U.S. FOOD & DRUG ADMINISTRATION

Agenda: Regulatory Science Innovations Catalyzing Medical Device Development

September 25, 2026

This is a preliminary agenda and is subject to change. The virtual component of this meeting is listen-only.

The FDA's Center for Devices and Radiological Health (CDRH) and the Medical Device Innovation Consortium (MDIC) are pleased to convene this collaborative forum bringing together leaders from government, industry, academia, and patient advocacy to explore the future of medical device innovation.

As the medical device landscape continues to evolve at a rapid pace, this discussion will engage in open, forward-looking dialogue on where regulatory science innovation can support the development of novel technologies.

Today's program will explore topics such as unique clinical care paradigms, cybersecurity, digital health, non-animal methods, and in silico tools, with the goal of fostering collaboration, identifying critical regulatory science gaps, and advancing the development of regulatory science and medical device development tools that support safe and effective technologies.

Time	Session
8:30 – 8:50 a.m. ET	Welcome and Opening Remarks
8:50 – 8:55 a.m.	The Science That Makes Innovation Possible: Regulatory Science
8:55 – 9:00 a.m.	Identifying the Frontier of Medical Device Innovation
9:00 – 9:45 a.m.	Landscape Overview: The Future of Medical Devices
9:45 – 10:15 a.m.	Break, Room Divide

Time	Session
10:15 a.m. – 12:30 p.m.	Regulatory Science Deep Dives (Parallel Breakout Sessions) • Breakout 1: Emerging Device Technologies, Artificial Intelligence and Digital Health • Breakout 2: Non-Clinical Evidence Generation and Testing Methods • Breakout 3: Clinical Evidence Generation and Testing Methods
12:30 – 1:30 p.m.	Lunch
1:30 – 2:30 p.m.	Breakout Session Report-Outs
2:30 – 2:45 p.m.	Break
2:45 – 3:45 p.m.	Synthesis
3:45 – 4:00 p.m.	Closing Remarks