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Introduction: *Journal of Regulatory Affairs*, Mar-Apr 2026

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Welcome to the *Journal of Regulatory Affairs*, featuring in-depth coverage of the EU Artificial Intelligence Act (EU AI Act) as well as articles on engineering safety and effectiveness in drug-device combination products and regulatory considerations for pharmaceutical excipient selection. These articles are exemplary of the mission of this new journal. They provide readers with valuable, evidence-based information on emerging issues in global healthcare regulation that can be used as guidance or a reliable resource in their daily regulatory work. They also flag the importance of companies, agencies, and professionals ensuring they are future-ready.

We thank the authors for sharing their real-world knowledge and expertise with their global regulatory peers. Their commitment, both in time and effort, to writing the articles and seeing them through to final publication is greatly appreciated. We acknowledge their contributions to the existing regulatory literature and hope others will also consider contributing in this way.

The EU AI Act and MDR: Interaction, divergence, implementation

In the first of two substantial explorations of the EU AI Act, **Attrayee Chakraborty** and **Geethapriya Setty** focus on the act's scope and its interplay with/divergence from the EU Medical Devices Regulation (EU MDR). In **Navigating convergence and divergence between the EU MDR and EU AI Act** (p. 4), they show how the EU AI Act's horizontal framework and risk-based classification system complement the EU MDR's basis in patient safety. They share practical examples and detailed decision pathways to explain when AI-enabled devices are classified as high-risk and how to effectively navigate overlapping rules. The takeaway message is that the EU AI Act and the EU MDR/IVDR are complementary, not competing, layers of a single regulatory system focused on risk, safety, and accountability.

Chakraborty and Setty's second article, **Build from the base: Operationalizing the EU AI Act through a decision-tree approach** (p. 19), homes in on the practical aspects of implementing the act. The authors consider how existing international and European standards and EU MDR processes can be used by manufacturers to meet the EU AI Act's requirements for risk management, data governance, transparency, and postmarket governance. They identify implementation gaps, focusing on the CEN-CENELEC harmonized standards and common specifications, earmarked for release later this year.

Professionals are advised to use current EU MDR processes and established international frameworks such as ISO/IEC 42001, ISO 23894, and ISO 5338 for risk management, data governance, transparency, and postmarket surveillance. The authors recommend that manufacturers set up cross-functional governance teams, run gap assessments, develop scalable roadmaps, and integrate

AI oversight into their evolving quality management systems. By layering these proven standards onto the EU MDR-based quality management systems, companies can meet current legal obligations, bridge implementation gaps, enhance safety and innovation, and position themselves ahead of enforcement.

Engineering and excipients

In **Engineering safety and effectiveness: A first-principles approach to drug-device combination products** (p. 31), **Fubin Wu and colleagues** present the case for integrated, purpose-driven decision making in pharmaceutical and device development focused on patient needs, intended use, and engineering principles rather than siloed, compliance-driven practices. They detail, both in writing and through detailed visual guides, how unifying design controls, quality by design, risk management, and structured justification frameworks lays the foundation for safety and effectiveness and establishes safety engineering as a discipline that transforms compliance into demonstrable, lifecycle-based assurance of safety and effectiveness in combination products. Wu and coauthors **Jiaying Shen, James Wabby, Darin Oppenheimer, Yu Tang,** and **Pooja Kartik** note that this shift requires infrastructure and tools that embed the logic, traceability, and system-level reasoning that first principles demand and caution organizations to "move away from performative compliance toward prioritizing true safety and effectiveness measures."

Excipients make up the predominant quantitative component in pharmaceutical formulations. Their selection requires both technical and regulatory considerations, with the associated regulations becoming more complex in recent years. In **Regulatory considerations for pharmaceutical excipient selection** (p. 49), **Yuri Ceragioli** discusses the role of excipients in medicines and the regulatory aspects for pharmaceutical companies. He emphasizes the importance of a comprehensive understanding of and compliance with several guidelines and requirements. Although pharmaceutical excipients do not require regulatory approval before being placed on the market, Ceragioli warns that inadequate regulatory evaluation of excipients may delay or prevent pharmaceutical products from reaching the desired market.

Citation Matthews R. Journal of Regulatory Affairs: March-April 2026. RAPS *Journal of Regulatory Affairs*. 2026;1(2):1-3. Published online 6 March 2026. https://www.raps.org/news-and-articles/News-Articles/2026/3/Journal-of-Regulatory-Affairs-March-April-2026

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- **Jul – Aug** Drug and device filings: A global perspective
- **Sep – Oct** FDA policy and practice: 18 months on
- **Nov – Dec** Global clinical trials
- Also see 2026 Editorial Calendar

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- *Regulatory Focus* monthly articles (2019-2025)
- *RF Quarterly* 2025 RAPS Convergence (December 2025; includes all past full issue PDFs)

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