SHOTUNE MEDICAL CONSULTING GROUP

Regulatory • Clinical • Quality • Scientific Strategy • Leadership Advisory

OUR MISSION

We accelerate medical device innovation by delivering integrated regulatory, clinical, and quality strategies that transform uncertainty into market-ready confidence — enabling breakthrough technologies to reach patients faster, safer, and with stronger commercial positioning.

ABOUT SHOTUNE

SHOTUNE Medical Consulting Group is a boutique, executive-level advisory firm serving Class I–III medical device manufacturers across global markets.

Founded by **Shola Sulaimon (DVM, MSc, PhD)**, SHOTUNE integrates 18+ years of Fortune 500 Medical device leadership into a unified commercialization framework spanning:

- 70+ EU Technical File submissions
- FDA 510(k), De Novo, PMA, and IDE programs
- EU MDR transition leadership
- High-risk cardiovascular and implantable technologies
- Global submission governance
- Regulatory remediation and portfolio transitions

We do not operate in silos.
We integrate Regulatory + Clinical + Quality + Leadership into one cohesive system to:

✓ Reduce rework
✓ Accelerate approvals
✓ Strengthen compliance resilience
✓ Protect enterprise value

OUR FIVE STRATEGIC PILLARS

1. REGULATORY STRATEGY & GLOBAL SUBMISSIONS

De-Risking Pathways. Protecting Timelines.

Regulatory misalignment is a leading cause of delay, rework, and valuation erosion. Unstructured submission strategy exposes organizations to deficiency cycles, authority scrutiny, and market entry disruption.

We design structured, defensible regulatory frameworks that align global pathways with commercial objectives.

Strategic Planning

- Device classification & claims positioning
- FDA pathway mapping (510(k), De Novo, PMA, IDE)
- EU MDR conformity strategy
- Global expansion roadmaps
- Regulatory timeline modelling
- Combination product strategy

Submissions & Authority Engagement

- FDA submissions & briefing packages
- EU MDR Technical Documentation (Annex II & III)
- Q-Submissions & IDE strategy
- Notified Body engagement & defense
- Deficiency response governance

Change Management & Governance

- Major vs. minor change classification
- FDA/MDR reporting trigger analysis
- Global notification strategy
- Regulatory heatmaps & executive dashboards
- Systemic regulatory risk reduction

2. CLINICAL STRATEGY & EVIDENCE GENERATION

Strengthening Benefit-Risk Narratives. Closing Evidence Gaps.

Insufficient or misaligned evidence weakens approvals, delays market access, and erodes investor confidence. Fragmented clinical planning increases regulatory scrutiny and reimbursement risk.

We design integrated evidence strategies aligned with regulatory expectations and commercial positioning.

Clinical Evidence Architecture

- Evidence generation strategy (Class I–III)
- Claims substantiation & benefit-risk modelling
- Gap analysis & data bridging
- Reimbursement alignment

EU MDR Clinical Evaluation

- CEP, CER, PMCF development
- SSCP
- Systematic literature reviews
- State-of-the-Art analyses
- Risk file integration

Clinical Investigation & Post-Market Strategy

- IDE and global study coordination
- Study design & statistical planning
- Clinical Study Reports
- PMCF and real-world evidence strategy
- PMS-clinical-risk integration

3. QUALITY MANAGEMENT & COMPLIANCE

Reactive quality systems create audit exposure, CAPA overload, and operational instability.

Misalignment between quality, regulatory, and clinical functions amplifies inspection risk.

We build scalable quality infrastructure aligned with regulatory and clinical strategy.

QMS Architecture

- ISO 13485 & 21 CFR 820 alignment
- QMS gap remediation
- SOP architecture & governance
- Cross-functional integration

Risk Management (ISO 14971)

- ISO 14971 hazard analysis & FMEA/FMECA
- Risk file development & GSPR alignment
- DHF traceability
- Design Controls & Validation strategy (IQ/OQ/PQ, software, labelling)

Inspection & Audit Defense

- Mock FDA inspections
- Notified Body readiness
- CAPA system transformation
- PMS & vigilance integration
- Systemic audit resilience

4. TRAINING, LEADERSHIP & ORGANIZATIONAL CAPABILITY

From Siloed Execution to Enterprise Alignment.

Execution risk rarely stems from lack of expertise.
It stems from fragmented governance and cross-functional misalignment.

When Regulatory, Clinical, Quality, R&D, and Commercial teams operate without integrated oversight, organizations experience repeated deficiencies, inspection vulnerability, and delayed commercialization.

We design structured alignment frameworks that institutionalize disciplined, cross-functional execution.

Enterprise Alignment Architecture

• Cross-functional regulatory-commercial governance frameworks
• Decision-rights and accountability mapping
• Integrated milestone planning
• Risk visibility and escalation models
• Regulatory–commercial synchronization strategy

Leadership & Organizational Design

• Regulatory/Clinica/ Quality leadership architecture and succession planning
• RA/Clin/QA organizational scaling strategy
• Cross-functional operating model refinement
• Board-level regulatory exposure briefings

Governance & Performance Infrastructure

• Regulatory heatmaps tied to portfolio value
• Cross-functional submission readiness scoring
• Commercial impact modelling
• Strategic global road mapping
• KPI architecture aligned to executive metrics

5. SCIENTIFIC PUBLICATION & STRATEGIC COMMUNICATION

Turning Data into Authority.

Scientific positioning influences regulators, clinicians, investors, and market adoption. Unstructured communication weakens credibility and strategic differentiation.

We design scientific communication strategies that strengthen regulatory narratives and commercial visibility.

Scientific Development

• Peer-reviewed manuscripts
• Systematic literature reviews
• Clinical Study Reports
• Investigator Brochures
• Regulatory white papers
• Benefit-risk narratives

Strategic Visibility & Influence

• Congress abstract strategy
• KOL engagement
• Advisory board facilitation
• Clinical-commercial value positioning

WHO WE SERVE

- Growth-stage MedTech innovators
- High-risk cardiovascular & implantable manufacturers
- Global manufacturers navigating EU MDR transition
- Organizations preparing for FDA inspection or acquisition

ENGAGE WITH CONFIDENCE

We partner directly with executive leadership to reduce regulatory-clinical-quality uncertainty and protect enterprise value.

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