myQARAmate

GLOBAL REGULATORY, QUALITY & TECH INTELLIGENCE REPORT

December 2025 Edition

Theme: The "Right First Time" Era & Regulatory Simplification



1. EXECUTIVE STRATEGY: From Bureaucracy to Predictability 4
2. EUROPEAN REGULATORY LANDSCAPE 6
A. The Simplification Proposal (COM(2025) 1023) 6
Abolishing the Recertification Cliff 6
PRRC Deregulation for SMEs 6
Digitalization Mandate 6
Modernized Clinical Evidence 7
B. The "3-Round Limit" (MDR Annex VII Revision) 7
Article 3(1)(c): The Mandatory Cap 7
"Structured Dialogue" (Round 0): The VIP Lane 7
C. EUDAMED: The Digital Backbone 7
3. US REGULATORY LANDSCAPE: The Cyber-Quality Convergence 8
A. The "Cyber Device" Redefined 8
B. QMSR: The Global Baseline (Effective February 2026) 8
4. GLOBAL SIGNALS & CONVERGENCE 9
Canada's MDEL Modernization 9
Real-World Evidence (RWE) Unlocked 9
5. FRONTIER TECHNOLOGY MONITOR 10
A. Brain-Computer Interfaces (BCI): The "Regulatory Lasagna" 10
B. Bio-Powered & Battery-Less Implants 10
C. AI-Native Imaging: The Invisible Infrastructure 10
6. OPERATIONAL EXCELLENCE TOOLKIT: The "Survival Gap Analysis" 12
I. The "Golden Thread" Check (Coherence) 12
II. The "Evidence" Check (Completeness) 12
III. The "Clinical" Check (Sufficiency) 12
Operational Execution Protocols 13
1. The "Red Team" Review Strategy 13
2. The "Data Freeze" Discipline 13
7. STRATEGIC EXECUTIVE ACTIONS: 2026 Readiness 14
For European Leaders (EU) 14
For US/Global Leaders (USA) 14
ANNEX A: MARKET INTELLIGENCE SPOTLIGHT — MEDICA 2025 15
Core Themes & Technologies 15
Strategic Takeaways 15
ANNEX B: CORPORATE SPOTLIGHT — MEDACTA INTERNATIONAL 16
Financial & Operational Performance (2025) 16
Technology & Portfolio Milestones 16
Strategic "Watch" Item 16
APPENDIX C: REGULATORY REFERENCE TRACKER 17

EXECUTIVE SUMMARY

December 2025 marks a decisive pivot in global medical device regulation. The EU is not lowering safety standards—it is raising the bar on process efficiency. The US is hardening market entry requirements around cybersecurity. The theme for 2026: **"Right First Time."**

The era of using Notified Body reviews as a consultancy phase has effectively ended.

Regulatory Radar 2026 — Risk Landscape

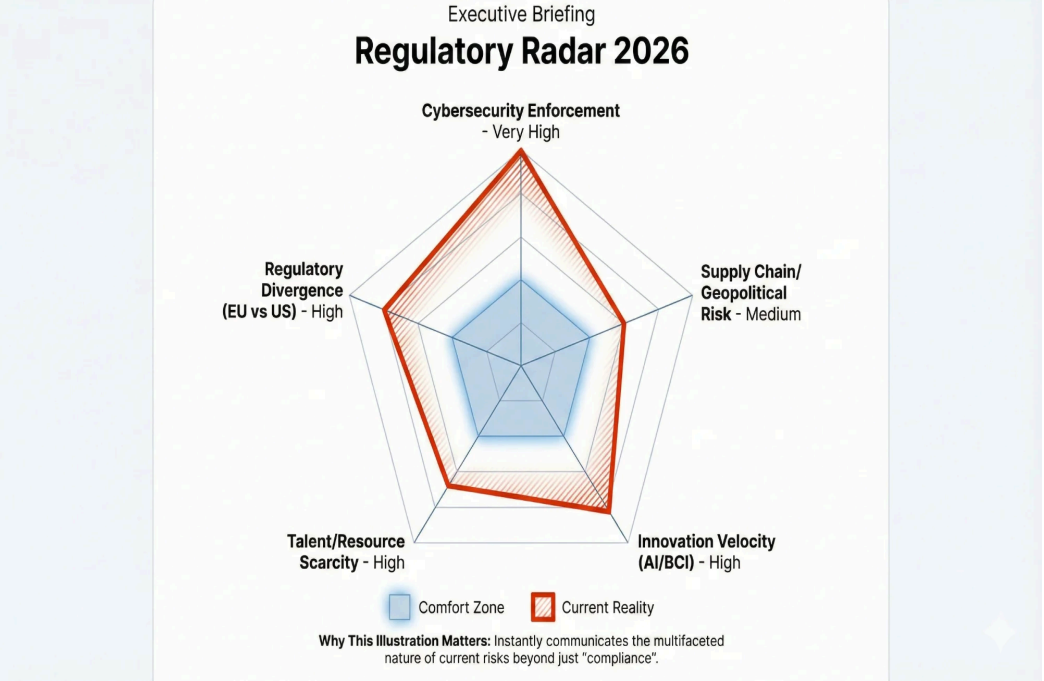


Figure 1: Current risk profile exceeds organizational comfort zones across all dimensions

1. EXECUTIVE STRATEGY: From Bureaucracy to Predictability

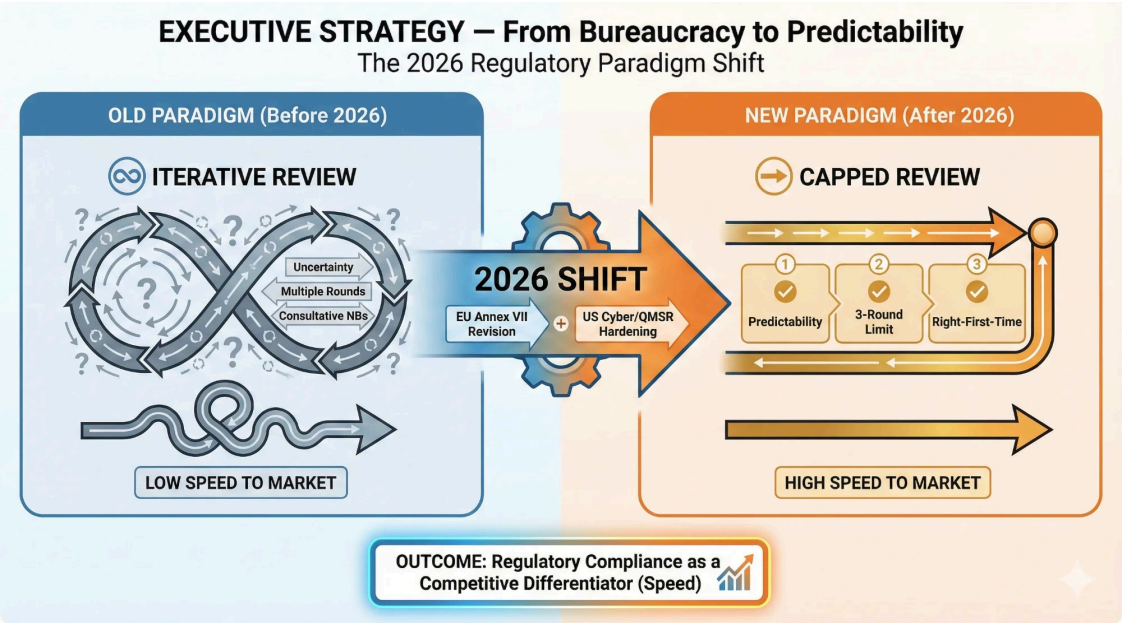


Figure 2: The 2026 regulatory paradigm shift — from iterative uncertainty to capped predictability

December 2025 marks a definitive pivot in the global regulatory landscape, shifting from passive monitoring to active re-engineering of compliance frameworks. In the European Union, the narrative of unpredictability is being dismantled by two coordinated actions:

1. **The draft revision of MDR Annex VII**, which operationalizes strict efficiency caps through a mandatory 3-Round Limit on Notified Body interactions.
2. **The Commission's legislative proposal (COM(2025) 1023)**, published on 16 December 2025, aimed at simplifying the MDR and IVDR through targeted amendments.

This "Simplification Package" addresses systemic bottlenecks by proposing the removal of the 5-year certificate validity limit, modernizing clinical evidence requirements, and reducing administrative burden—particularly for SMEs.

Simultaneously, the United States is hardening its market entry requirements. With the transition to the Quality Management System Regulation (QMSR) effective February 2026 and new "Cyber Device" guidance in effect, the US market is becoming a "fortress" requiring sophisticated digital security architectures integrated from Phase 1 of design.

For RA/QA and Strategy leaders, the competitive advantage now belongs to organizations that can operationalize "Structured Dialogue" in Europe and "Security-by-Design" in the US to bypass the churning delays that trap their competitors.

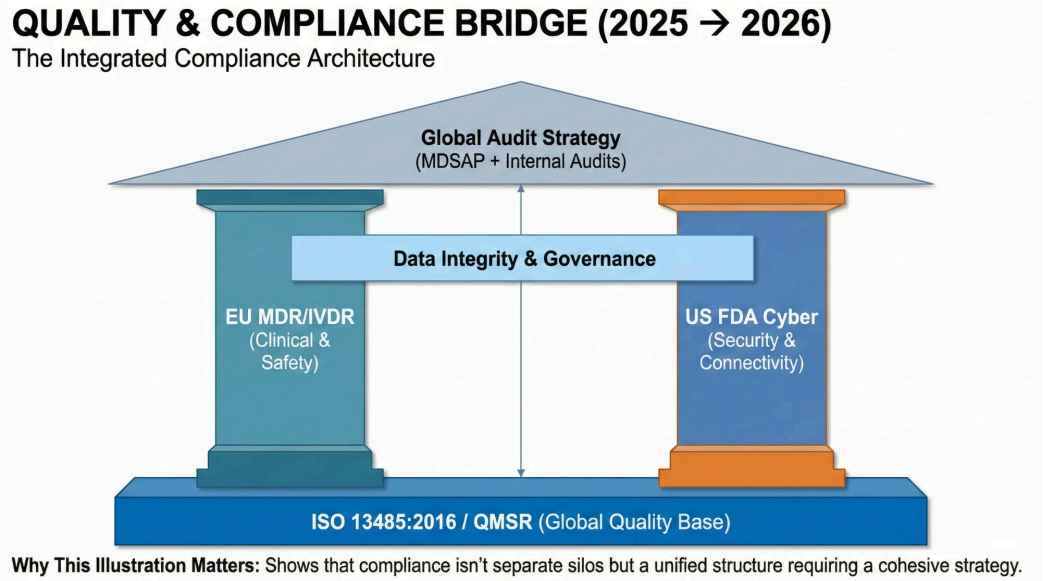


Figure 3: The integrated compliance architecture — ISO 13485/QMSR as the global quality foundation

2. EUROPEAN REGULATORY LANDSCAPE



Figure 4: The European Simplification & Digitalization Pivot — COM(2025) 1023

REGULATORY STATUS MONITOR

- **Legal Status:** Commission Proposal (COM(2025) 1023); currently entering legislative review.
- **Entry into Force:** 20 days after publication in the Official Journal of the European Union (OJEU).
- **Staggered Applicability:** Provisions apply at entry into force, 12 months, 3 years, and 5 years post-entry.
- **Immediate Impact:** Notified Bodies expected to voluntarily pilot "Structured Dialogue" mechanisms in 2026.

A. The Simplification Proposal (COM(2025) 1023)

On 16 December 2025, the European Commission published a proposal to amend Regulations (EU) 2017/745 (MDR) and 2017/746 (IVDR), signaling a fundamental shift in how compliance is maintained while preserving public health and patient safety objectives.

Abolishing the Recertification Cliff

The proposal removes the maximum 5-year validity for certificates. Instead of a "hard stop" recertification cycle, Notified Bodies will transition to **"periodic reviews" proportionate to the risk of the device**. This aligns the EU model closer to a continuous surveillance approach, reducing administrative redundancy and capacity-based bottlenecks.

PRRC Deregulation for SMEs

To support small and medium enterprises, the proposal **removes the requirement for the Person Responsible for Regulatory Compliance (PRRC) to be "permanently and continuously available"** when an external consultant is used. This legalizes and simplifies flexible staffing models often used by smaller innovators.

Digitalization Mandate

The amendment explicitly states that the submission of information and documents to Notified Bodies shall take place electronically (MDR: proposed Article 110a; IVDR: proposed Article 103a). This formalizes the move toward paperless technical documentation.

Modernized Clinical Evidence

The proposal fundamentally broadens the evidence framework:

- **Broader "Clinical Data" definition:** A wider range of data may qualify, including published studies that may not be peer-reviewed.
- **Non-Clinical Evidence Acceptance:** Explicit allowance for in vitro, ex vivo, in silico, and modelling/simulation evidence.
- **"Well-Established Technologies" (WET):** A new definition to drive more proportionate requirements.
- **Equivalence Flexibility:** Expanded ability to justify safety/performance based on equivalence.

B. The "3-Round Limit" (MDR Annex VII Revision)

While the legislative proposal simplifies the rules, the draft revision of MDR Annex VII tightens the process for conformity assessment.

Article 3(1)(c): The Mandatory Cap

The draft introduces a mandatory cap on Technical Documentation assessments: **three rounds of interaction** (Round 1 Review -> Applicant Response -> Round 2 Review -> Final Decision).

- **The Old World:** Manufacturers often submitted "draft-quality" files, expecting 4-6 rounds. This created the "endless loop" phenomenon, stretching timelines to 18+ months.
- **The New Competitiveness:** By capping interactions, the EU forces Notified Bodies to be comprehensive in their initial review. For manufacturers with high-quality files, this promises a predictable, finite timeline.
- **The Risk:** The "draft submission" habit is now a **lethal commercial risk**. A submission with major gaps burns one of only three strikes immediately.

"Structured Dialogue" (Round 0): The VIP Lane

- **The Mechanism:** A pre-submission interaction phase that does not count against the review rounds. It allows manufacturers to resolve "showstopper" issues before the official clock starts.
- **Strategic Use:** This is Europe's answer to the FDA Q-Submission (Pre-Sub). It turns the Notified Body from a "grader" into a "stakeholder" in the submission's logic.

C. EUDAMED: The Digital Backbone

Decision (EU) 2025/2371 fixes the mandatory usage of four core modules (Actor Registration, UDI/Devices, Certificates, Market Surveillance) for **28 May 2026**. This creates a single source of truth for the EU market.

3. US REGULATORY LANDSCAPE: The Cyber-Quality Convergence



Figure 5: The US Cyber-Quality Fortress — QMSR transition effective February 2, 2026

If Europe is focused on process, the United States is focused on architecture. December 2025 confirmed that the FDA views the medical device not just as a physical tool, but as a digital node in the healthcare network.

A. The "Cyber Device" Redefined

- **New Scope:** Any device that includes software and can connect to a network (even intermittently, e.g., via USB for service) is captured.
- **The Mandate: "Reasonable Assurance of Cybersecurity"** requires:
  - **SBOM (Software Bill of Materials):** Complete inventory of every software library.
  - **VEX (Vulnerability Exploitability eXchange):** Explaining why bugs do or do not matter.
  - **Patching Plan:** A defined lifecycle process for pushing updates.
- **Business Risk:** FDA Refuse-to-Accept (RTA) policies are increasingly triggering on missing cyber documentation.

B. QMSR: The Global Baseline (Effective February 2026)

- **The Shift:** The QMSR harmonizes 21 CFR Part 820 with ISO 13485:2016, removing specific US barriers that necessitated dual systems.
- **The "Cyber" Integration:** Cybersecurity risks must be treated as "Design Inputs" within the ISO 14971 framework.
- **Enforcement:** FDA inspectors will use ISO 13485 structure, focusing on "Management Responsibility" (Clause 5).

4. GLOBAL SIGNALS & CONVERGENCE

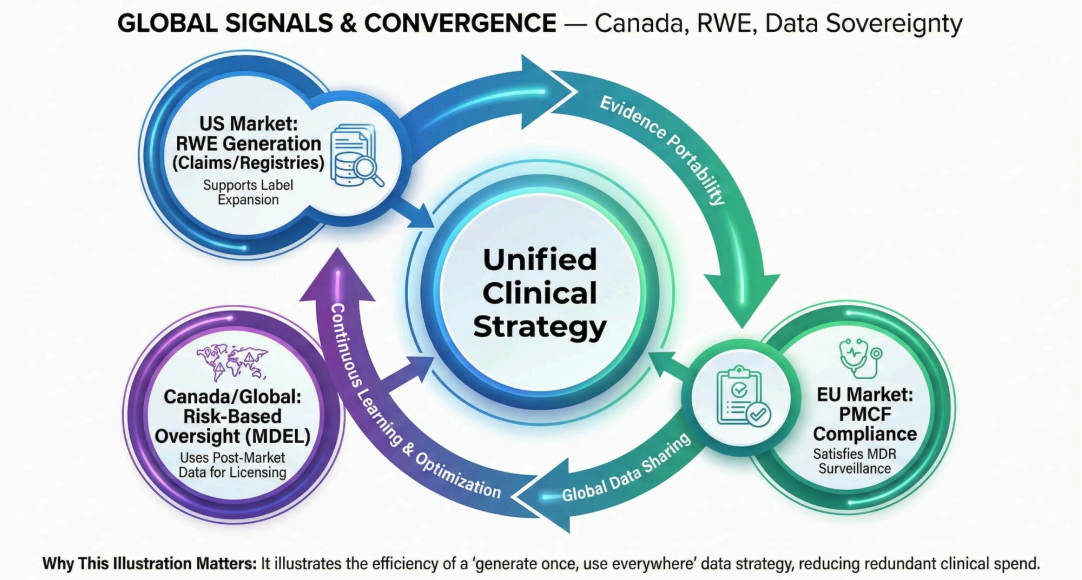


Figure 6: Unified Clinical Strategy — Generate once, use everywhere

Canada's MDEL Modernization

Health Canada's consultation on the Medical Device Establishment Licence (MDEL) framework signals a move toward risk-based oversight. Canada is becoming an increasingly attractive "reference market." An early Canadian approval can generate post-market data needed to support complex EU/US submissions.

Real-World Evidence (RWE) Unlocked

- **Strategy:** Instead of running a new RCT for label expansion, manufacturers can potentially use high-quality registry data.
- **EU Synergy:** A well-designed US RWE study can double as your EU PMCF plan, satisfying both regulators with one dataset.

5. FRONTIER TECHNOLOGY MONITOR

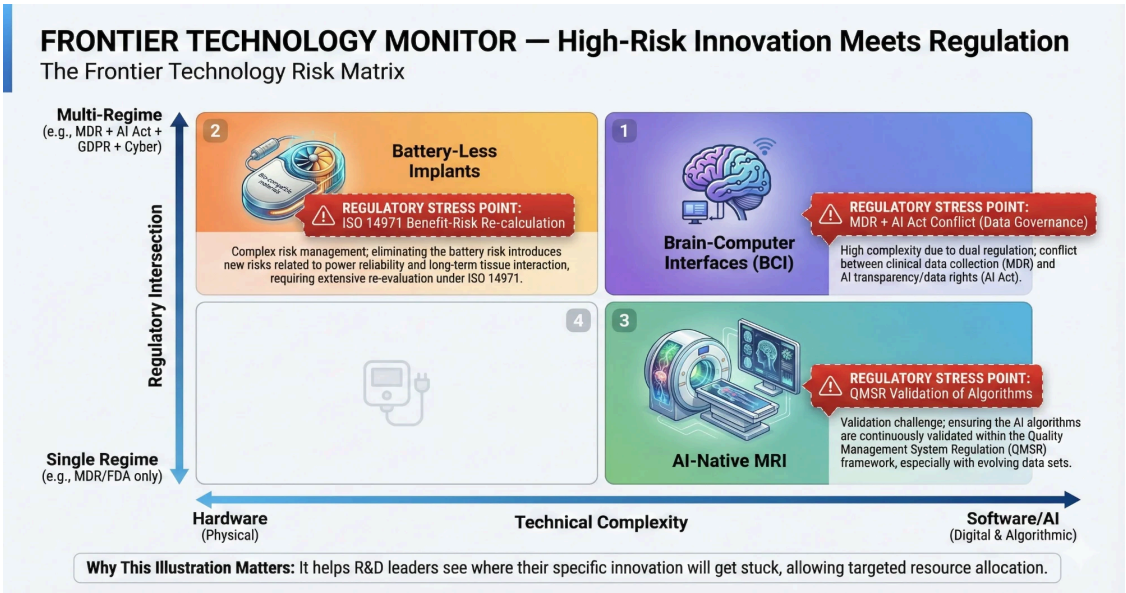


Figure 7: Frontier Technology Risk Matrix — Regulatory intersection vs. technical complexity

A. Brain-Computer Interfaces (BCI): The "Regulatory Lasagna"

- **The Signal:** Paradromics received FDA IDE approval for its Connexus Direct Data Interface, targeting speech restoration with data rates exceeding 200 bits/second.
- **The Regulatory Challenge:** Under EU MDR, a high-bandwidth BCI is subject to both MDR Annex I (benefit-risk) AND AI Act Annex IV (data governance, robustness).
- **The Solution:** Prime candidate for "Structured Dialogue" to agree on a single Technical File structure tracing AI Act requirements into MDR logic.

B. Bio-Powered & Battery-Less Implants

- **The Signal:** The UK-led GLUTRONICS project develops glucose-powered implants. MIT demonstrated injectable antennas harvesting wireless power.
- **The Benefit:** Elimination of battery-replacement surgeries is a massive clinical benefit.
- **The New Hazard:** "Power intermittency" is a novel failure mode requiring updated ISO 10993 Biological Evaluation Plans and risk files defining "safe states."

C. AI-Native Imaging: The Invisible Infrastructure

- **The Signal:** Ultra-low-field MRI systems (like Hyperfine) use AI to generate diagnostic-quality images from noisy raw data.
- **The Regulatory Challenge:** If AI creates the image structure, validation must prove the AI does not "hallucinate" anatomical features.

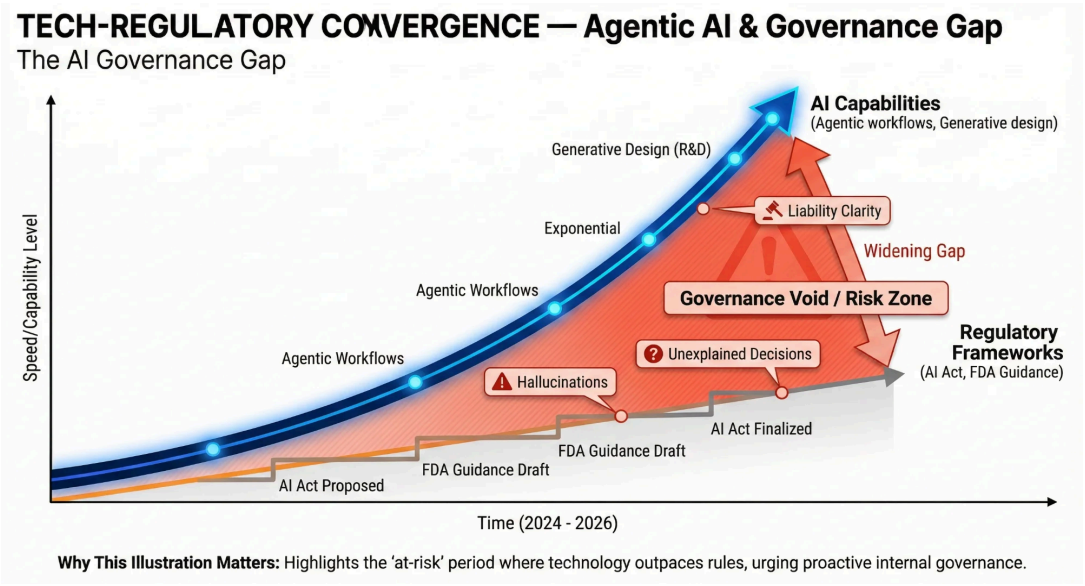


Figure 8: The AI Governance Gap — Technology velocity vs. regulatory framework maturity

6. OPERATIONAL EXCELLENCE TOOLKIT: The "Survival Gap Analysis"

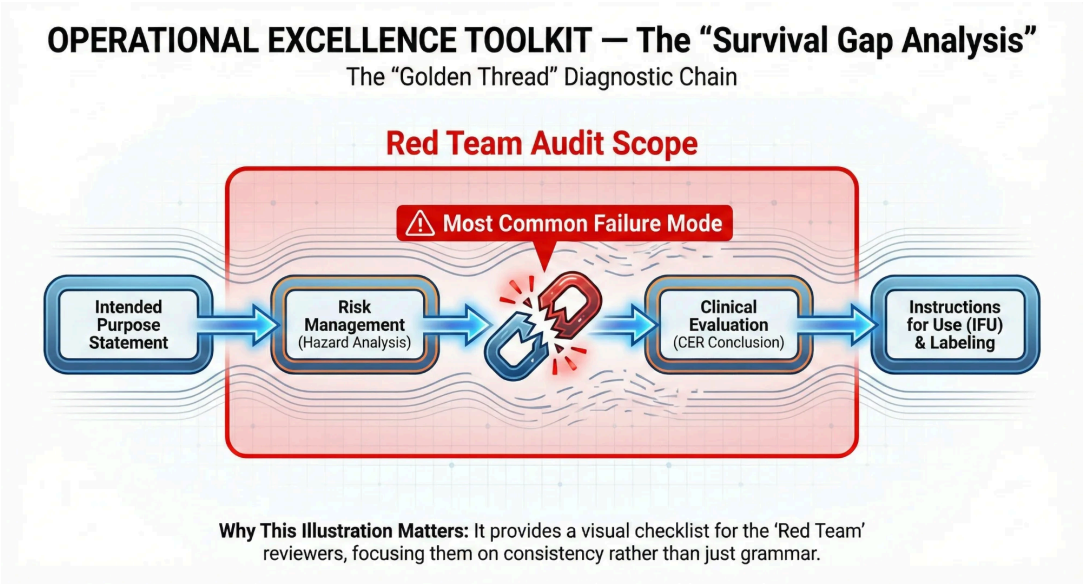


Figure 9: The Golden Thread Diagnostic Chain — Red Team audit scope for consistency checks

With the 3-Round Limit, the "Right First Time" standard is no longer aspirational—it is operational. Below is the **Survival Gap Analysis Checklist** to stress-test files before submission.

I. The "Golden Thread" Check (Coherence)

Check Requirement	Fail Condition (Red Flag)
Intended Purpose Consistency	Text varies between IFU, Risk Management Plan, CER, GSPR Checklist
Device Description Alignment	Components not listed in DoC or Basic UDI-DI data
Version Control	Referenced documents don't match versions in submission
Risk vs. Clinical	Residual risks NOT explicitly evaluated in CER Conclusion

II. The "Evidence" Check (Completeness)

Check Requirement	Fail Condition (Red Flag)
GSPR "N/A" Justification	No specific technical justification provided
Pre-Clinical Testing	Reports not final/signed; protocols without results
Shelf-Life Evidence	Real-time data doesn't cover claimed shelf-life

III. The "Clinical" Check (Sufficiency)

Highest risk for fatal non-compliance that cannot be fixed in 3 rounds.

Check Requirement	Fail Condition (Red Flag)
State of the Art (SOTA)	CER SOTA not updated with literature from last 6-12 months

Check Requirement	Fail Condition (Red Flag)
Equivalence (Class III)	No signed contract for full access to technical data (Art. 61(5))
PMCF Plan Specificity	Vague promises to "monitor complaints" without sample sizes/timelines

Operational Execution Protocols

1. The "Red Team" Review Strategy

- **The Rule:** Do not let the author of the Technical File review it.
- **The Action:** Assign a "Red Team" (senior engineer or external consultant) to act as the Notified Body.
- **The Metric:** If the Red Team finds a gap, the NB definitely will.

2. The "Data Freeze" Discipline

- **The Rule:** Last-minute tweaks break the "Golden Thread."
- **The Action:** Implement a strict 30-day freeze on technical documentation before submission.

7. STRATEGIC EXECUTIVE ACTIONS: 2026 Readiness



Figure 10: The 2026 Executive Decision Matrix — Prioritizing actions by urgency and impact

As we close 2025, the mandate for leadership is to pivot from "reacting to regulation" to "designing for it."

For European Leaders (EU)

1. **Mandate "Structured Dialogue" (Round 0):** For every Class III or novel device, explicitly request a pre-submission meeting.
2. **Institutionalize the "Survival Gap Analysis":** Embed the checklist into your QMS as a mandatory gate.
3. **Industrialize EUDAMED:** Ensure UDI and registration data is validated and uploaded by Q1 2026.
4. **Audit PRRC Arrangements:** Update agreements to reflect the removed "permanently available" clause for SMEs.
5. **Stress-Test Cybersecurity Reporting:** Align vigilance processes with CSIRTs/ENISA pathways via EUDAMED.

For US/Global Leaders (USA)

1. **Retrospective "Cyber-Audit":** Screen legacy portfolio against December 2025 "Cyber Device" guidance. Initiate SBOM remediation now.
2. **Harmonize AI Governance:** Create a single AI Risk Management policy satisfying both US QMSR and EU AI Act.
3. **Leverage RWE for Growth:** Identify one "label expansion" opportunity for 2026 supported by Real-World Evidence.

ANNEX A: MARKET INTELLIGENCE SPOTLIGHT — MEDICA 2025

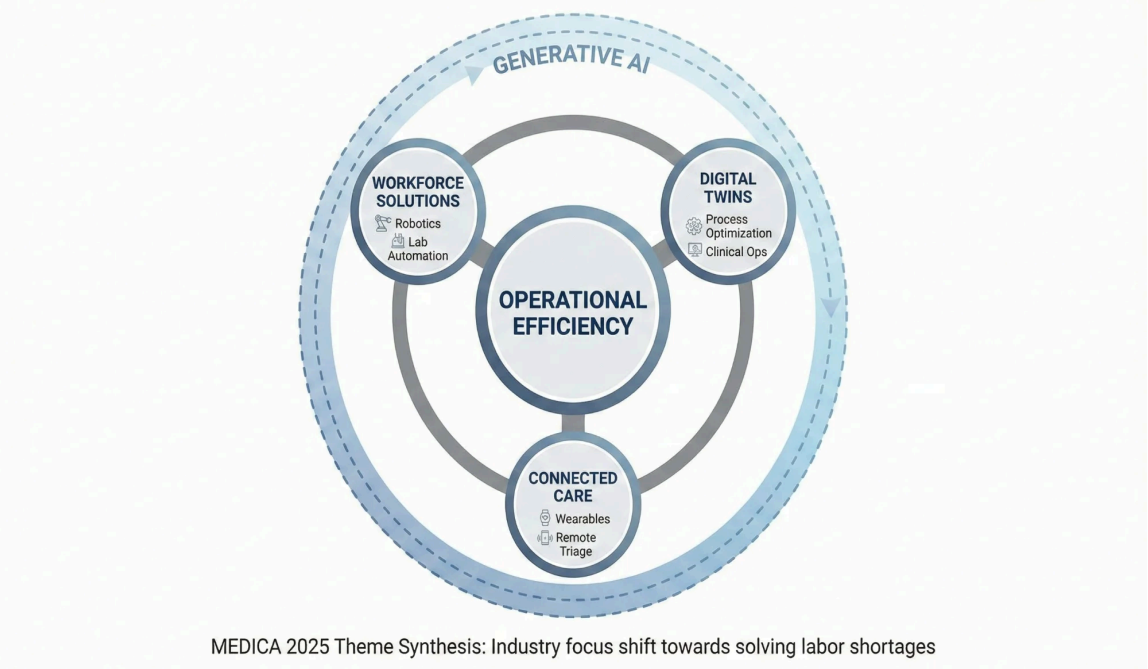


Figure 11: MEDICA 2025 Theme Synthesis — Industry focus shift toward solving labor shortages

Dates: 17-20 November 2025 | **Location:** Dusseldorf, Germany

Over 5,300 exhibitors from 70 nations, with a distinct shift from "hardware" to "process intelligence."

Core Themes & Technologies

- **The "Digital Twin" Era:** Virtual patient models for pre-surgical planning and hospital workflow optimization.
- **Generative AI & Robotics:** Focus moved to logistics and lab automation as a response to the healthcare workforce crisis.
- **Connected Care & Wearables:** "24/7 sensor data" integration. Focus on adhesion technology and continuous monitoring.

Strategic Takeaways

- **Workforce Solutions are King:** Technologies reducing staffing burdens attracted the most attention.
- **Regulatory Independence:** Start-Up Competition explicitly stated MDR/FDA compliance was not a prerequisite, signaling appetite for disruptive concepts.

ANNEX B: CORPORATE SPOTLIGHT — MEDACTA INTERNATIONAL

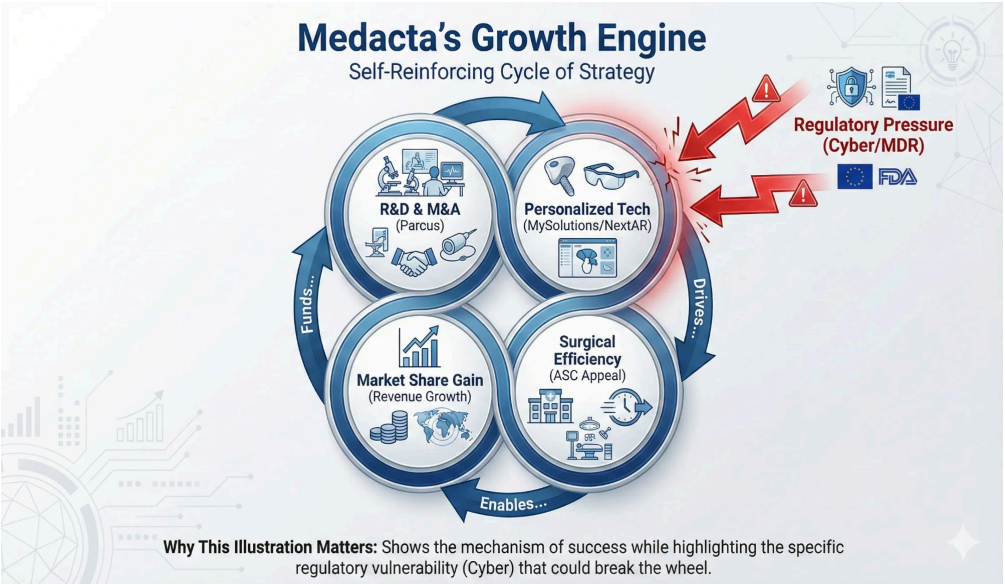


Figure 12: Medacta's Growth Engine — With regulatory pressure (Cyber/MDR) as the key vulnerability

Focus: 2025 Performance & Strategic Portfolio | **Status:** High-Growth "Challenger" in Orthopedics & Spine

Financial & Operational Performance (2025)

- **Revenue Surge:** H1 2025 revenue growth of 19.8% (constant currency), outperforming the broader orthopedic market.
- **Profitability:** Adjusted EBITDA margin of 29.6%.
- **Workforce Expansion:** Added over 130 employees in H1 2025, reaching 2,000+ global headcount.

Technology & Portfolio Milestones

- **Kinematic Alignment Dominance:** 10-year anniversary. GMK SpheriKA rollout continued with SensiTiN coating.
- **NextAR Rod Optimizer:** 2024 Spine Technology Award winner. AR tool eliminating manual rod-bending.
- **Sports Medicine Expansion:** Parcus Medical acquisition (March 2025) integrated full sports medicine portfolio.

Strategic "Watch" Item

MySolutions Ecosystem: Medacta's competitive moat (3D planning, patient-matched guides). Integration of cloud-based planning tools into hospital IT systems will test their "Cyber-Device" compliance posture.

APPENDIX C: REGULATORY REFERENCE TRACKER

This appendix provides source references for audit traceability.

Reference	Description / Status
COM(2025) 1023	Commission Proposal to amend MDR 2017/745 and IVDR 2017/746 (Simplification Package). Published 16 December 2025.
Decision (EU) 2025/2371	EUDAMED mandatory usage decision. Four core modules mandatory from 28 May 2026.
MDR Annex VII Revision (Draft)	Proposed 3-Round Limit (Art. 3(1)(c)) and Structured Dialogue. Est. entry Q4 2026 / Q1 2027.
FDA QMSR	Quality Management System Regulation. Harmonizes 21 CFR Part 820 with ISO 13485:2016. Effective February 2, 2026.
FDA Cyber Device Guidance	Expanded "Cyber Device" definition. Requires SBOM, VEX, and Patching Plan.
EU AI Act (2024/1689)	Regulation on artificial intelligence. COM(2025) 1023 limits AI Act application per Art. 2(2).

--- End of Report ---

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