could actually answer the question it was assigned to address.
- Defined how future PMCF Evaluation Reports would support monitoring, escalation, or claims decisions, connecting PMCF investment to portfolio decisions rather than treating it as a stand-alone obligation.

WHAT CHANGED

- The PMCF program became more targeted and decision-useful rather than activity-driven.
- Leadership gained clearer visibility into how post-market evidence supported certification confidence and where exposure remained open.
- Commercial and portfolio teams could see where PMCF protected value and where activity lacked sufficient decision value.

WHEN TO BRING SHOTUNE IN

- PMCF activities are underway, but no one can state the uncertainty, decision, and success criterion for each one.
- The PMCF Plan, CER, PMS, risk-management file, and claims do not clearly connect to one evidence strategy.
- A certification milestone is approaching, and leadership needs to know what the current program can realistically defend.

BOOK A CONFIDENTIAL STRATEGY DISCUSSION

Bring your highest-cost or highest-risk PMCF activity. SHOTUNE will help clarify which uncertainty it is expected to close, whether the design can answer that question, and which decision the result should inform.

Secondary path: *Take the Portfolio Cliff™ Risk Exposure Diagnostic to identify where leadership visibility may be weakest before scheduling a discussion.*

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CASE STUDY 05 OF 5

LEGACY DEVICE MDR READINESS | CLINICAL EVALUATION

Rebuilding Clinical Evaluation Logic for a Legacy Device Portfolio Under Current EU MDR Expectations

DEVICE CLASS EU MDR Class IIb / III (legacy, long-marketed portfolio; SSCP-applicable where Class III)

BUYER MIRROR

A legacy device can have years of market history, familiar claims, and prior CE certification — and still carry a weak current MDR evidence architecture.

YOU MAY RECOGNIZE THIS SITUATION IF

- The CER has been updated incrementally, but its core logic still reflects older assumptions and expectations.
- Claims, intended purpose, state of the art, PMS, PMCF, and risk management do not clearly connect.
- Long market history is repeatedly used as reassurance without testing whether current evidence supports today's claims.
- Leadership cannot distinguish certification-critical gaps from issues manageable through a planned evidence-development strategy.

EXECUTIVE STAKES

TIMING	MARKET ACCESS	COMMERCIAL	LEADERSHIP
MDR review and remediation sequence	Certification and continued EU availability	Established revenue and claim continuity	Support, remediate, invest, narrow, or exit

THE EXPOSURE

A portfolio of long-marketed legacy devices required stronger clinical evaluation support under current EU MDR expectations. Historical data, prior CE certification, and existing documentation were available, but the evidence position was not consistently organized around current intended purpose, claims, state of the art, benefit-risk conclusions, and risk management. The organization had substantial information — what it lacked was a current architecture showing how that information supported each device today.

THE DECISION AT RISK

Leadership needed to determine which devices remained adequately supported, which required focused remediation or additional PMCF, which claims should be reconsidered, and where evidence limitations could affect certification or continued market access.

WHY IT MATTERED

Prior market history does not automatically establish current MDR readiness. When evidence is not clearly connected to today's claims and risk conclusions, a commercially established device can still become vulnerable during Notified Body review — creating concentrated remediation, unplanned evidence costs, and difficult decisions about products long treated as stable.

> **WHAT DR. SHOLA RECOGNIZES QUICKLY**
>
> *Legacy portfolios often look safest because they are familiar. That familiarity can hide how much the claims, state of the art, and risk conclusions have changed around the device.*

THE SHOTUNE DECISION LENS

- Reviewed the clinical evaluation architecture against current MDR expectations rather than relying on legacy document structure.
- Tested whether available clinical evidence continued to support intended purpose, claims, state of the art, and benefit-risk conclusions.
- Strengthened the connection among CER conclusions, PMS data, PMCF strategy, SSCP content, and risk management.
- Separated certification-critical gaps from issues manageable through a defined evidence-development plan, and repositioned PMCF as a forward-looking mechanism rather than a historical formality.

WHAT CHANGED

- The organization gained a clearer current view of the evidence position across the legacy portfolio.
- Leadership could prioritize remediation, additional evidence, and product sequencing according to materiality.
- The clinical evaluation architecture became more coherent and better aligned with current review expectations.

WHEN TO BRING SHOTUNE IN

- A legacy device relies heavily on historical market experience or previously accepted clinical logic.
- Several established devices are approaching MDR certification or remediation decisions together.
- Leadership needs to decide where continued evidence investment remains justified and where claims or strategy should change.

BOOK A CONFIDENTIAL STRATEGY DISCUSSION

Bring one established device, its current claims, and the latest clinical evaluation. SHOTUNE will examine whether market history is being asked to carry more than the current evidence architecture can defend.

Secondary path: *Take the Portfolio Cliff™ Risk Exposure Diagnostic to identify where leadership visibility may be weakest before scheduling a discussion.*

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CONFIDENTIAL EXECUTIVE ADVISORY

Where Is Your Portfolio Most Exposed?

Preparing for EU MDR certification or renewal, a Notified Body response, CER remediation, PMCF strategy, commercialization planning, or a portfolio-level market-access decision?

SHOTUNE provides founder-led advisory support that connects regulatory, clinical, quality, and commercial evidence to the decisions that protect timing, market access, and portfolio value. The objective is to identify the material exposure, determine what leadership must decide, and establish a defensible path forward.

BOOK A CONFIDENTIAL STRATEGY DISCUSSION

Bring one product, one deadline, one open finding, or one portfolio decision. SHOTUNE will help clarify the decision at risk, the evidence dependencies, and the executive action that cannot wait.

Secondary path: *Take the Portfolio Cliff™ Risk Exposure Diagnostic to identify where leadership visibility may be weakest before scheduling a discussion.*