

GLOBAL REGULATORY, QUALITY & TECH INTELLIGENCE REPORT

January 2026 Edition

Theme: The "Regulatory Reckoning" Era & Lifecycle Evidence Paradigm

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EXECUTIVE SUMMARY

January 2026 marks a decisive pivot in global medical device regulation. The EU is shifting from "certification treadmill" compliance to lifecycle-based evidence governance.¹ The US is completing its ISO 13485 harmonization through the QMSR.⁵ The theme for 2026: "Regulatory Reckoning."

The era of passive monitoring has ended. Quality and Regulatory functions must now operate as strategic engineering disciplines leveraging data governance to ensure market access and patient safety.

1. EXECUTIVE STRATEGY: The Regulatory Reckoning

The medical device and in vitro diagnostic (IVD) sectors have entered a period of unprecedented structural transformation as of January 2026. This "Regulatory Reckoning" is characterized by a global pivot toward lifecycle-based evidence, digitalized governance, and the integration of emerging artificial intelligence frameworks.'

In the European Union, the long-awaited targeted revision of the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR), formalized in the European Commission's proposal COM(2025) 1023³, signals a move away from the "certification treadmill" toward a more sustainable, risk-based surveillance model. Concurrently, the United States is finalizing its transition to the Quality Management System Regulation (QMSR), effective February 2, 2026, which formally aligns 21 CFR Part 820 with ISO 13485:2016.⁴

This intelligence report analyzes the convergence of these high-impact developments, identifying real-world evidence (RWE) and post-market surveillance (PMS) data as the new "regulatory currency". While legislative easing offers a potential €3.3 billion in annual sector savings⁵, the operational reality remains complex, with EUDAMED modules becoming mandatory in May 2026^{6,7} and the EU AI Act (Regulation 2024/1689) requiring immediate cessation of prohibited practices.'

2. EUROPEAN REGULATORY LANDSCAPE

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.
- **EUDAMED Mandatory:** Four core modules mandatory from May 28, 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.^{2,3,4}

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.^{10,11} This aligns the EU model closer to a continuous surveillance approach, reducing administrative redundancy and capacity-based bottlenecks.

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.

Table: COM(2025) 1023 Proposed Changes and Impact on SMEs

Feature	Current MDR/IVDR	Proposed Revision	Impact on SMEs
Certificate Validity	Fixed 5-year maximum	Indefinite with risk-based reviews	Significant reduction in administrative overhead
PRRC Requirements	Permanent and continuous availability	Removal of detailed qualifications; "available" status for SMEs	Lower organizational barrier

Fee Reductions	Discretionary by Notified Body	Mandatory 50% for micro, 25% for small enterprises	Direct improvement in profitability
Auditing Frequency	Annual mandatory audits	Biennial or risk-based/remote audits	Reduced operational disruption
SSCP Scope	Broad application to many devices	Narrowed to devices requiring TD assessment	Streamlined transparency reporting

B. 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. For manufacturers, this is no longer an IT project but a core compliance pillar; failure to obtain a Single Registration Number (SRN) or populate the UDI database will result in immediate market access being blocked.

C. AI Act Integration

The EU AI Act (Regulation 2024/1689), which began its phased application in February 2025, now requires the cessation of prohibited practices and the initiation of AI literacy obligations for all providers and deployers. However, recognizing the potential for regulatory overlap, the Commission's late 2025 proposal recalibrates the intersection of the AI Act and MDR/IVDR. High-risk AI requirements for medical devices are now delayed until August 2028 (at the latest), with the compliance assessment formalized as "one device, one assessment" through the existing MDR/IVDR Notified Body infrastructure.

Table: Digital/Data Compliance Deadlines

Deadline	Requirement	Target Organization	Mandatory Action
Ongoing (Feb 2025)	EU AI Act Prohibitions	All AI device providers	Cease manipulative/deceptive AI practices
May 28, 2026	EUDAMED Core Modules	All EU Economic Operators	Obtain SRN; register all MDR/IVDR devices
July 1, 2026	Swissdamed UDI Module	All CH Economic Operators	Mandatory registration for devices in Switzerland
Nov 27, 2026	EUDAMED Legacy Devices	Legacy (MDD/IVDD) makers	Back-entry of devices already on market
Late 2026	EU Cyber Resilience Act	Connected device makers	Mandatory vulnerability reporting begins

3. US REGULATORY LANDSCAPE: The QMSR Convergence

If Europe is focused on process simplification, the United States is focused on quality system architecture. January 2026 represents the final month of the two-year transition period to the Quality Management System Regulation (QMSR).

A. QMSR: The Global Baseline (Effective February 2, 2026)

This shift, effective February 2, 2026, completes the alignment of 21 CFR Part 820 with ISO 13485:2016, a move intended to foster global regulatory convergence and allow manufacturers to leverage single audits through the Medical Device Single Audit Program (MDSAP) to satisfy multiple jurisdictions simultaneously.

- **The Shift:** The QMSR harmonizes 21 CFR Part 820 with ISO 13485:2016, removing specific US barriers that necessitated dual systems.^{13,14}
- **Risk-Based Approach:** Manufacturers must explicitly document the overarching risk strategy used in developing their QMS.¹⁵
- **Enforcement:** FDA inspectors will use ISO 13485 structure, focusing on "Management Responsibility" (Clause 5).^{16,17}

Table: QMSR Transformation Elements

Element	Legacy QSR (Pre-2026)	New QMSR (Feb 2, 2026)	Executive Action Required
Foundation	21 CFR Part 820 (US-specific)	ISO 13485:2016 by reference	Update Quality Manual and SOP references
Risk Focus	Product-focused risk management	Process-focused risk-based approach (RBA)	Document how risk drives QMS decisions
Design Control	Independent reviewer requirement	Alignment with ISO 13485 design stages	Re-evaluate independent reviewer necessity
Supplier Quality	General purchasing controls	Risk-proportionate supplier evaluation	Classify suppliers by risk; update criteria
Records	DHF, DMR, DHR focus	Medical Device File (MDF) requirements	Map legacy files to MDF structure

B. The RWE Evidence Engine

The FDA's December 2025 Real-World Evidence (RWE) guidance signals a shift toward accepting Real-World Data (RWD) from registries, EHRs, and medical claims as valid scientific evidence for regulatory decision-making.^{19,20,21} This shift allows RWE to be used as a "historical control" or informative prior in Bayesian analyses, potentially reducing the sample size needed for traditional clinical trials.

Table: RWE Regulatory Use Cases

RWE Use Case	Application Area	Data Source Examples	Regulatory Benefit
Marketing Authorization	510(k), PMA, De Novo	Registries, medical claims	Efficient generation of clinical evidence
Labeling Expansion	New indications for use	EHRs, patient-generated data	Lower barrier for expanding product reach
Post-Approval Studies	Mandated conditions of approval	Continuous surveillance studies	Timely completion of post-market commitments
Signal Refinement	Post-market safety monitoring	MAUDE database, EHR analysis	Informed corrective actions and communications
EUA Support	Emergency Use Authorizations	Routinely collected clinical use data	Accelerated pathway for emergency tools

4. GLOBAL SIGNALS & CONVERGENCE

Quality-as-Engineering Paradigm

A subtle but structural transition is occurring in early 2026: post-market surveillance (PMS) and real-world evidence (RWE) are replacing clinical trials as the dominant evidence engine for medical devices. The European Medical Device Coordination Group (MDCG) guidance 2025-10, published in December 2025^{29,30,31}, clarifies that PMS is not a "checkmark" activity but a continuous, proactive process that must begin during the design phase.

Global Data Sovereignty

For organizations, the 2026 paradigm is one of "Data Sovereignty," where the accuracy and consistency of UDI data across EUDAMED, GUDID, ERP systems, and labeling determine the speed of export and the precision of field safety corrective actions.^{22,23,24} The UK is also contributing to this global data governance shift with the MHRA's 2026 fee overhaul, which funds enhanced post-market monitoring through a new annual recurring charge based on GMDN categories.

5. FRONTIER TECHNOLOGY MONITOR

This section tracks emerging technology signals with potential regulatory and strategic implications for medical device and life sciences organizations. Each signal is anchored to verifiable January 2026 developments and assessed for time-to-impact horizon.

A. Regulatory-Enabled Digital Health Infrastructures (TEMPO)

- **The Signal:** FDA's TEMPO (Technology-Enabled Meaningful Patient Outcomes) pilot formally opens to manufacturers in January 2026, representing a first-of-its-kind, outcomes-focused regulatory model for digital health devices.^{53,54}
- **Risk/Opportunity:** Organizations without robust outcomes-capture infrastructure risk competitive disadvantage in chronic-care software markets.
- **Horizon:** 0–2 years operational

B. Agentic AI and Clinical Copilots

- **The Signal:** January 2026 industry analyses highlight rapid emergence of AI agents in healthcare capable of autonomously planning and executing multistep tasks—summarizing charts, coordinating referrals, optimizing schedules.
- **Risk/Opportunity:** Near-term automation will pressure organizations to urgently define governance, liability, and validation frameworks for agentic AI.
- **Horizon:** 0–2 years operational (documentation); 3–5 years strategic (continuous-care integration)

C. AI-Accelerated Diagnostics and Imaging

- **The Signal:** January 2026 analyses document accelerating deployment of AI for radiology, cardiology, and stroke workflows, with tools transitioning from pilot to routine clinical use.
- **Risk/Opportunity:** More devices are falling under AI-specific conformity assessment and PMS expectations, requiring continuous performance monitoring infrastructure.
- **Horizon:** 0–2 years operational

D. Next-Generation Therapeutic Platforms

- **The Signal:** Global vaccine experts emphasize the maturing of mRNA, self-amplifying RNA, and new vector platforms, with active pipelines for HIV, TB, and pan-coronavirus candidates.
- **Risk/Opportunity:** Expansion of RNA-based technologies will generate knock-on implications for cold-chain logistics, pharmacovigilance systems, and combination-product regulation.
- **Horizon:** 3–5 years strategic

6. OPERATIONAL EXCELLENCE TOOLKIT: Quality Management & PMS

Quality Management Standards Evolution

The technical methodology for managing device data is undergoing a paradigm shift as the industry moves toward standardized data modeling for technical documentation (TD). January 2026 marks the publication of a draft international standard (ISO/DIS 18969) for clinical evaluation, which codifies the structured process for ongoing assessment of clinical data against the current state-of-the-art.

Table: QMS Technical Framework Evolution

Standard/Framework	Current Status (Jan 2026)	Key Technical Change	RA/QA Impact
ISO 13485:2016	Global quality baseline	Integrated into US QMSR	Single global QMS achievable
ISO/DIS 18969	Draft international standard	Codified clinical evaluation process	Structured SOTA assessments
DIN SPEC 91509	Active in EU market	Standardized TD data model	Improved NB data exchange
MDCG 2025-10	Published Dec 2025	PMS-QMS-RM integration requirements	Proactive surveillance mandate
ISO 14971:2019	Risk management baseline	Lifecycle risk integration	RBA summary requirement for QMSR

Post-Market Surveillance Methodologies

The technical execution of post-market surveillance (PMS) is no longer a peripheral quality task but a data-intensive engineering discipline. MDCG 2025-10 provides the regulatory roadmap, emphasizing that a robust PMS system must be integrated into the organization's QMS and linked bidirectionally to risk management (ISO 14971) and clinical evaluation.

Table: Proactive Data Collection Matrix (Per ISO/TR 20416)

Methodology	Data Source	Information Output	Lifecycle Contribution
Proactive	Surveys / Questionnaires	Degree of user satisfaction; usability	Input for iterative design improvements
Proactive	Literature Search	Evolution of the "state of the art"	Identifying if similar devices face new risks
Proactive	Device Registries	Long-term performance and survival rates	Real-world evidence for labeling expansion

Proactive	PMCF Studies	Long-term safety and clinical benefit data	Closure of clinical evidence gaps
Reactive	Service / Maintenance	Reliability indicators; failure modes	Re-evaluation of maintenance schedules
Reactive	Regulatory Notices	Recalls of similar devices in other markets	Prioritizing identified risks in internal files

7. STRATEGIC EXECUTIVE ACTIONS: 2026 Readiness

The start of 2026 confirms that the medical technology industry has shifted from a state of regulatory compliance to a state of regulatory strategy. The mandate for leadership is to pivot from "reacting to regulation" to "designing for it."

For European Leaders (EU)

1. **Mandate EUDAMED "M2M" Readiness by May 28, 2026:** Ensure internal ERP and PLM systems are technically ready for machine-to-machine (M2M) integration via XML uploads.
2. **Audit Product Portfolios Against "WET" and "Orphan" Criteria:** Identify products that qualify for "Well-Established Technology" status or orphan device pathways.
3. **Execute Immediate Gap Analysis for MDCG 2025-10:** Review all PMS plans to include proactive data sources and clear thresholds for benefit-risk reassessment.

For US/Global Leaders (USA)

1. **Conduct Final QMSR Simulation Before Feb 2, 2026:** Final pre-deadline internal audit focusing on Risk-Based Approach (RBA) summary and evidence of risk integration.
2. **Institutionalize RWE as a Core Evidence Pillar:** Integrate Real-World Evidence protocols into all lifecycle management strategies.
3. **Optimize UK and Global Portfolio Registrations:** Audit UK registrations before April 1, 2026 MHRA fee snapshot to ensure GMDN classifications are accurate.

ANNEX A: EUROPEAN INDUSTRY NEWS — JANUARY 2026

- **Targeted MDR/IVDR Revision Proposal (COM(2025) 1023):** European Commission officially proposed amendments on December 16, 2025, aimed at streamlining MDR/IVDR and reducing administrative burden by over €3 billion annually.^{2,3,4}
- **EUDAMED Functionality Notice Published:** Decision (EU) 2025/2371, published November 27, 2025, confirmed full functionality of first four EUDAMED modules, starting six-month countdown to mandatory use on May 28, 2026.^{23,24,25}
- **MDCG Breakthrough Device (BtX) Guidance:** MDCG 2025-9 issued in December 2025, establishing formal designation process for highly novel devices with significant positive clinical impact.^{41,42}
- **Joint Clinical Assessment (JCA) Framework Finalized:** Adoption of Implementing Regulation (EU) 2025/2086 completed legal structure for joint clinical assessment under HTA Regulation.⁴³
- **MDCG 2025-10 PMS Guidance:** Comprehensive roadmap released late December 2025, detailing expectations for system integration, proactive data collection, and benefit-risk reassessment indicators.^{30,31,32}
- **Swissdamed Mandatory Use Date Set:** Switzerland announced mandatory device registration in Swissdamed UDI module begins July 1, 2026.
- **EU AI Act Prohibitions Take Effect:** As of February 2, 2025, prohibitions on unacceptable-risk AI practices fully applicable, with fines up to €35 million.^{8,26,27}
- **Packaging Regulation (PPWR) 2025/40 Adoption:** Published January 22, 2025, introducing recyclability and minimization requirements with sector-specific exemptions for medical grade materials.^{46,47}

ANNEX B: AMERICAN INDUSTRY NEWS — JANUARY 2026

- **Final Countdown to QMSR (Feb 2, 2026):** FDA in final phase of implementing the Quality Management System Regulation, incorporating ISO 13485:2016 by reference into 21 CFR Part 820.^{5,6,13}
- **Revised Clinical Decision Support (CDS) Software Guidance:** FDA Commissioner Makary announced updated guidance on January 6, 2026, expanding enforcement discretion for software providing a single clinically appropriate recommendation.^{51,52}
- **General Wellness Guidance Update:** Revised guidance expands scope of wellness products to include non-invasive wearables estimating physiologic parameters.^{19,20}
- **Final Guidance on Real-World Evidence (RWE) for Devices:** Issued December 18, 2025, providing updated recommendations on assessing RWD relevance and reliability.¹⁹
- **TEMPO Digital Health Pilot Launch:** FDA began seeking statements of interest for the TEMPO pilot, a risk-based enforcement approach for digital technologies treating chronic conditions.⁵³
- **Abbott FreeStyle Libre 3 Correction Alert:** FDA issued Early Alert on December 2, 2025, warning of inaccurate low glucose readings in 3 million Abbott CGM sensors.^{37,38}
- **Dexcom G6 App Software Correction:** Federal regulators issued Class I correction for version 1.15.0 of Dexcom G6 Android app due to unexpected shutdown defect.³⁹
- **Cell and Gene Therapy (CGT) Flexibility:** FDA announced flexible approach to CMC requirements for CGTs on January 11, 2026, to expedite development for serious conditions.⁵⁵

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.
FDA QMSR	Quality Management System Regulation. Harmonizes 21 CFR Part 820 with ISO 13485:2016. Effective February 2, 2026.
EU AI Act (2024/1689)	Regulation on artificial intelligence. Prohibitions effective Feb 2025. High-risk device requirements delayed to Aug 2028.
MDCG 2025-9	Breakthrough Device (BtX) designation guidance. Published December 2025.
MDCG 2025-10	Comprehensive Post-Market Surveillance guidance. Published December 2025.
ISO/DIS 18969	Draft international standard for clinical evaluation. Under development January 2026.
FDA RWE Guidance	Real-World Evidence guidance for devices. Issued December 18, 2025.

ANNEX D: CORPORATE SPOTLIGHT — CHATGPT HEALTH

Focus: AI-Enabled Health Platform Launch (January 2026) | **Status:** High-Impact "Watch" Item for AI-Health Regulatory Convergence

OpenAI officially launched ChatGPT Health on 7 January 2026 as a dedicated health-focused space within the broader ChatGPT platform, enabling users to connect personal medical records and wellness data for contextualized AI responses.

ChatGPT Health—style functionality sits at the intersection of medical, data-protection, and AI-specific law, creating both strong opportunities and non-trivial compliance risks in the EU and the USA. The inclusion of ChatGPT Health in this January 2026 regulatory vigilance report reflects both the novelty of its formal entry into the healthcare domain and the speed with which regulators and market actors are grappling with hybrid AI-health products.

Opportunity Landscape

Generative models integrated with electronic health records (EHRs), patient portals, and wellness applications can provide patients with longitudinal, comprehensible views of their health data, translating laboratory results, medication lists, and lifestyle metrics into plain-language explanations that support shared decision-making and treatment adherence.

- **EU Compliance Asset:** An AI assistant designed from the outset as "high-risk AI" under the EU AI Act, with structured risk management, data governance, robustness, cybersecurity, transparency, and human-oversight controls, can become a reusable compliance asset across multiple clinical use cases.
- **GDPR-AI Act Alignment:** The combination of AI Act obligations with GDPR requirements—DPIAs, legal basis for processing, data-subject rights, and purpose limitation—creates a clearer governance framework for profiling, secondary use, and cross-border processing of health data.
- **US HIPAA Architecture:** OpenAI-type healthcare offerings are positioned as supporting HIPAA-compliant operational environments through segregated data processing, access controls, audit trails, and purpose-built encryption.

Risk and Regulatory Constraints

A GPT-based health feature that connects directly to medical records or whose outputs can reasonably be expected to influence diagnosis, triage, or treatment decisions will, in most cases, fall into the high-risk category under the EU AI Act. This classification triggers full lifecycle obligations.

- **MDR/IVDR Overlay:** Where the system performs medical-device-like functions—such as clinical decision support, risk stratification, or treatment guidance—manufacturers must still comply with MDR or IVDR requirements. AI Act obligations must be demonstrated within the same technical documentation, not in parallel regulatory files.

- **GDPR Data Governance:** Any reuse of interaction logs or connected EHR data for model training, tuning, or performance monitoring is particularly sensitive. AI-specific impact assessments must build upon—not bypass—GDPR DPIAs.
- **FDA SaMD Expectations:** In the US, adaptive or learning models that affect diagnosis or treatment increasingly fall under FDA's AI-enabled SaMD lifecycle expectations, including training-data transparency, predetermined change-control plans, and risk-based performance monitoring.
- **Cross-Border Segmentation:** A single GPT Health product serving both EU and US users must segment infrastructure, data flows, consent mechanisms, logging practices, and model-update pathways so that no region's data is silently repurposed or transferred.

Strategic "Watch" Item

ChatGPT Health represents a bellwether for how large platform providers will navigate the convergence of AI Act, MDR/IVDR, GDPR, and HIPAA obligations. Its integration of personal health records with generative AI creates a regulatory test case that will inform guidance development and enforcement priorities throughout 2026. Organizations developing similar AI-health products should monitor OpenAI's conformity assessment approach and any regulatory feedback as leading indicators for the sector.

APPENDIX E: SOURCES AND CITATIONS

This appendix provides complete source references for audit traceability and verification.

1. EMD-Mag-Issue-3-Jan-Feb-2026-Final.pdf
2. European Commission - EUR-Lex.
<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52025PC1023>
3. European Commission Issues Proposal to Simplify Medical Devices Regulations - Morgan Lewis.
<https://www.morganlewis.com/blogs/asprescribed/2025/12/european-commission-issues-proposal-to-simplify-medical-devices-regulations>
4. EU Commission proposes major reforms to MDR - RAPS.
<https://www.raps.org/news-and-articles/news-articles/2025/12/eu-commission-proposes-major-reforms-to-mdr>
5. Top Medical Device Regulations to Watch in 2026 - Xtalks.
<https://xtalks.com/top-medical-device-regulations-to-watch-in-2026-4549/>
6. Overview of the FDA's new Quality Management System Regulation - ECA Academy.
<https://www.gmp-compliance.org/gmp-news/overview-of-the-fdas-new-quality-management-system-regulation-effective-from-2-february-2026>
7. EUDAMED: gradual implementation confirmed - FAMHP.
https://www.famhp.be/en/news/eudamed_gradual_implementation_confirmed
8. First Milestone in the Implementation of the EU AI Act - Alston Privacy.
<https://www.alstonprivacy.com/first-milestone-in-the-implementation-of-the-eu-ai-act/>
9. COM(2025) 1023 final - European Parliament.
[https://www.europarl.europa.eu/RegData/docs_autres_institutions/commission_europeenne/com/2025/1023/COM_COM\(2025\)1023_EN.pdf](https://www.europarl.europa.eu/RegData/docs_autres_institutions/commission_europeenne/com/2025/1023/COM_COM(2025)1023_EN.pdf)
10. The EU's 2025 proposal to simplify MDR/IVDR - Baker McKenzie.
<https://healthcarelifesciences.bakermckenzie.com/2025/12/19/the-eus-2025-proposal-to-simplify-the-medical-and-in-vitro-diagnostic-devices-regulations-mdr-ivdr/>
11. EU officials detail proposed MDR, IVDR revisions - RAPS.
<https://www.raps.org/news-and-articles/news-articles/2026/1/eu-officials-detail-proposed-mdr-ivdr-revisions>
12. EU Commission Proposes Reform of the Medical and In Vitro Device Regulations - MHC.
<https://www.mhc.ie/latest/insights/eu-commission-proposes-reform-of-the-medical-devices-regulation>
13. Countdown to February 2026: FDA's New QMSR and ISO 13485 Alignment - TÜV SÜD.
<https://www.tuvsud.com/en-us/resource-centre/webinar/fdas-new-qmsr-and-iso-13485-alignment>
14. FDA Issues First Draft Guidance in the Countdown to QMSR - FDA Law Blog.
<https://www.thefdalawblog.com/2025/11/fda-issues-first-draft-guidance-in-the-countdown-to-qmsr/>
15. FDA QMSR Inspection Readiness for 2026 and Beyond - QT9 Software.
<https://qt9software.com/blog/fda-qmsr-2026-inspections>
16. FDA readies for QMSR implementation with draft QMS information guidance - Hogan Lovells.
<https://www.hoganlovells.com/en/publications/fda-readies-for-qmsr-implementation-with-draft-qms-information>
17. Major Shift for QMSR Transition for Medical Device Applications - Alston & Bird.
<https://www.alston.com/en/insights/publications/2025/11/fda-shift-qmsr-transition-medical-devices>
18. Readiness Checklist: Preparing for FDA's 2026 QMSR - Veranex.
<https://veranex.com/blog/readiness-checklist-preparing-for-fdas-2026-qmsr>
19. FDA Adapts with the Times on Digital Health - Ropes & Gray.
<https://www.ropesgray.com/en/insights/alerts/2026/01/fda-adapts-with-the-times-on-digital-health-updated-guidances-on-general-wellness-products>
20. FDA guidance eases wearables oversight - MedTech Dive.
<https://www.medtechdive.com/news/fda-guidance-eases-wearables-oversight-but-experts-have-questions-about-wh/810581/>
21. FDA Issues Updated Guidance Loosening Regulatory Approach to Certain Digital Health Tools - Latham & Watkins.
<https://www.lw.com/en/insights/fda-issues-updated-guidance-loosening-regulatory-approach-to-certain-digital-health-tools>

22. EUDAMED: 1st four fully functional modules - GMED.
<https://lne-gmed.com/news/eudamed-1st-four-fully-functional-modules>
23. The EUDAMED four first modules will be mandatory to use as from 28 May 2026 - European Commission.
https://health.ec.europa.eu/latest-updates/eudamed-four-first-modules-will-be-mandatory-use-28-may-2026-2025-11-27_en
24. EUDAMED Mandatory from May 2026: Key MDR & IVDR Deadlines - Obelis Group.
<https://www.obelis.net/news/eudamed-becomes-mandatory-on-28-may-2026-deadlines-for-actor-device-and-certificate-registrations/>
25. Date Set for Mandatory Application of European Database on Medical Devices - Morgan Lewis.
<https://www.morganlewis.com/blogs/asprescribed/2025/12/date-set-for-mandatory-application-of-european-database-on-medical-devices>
26. EU and Luxembourg Update on the European Harmonised Rules on AI - K&L Gates.
<https://www.klgates.com/EU-and-Luxembourg-Update-on-the-European-Harmonised-Rules-on-Artificial-IntelligenceRecent-Developments-1-20-2026>
27. EU AI Act - Updates, Compliance, Training. <https://www.artificial-intelligence-act.com/>
28. Health-ISAC Hacking Healthcare 1-26-2026. <https://health-isac.org/health-isac-hacking-healthcare-1-26-2026/>
29. MDCG outlines postmarket surveillance expectations under MDR/IVDR - RAPS.
<https://www.raps.org/news-and-articles/news-articles/2026/1/mdcg-outlines-postmarket-surveillance-expectations>
30. MDCG 2025-10 Guidance on post-market surveillance - European Commission.
https://health.ec.europa.eu/document/download/a9ad86b7-1b8e-4bae-beb4-48b2b3ed2f05_en?filename=mdcg_2025-10_en.pdf
31. MDCG publishes new guideline on post-market surveillance - SCC Regulatory Services.
<https://scc-medical-devices.com/mdcg-publishes-new-guideline-on-post-market-surveillance/>
32. MDCG 2025-10: New MDR/IVDR Guidance on PMS - Casus Consulting.
<https://casusconsulting.com/mdcg-2025-10-new-mdr-ivdr-guidance-on-post-market-surveillance-pms/>
33. MDCG 2025-10: Guidance on post-market surveillance - LNE-GMED.
<https://lne-gmed.com/news/mdcg-2025-10-guidance-on-pms>
34. EU Publishes MDCG Guidance on Post-Market Surveillance - MedEnvoy.
<https://medenvoyglobal.com/blog/eu-publishes-mdcg-guidance-on-post-market-surveillance/>
35. Clinical Evaluation - ISO 18969: What's Actually Changing - CENIT Consulting.
<https://cenitconsulting.com/iso-18969/>
36. ISO 18969 Clinical Evaluation: Key Changes to Know - Chemsafe Consulting.
<https://www.chemsafe-consulting.com/2026/01/20/iso-dis-18969-clinical-evaluation/>
37. Abbott issues correction for millions of glucose sensors - MedTech Dive.
<https://www.medtechdive.com/news/abbott-libre-3-correction-accuracy/806345/>
38. Early Alert: Glucose Monitor Sensor Issue from Abbott Diabetes Care - FDA.
<https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/early-alert-glucose-monitor-sensor-issue-abbott-diabetes-care>
39. FDA Flags Serious Software Issue in Dexcom Glucose Monitoring App - Drugwatch.
<https://www.drugwatch.com/news/2026/01/21/fda-flags-serious-software-issue-in-dexcom-glucose-monitoring-app/>
40. New Measures for the EU Health Sector: Update of the Medical Device Regulation - TMF.
<https://www.tmf-ev.de/en/news/new-measures-for-the-eu-health-sector>
41. EU Guidance on Breakthrough Devices guidance issued by MDCG - Donawa Lifescience.
<https://www.donawa.com/global-news/eu-guidance-on-breakthrough-devices-guidance-issued-by-mdcg/>
42. MDCG on Breakthrough Devices Released - QbD Group.
<https://www.qbdgroup.com/en/regulatory-updates/mdcg-on-breakthrough-devices-released>
43. Adoption of Commission Implementing Regulation (EU) 2025/2086 - Taylor Wessing.
<https://www.taylorwessing.com/en/insights-and-events/insights/2026/01/adoption-of-commission-implementing-regulation-eu-2025-2086>
44. Medical Device Compliance: 2025 Insights & 2026 Priorities - MedEnvoy.
<https://medenvoyglobal.com/blog/medical-device-compliance-2025-insights-2026-priorities/>

45. EU Regulation 2024/1689 and How It Will Affect the Use of AI in Europe - Facephi.
<https://facephi.com/en/eu-ai-regulation/>
46. Recycling Obligation Meets Reality: What the New EU Packaging Regulation Means for Medical Devices - Taylor Wessing.
<https://www.taylorwessing.com/en/insights-and-events/insights/2025/06/what-the-eu-packaging-regulation-means-for-medical-devices>
47. New EU packaging and packaging waste rules: 10 key things every global business should know - Fieldfisher.
<https://www.fieldfisher.com/en/insights/new-eu-packaging-and-packaging-waste-rules-10-key-things-every-global-business-should-know>
48. What are the new deadlines for medical device manufacturers to transition from the MDD to the MDR? - Advisera.
<https://advisera.com/articles/deadlines-for-medical-device-manufacturers-to-transition-from-mdd-to-mdr/>
49. Guidance on the application of the revised variations framework - EMA.
<https://www.ema.europa.eu/en/guidance-application-revised-variations-framework>
50. FDA in Flux — January 2026 Newsletter - Mintz.
<https://www.mintz.com/insights-center/viewpoints/2791/2026-01-20-fda-flux-january-2026-newsletter>
51. 5 Key Takeaways from FDA's Revised Clinical Decision Support (CDS) Software Guidance - Covington.
<https://www.cov.com/en/news-and-insights/insights/2026/01/5-key-takeaways-from-fdas-revised-clinical-decision-support-cds-software-guidance>
52. FDA Updates Broaden Wellness and Clinical Decision Support Software Devices Under Enforcement - Emergo by UL.
<https://www.emergobyul.com/news/fda-updates-broaden-wellness-and-clinical-decision-support-software-devices-under-enforcement>
53. FDA Launches TEMPO: A First-of-Its-Kind Digital Health Pilot - FDA.
<https://www.fda.gov/news-events/press-announcements/fda-launches-tempo-first-its-kind-digital-health-pilot-expand-access-chronic-disease-technologies>
54. Press Announcements - FDA. <https://www.fda.gov/news-events/fda-newsroom/press-announcements>
55. FDA Increases Flexibility on Requirements for Cell and Gene Therapies - FDA.
<https://www.fda.gov/news-events/press-announcements/fda-increases-flexibility-requirements-cell-and-gene-therapies-advance-innovation>
56. Tech Watch: The Latest in Diabetes Tech News - diaTribe.
<https://diatribe.org/diabetes-technology/tech-watch-diabetes-tech-news>
57. EU digital by default medtech plans signal shift in submissions - Osborne Clarke.
<https://www.osborneclarke.com/insights/eu-digital-default-medtech-plans-signal-shift-submissions-product-information-and-online>
58. EU Commission proposes a targeted revision of the medical devices regulations - PharmaVibes.
<https://www.pharmavibes.co.uk/2026/01/20/eu-commission-proposes-a-targeted-revision-of-the-medical-devices-regulations/>
59. The QMSR Transition, New FDA Guidance, and Their Impacts on Active Implantable Medical Devices - FDLI.
<https://www.fdl.org/2025/12/the-qmsr-transition-new-fda-guidance-and-their-impacts-on-active-implantable-medical-devices/>
60. QMSR Timeline: Every Critical Date Before February 2026 - QMS.Coach.
<https://www.qms.coach/qmsr-timeline-every-critical-date-before-february-2026/>
61. EU MDCG 2025-10 Guidance on Post-Market Surveillance (2025) - Pure Global.
<https://www.pureglobal.com/news/eu-mdcg-2025-10-guidance-on-post-market-surveillance-2025>
62. EUDAMED Milestone: Mandatory Modules from 28 May 2026 - NSF.
<https://www.nsf.org/life-science-regulatory-news/eudamed-milestone-mandatory-modules-from-28-may-2026>

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