US FDA
CDRH Update

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Center for Devices and Radiological Health

U.S. Food and Drug Administration

March 10, 2026
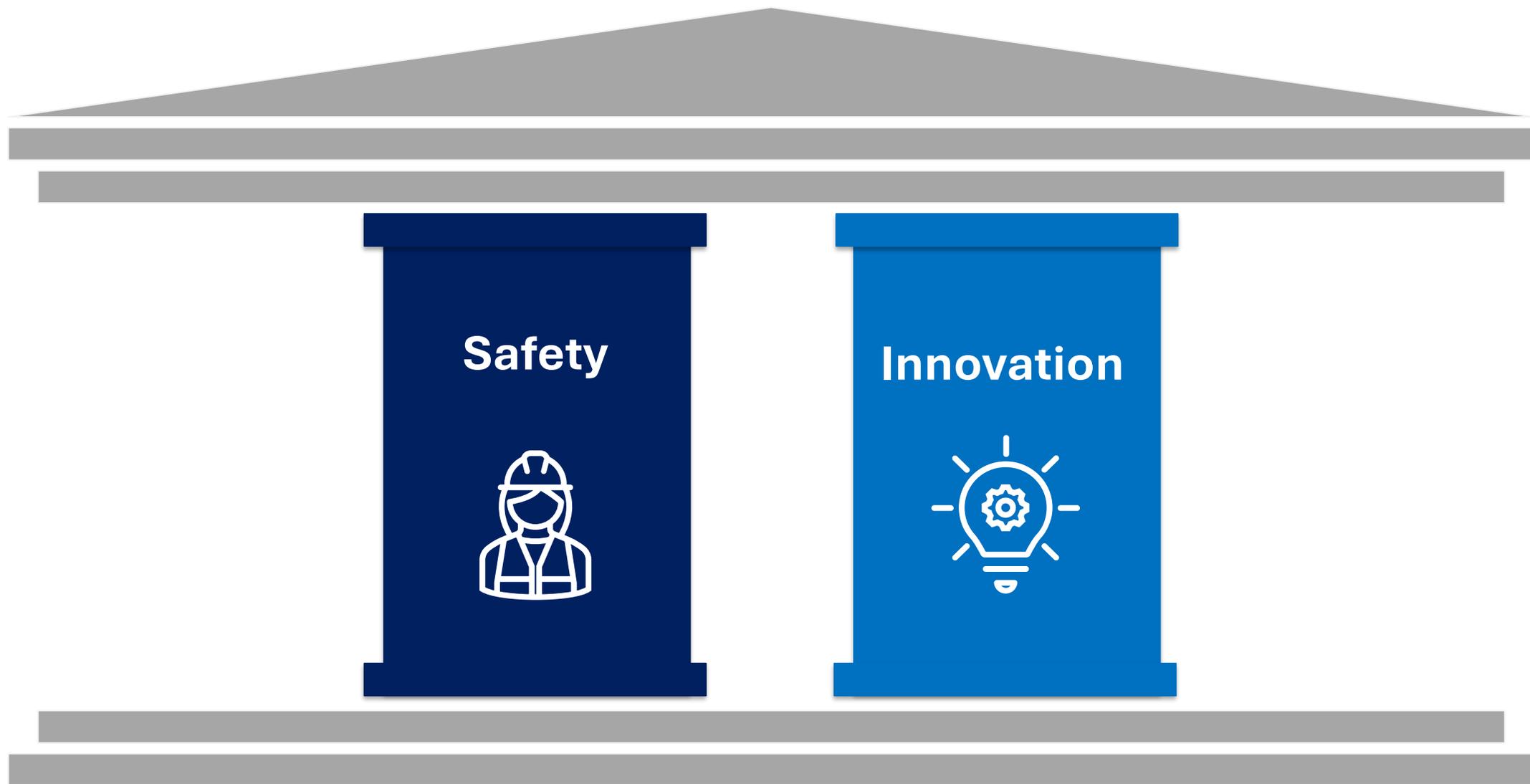
Patients are at the Heart of What We Do

FDA

Center for Devices and Radiological Health (CDRH) Vision

Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance

Real-World Evidence Activities

Regulatory Decision Making
- Supported over 100 premarket authorizations (FY21-FY24)
- RWE used to meet 56 post-market study commitments (FY21-FY24)

Innovation
- Device Identification (UDI & SHIELD)
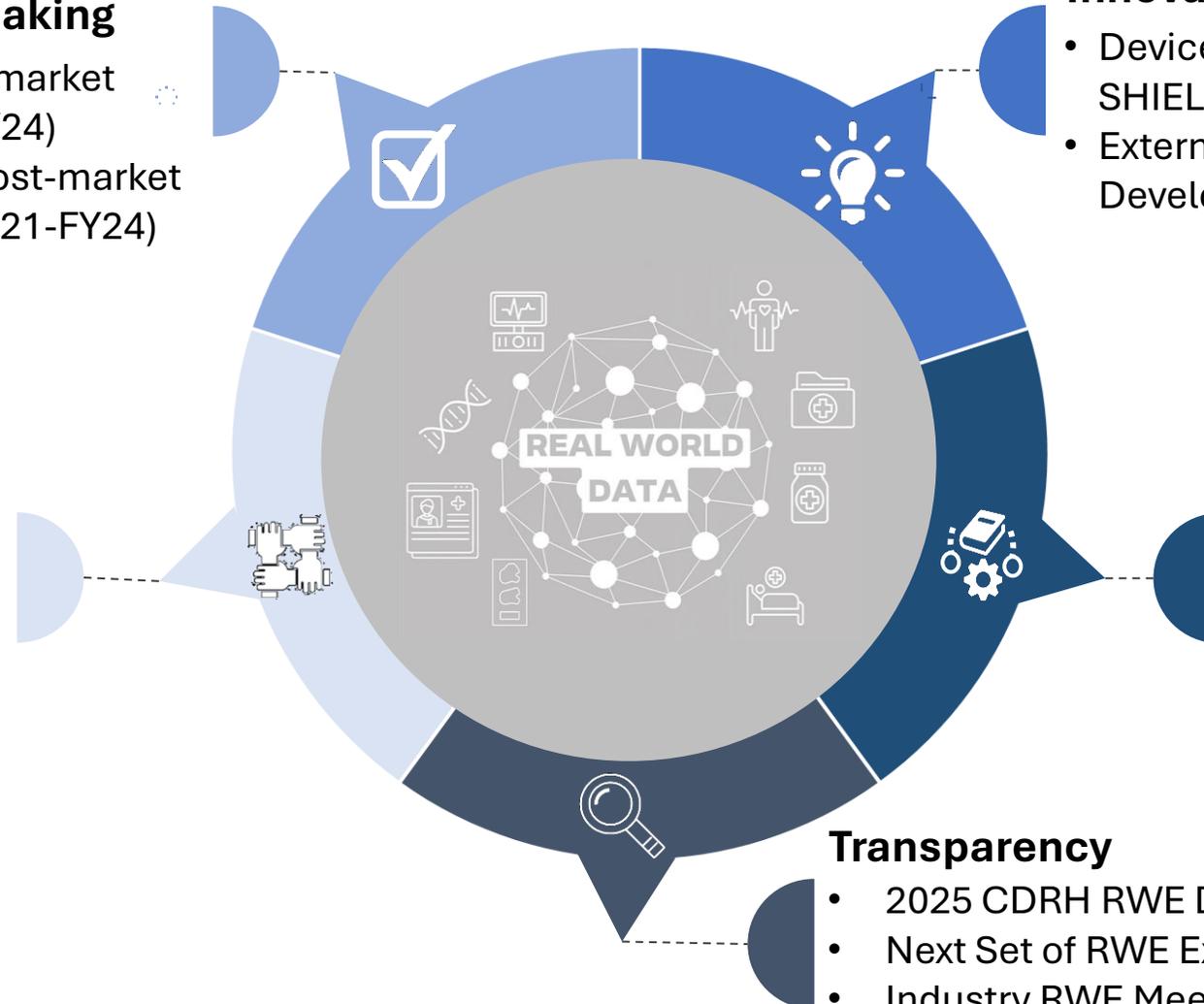- External Evidence Methods Development

Collaborations
- FDA RWE-ACCELERATE
- FDA Sentinel 3.0
- MDIC

Knowledge Management
- Training (e.g., SME, Focal Points)
- RWD Source Catalog

Transparency
- 2025 CDRH RWE DGuidance
- Next Set of RWE Examples
- Industry RWE Meetings
- MDUFA V to VI

REAL WORLD DATA

Digital Health Innovation

New!

Regulatory Accelerator – Curated resources to support development of medical device software

Resource Index

Visual guide to FDA tools and resources available throughout the process of bringing a device to market

Early Orientation

Best practices for engaging early with the FDA on marketing submissions on medical device software

Guidance Navigator

Resource for identifying guidances that may be applicable to a device across the development life cycle

www.fda.gov/medical-devices/digital-health-center-excellence/regulatory-accelerator

Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot

FDA

Center for Medicare and Medicaid Innovation (CMMI), CMS

Launched Advancing Chronic Care with Effective Scalable Solutions (ACCESS) Payment Model

- Emphasizes patient outcomes related to improving patient health and preventing and managing chronic disease
- Introduces recurring payments tied to achieving specific measurable health outcomes
- Includes several safeguards to support clinical quality and accountability

TEMPO Pilot, FDA

A manufacturer may request that FDA exercise enforcement discretion and not enforce certain requirements for devices with an intended use to improve patient outcomes, when the device is offered to or by CMMI ACCESS participants in providing care expected to be covered by the CMMI ACCESS model

Participating manufacturers will collect RWD and share with FDA

Participating manufacturers will be offered "sprint" discussions

Participants selected in clinical areas of early cardio-kidney-metabolic, cardio-kidney-metabolic, musculoskeletal, and behavioral health

AI in Medical Devices

FDA

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 4, 2024.

The draft of this document was issued on April 3, 2023.

Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations

Draft Guidance for Industry and Food and Drug Administration Staff

FDA's Digital Health Advisory Committee

Authorized AI/ML-Enabled Medical Devices*

Over 1,300 AI-enabled devices have been authorized by FDA

Search: _____ Show 50 entries

Date of Final Decision	Submission Number	Device	Company	Panel (lead)	Primary Product Code
05/30/2025	K251406	BriefCase-Triage	Aidoc Medical, Ltd.	Radiology	QAS
05/30/2025	K250236	Swoop® Portable MR Imaging® System (V2)	Hyperfine, Inc.	Radiology	LNH
05/30/2025	K243863	Opulus™ Lymphoma Precision System	Roche Molecular System	Radiology	QIH
05/30/2025	K243005	AudaxCeph Cephalogram Analysis Software	Audax d.o.o.	Radiology	QIH
05/30/2025	K242830	LensHooke X3 PRO Semen Quality Analyzer; LensHooke X3 PRO SE Semen Quality Analyzer	Bonraybio Co., LTD.	Hematology	POV
05/30/2025	DEN240047	Allix5	Clairity, Inc.	Radiology	SEZ
05/29/2025	K250543	Voluson™ Performance 16; Voluson™ Performance 18	GE Medical Systems Ultr	Radiology	IYN
05/28/2025	K243378	Rapid MLS	iSchemaview Inc.	Radiology	QIH

*Updated July 2025

Quality Management System Regulation (QMSR)

Final QMSR rule published on February 2, 2024
*QMSR became effective on **February 2, 2026** (two-year transition)*

QMSR Core Actions

- Replaces the long- standing CGMP regulation: Quality System regulation
- Directly incorporates requirements from international quality management system standards (ISO 13485:2016 and ISO 9001:2015 Clause 3)
- Embeds risk-based quality requirements and globally harmonizes device quality expectations

QMSR Major Impacts

- Aligns FDA expectations more closely with international practice and risk-based lifecycle approach
- Harmonization that can simplify global quality system management expectations

Medical Device Single Audit Program

Chair & Secretariat 2026-2027

MDSAP
Medical Device Single Audit Program

7,500
MANUFACTURING SITES
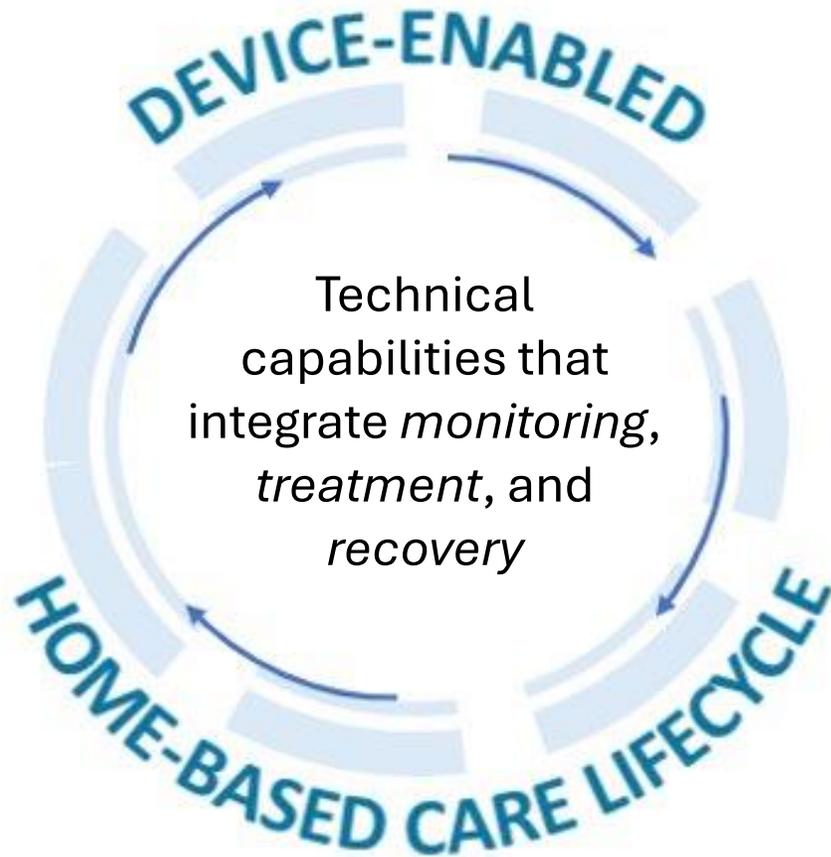
81
COUNTRIES

30K+
Audits

2026 MDSAP FORUM

KYOTO, JAPAN
JUNE 15-19, 2026

Home as a Health Care Hub Initiative

FDA

DEVICE-ENABLED

Technical capabilities that integrate *monitoring*, *treatment*, and *recovery*

HOME-BASED CARE LIFECYCLE

All people, from children to older adults, can optimize their health and wellbeing through medical technologies where they live

Focus on high impact areas while keeping the person, not the devices, at the center

U.S. FOOD & DRUG ADMINISTRATION