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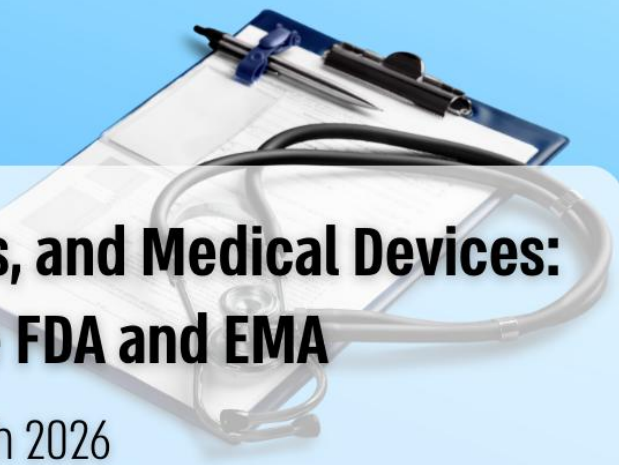

# AI in Drug Development, Biologics, and Medical Devices: Recent Signals from the FDA and EMA

Client Update - March 2026

**Dear Clients,**

February 2026 brought significant developments in AI regulation from both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). For Israeli healthcare companies seeking access to these markets, these signals underscore AI's growing centrality to regulatory compliance.

**Key Regulatory Developments**

During February 2026, the EMA highlighted a series of developments reflecting the growing regulatory significance of AI, including a dedicated meeting with industry stakeholders focused on AI across the medicines lifecycle (click here for the EMA meeting materials) and the Committee for Medicinal Products for Human Use's recommendation of 12 new medicines for approval. Among these was mCombriax, described by the EMA as the first combined mRNA vaccine for influenza and COVID 19 for adults aged 50 and older (click here for the EMA CHMP meeting highlights), a milestone reflecting the increasing sophistication of product development processes in which AI-related tools and methods may play a growing role.

In the United States, February 2, 2026 marked the effective date of the FDA's Quality Management System Regulation (QMSR) and the agency's transition away from the Quality System Inspection Technique (QSIT) toward an updated inspection framework for device manufacturers (click here for the FDA Town Hall on QMSR and Medical Device Risk-Based

Inspections). On that date, the FDA stopped using the QSIT for device inspections and began utilizing the inspection process described in the updated Inspection of Medical Device Manufacturers Compliance Program Manual. While this development is not limited to AI, it reflects a broader regulatory trend toward increased scrutiny of how companies build, validate, document, and oversee technology driven processes throughout the product lifecycle.

These developments build on policy groundwork laid over the past year. In January 2025, the FDA issued draft guidance on the use of artificial intelligence to support regulatory decision making for drug and biological products (click here for the FDA draft guidance), providing a risk-based credibility assessment framework for establishing and evaluating the credibility of an AI model for a particular context of use. In January 2026, the FDA and the EMA jointly published guiding principles on Good AI Practice in drug development, emphasizing a risk-based approach, data governance, context of use, lifecycle management, and appropriate documentation (click here for the FDA and EMA guiding principles).

**What This Means for Israeli Healthcare Companies**

Taken together, these developments suggest that for Israeli companies operating in healthcare, biotech, pharmaceuticals, and medical devices, whether seeking FDA clearance, EMA marketing authorization, or both, AI is no longer simply part of a broader innovation narrative. It is part of the core regulatory conversation. The central question is no longer whether AI is being used, but whether companies can clearly explain how it is being used, what role it plays in development and decision making, how it has been validated, and what governance and oversight mechanisms surround it.

This shift has practical implications across the product lifecycle. Regulatory scrutiny is increasingly extending to the use of AI in drug and biologic development, clinical trial design and management, data analysis, regulatory submissions, and device related applications. In parallel, regulators are signaling that companies should be prepared to articulate the intended use of AI tools, the quality and appropriateness of the underlying data, the

boundaries of model performance, the governance framework surrounding the technology, and the role of human oversight.

The trend is not limited to medicinal products. In the medical device space, the FDA continues to emphasize cybersecurity, quality systems, and lifecycle oversight, all of which may become increasingly relevant where AI functionality is embedded in the product itself or used as part of quality or post market processes.

**Implications for Cross-Border Collaborations**

For Israeli companies engaged in cross-border collaborations with US or EU partners, the joint FDA-EMA guiding principles on Good AI Practice published in January 2026 are particularly significant. These principles reflect growing regulatory alignment between the two jurisdictions on core issues such as risk-based approaches, data governance, context of use, lifecycle management, and documentation standards.

This convergence has practical implications for Israeli companies structuring collaborative arrangements. Where AI is used in joint development programs, clinical trials, or shared manufacturing processes, partners may increasingly expect contractual provisions addressing AI governance, validation standards, and regulatory responsibilities. Israeli companies that can demonstrate alignment with both FDA and EMA expectations will be better positioned to participate in such collaborations and to satisfy due diligence requirements from US and EU counterparts.

**Practical Steps for Israeli Companies**

Against this backdrop, Israeli healthcare companies should consider several practical steps:

First, companies should map where AI is already being used across development, quality, regulatory, clinical, and operational functions. For Israeli companies with products at various stages of development or commercialization in the EU or US markets, this exercise is particularly important to ensure alignment with evolving expectations.

Second, companies should assess whether they maintain sufficiently robust documentation addressing data inputs, validation methodology, intended use, performance limitations, and internal decision making.

Third, internal governance should be reviewed to confirm that AI related activities are subject to appropriate human oversight, accountability, and risk management.

Finally, companies should be prepared for increasing regulatory expectations not only around innovation, but also around the clarity, consistency, and defensibility of their approach to AI in practice.

**Strategic Benefits**

For Israeli healthcare companies that address these issues early, the benefit is likely to extend beyond regulatory readiness. A well structured approach to AI governance may also strengthen the company's position in discussions with regulators, investors, strategic partners, and potential acquirers, while helping reduce the risk of delays or challenges at later stages of development, review, or commercialization.

Israel's healthcare sector has long been recognized for its innovation and global reach. As AI becomes more deeply embedded in the regulatory frameworks of key markets, companies that proactively align their practices with these expectations will be better positioned to navigate the path to market access and long-term growth.

**We note that while the foregoing developments provide useful sector guidance, they should be considered alongside the broader U.S. and EU legal and regulatory frameworks governing artificial intelligence.**

**The information provided in this client update is for general informational purposes only and should not be construed as legal advice or a substitute for professional legal counsel.**

As always, the team at Agmon with Tulchinsky remains at your disposal.

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