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Introduction: Journal of Regulatory Affairs, November-December 2026



Anna Han

Welcome to the November-December 2026 issue of the *Journal of Regulatory Affairs*, which features articles on the use of AI in regulatory affairs, iterative medical device software development in the US and EU, integrating China into global drug development, Class I medical device recall trends, and oncology accelerated approvals and withdrawals.

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.

AI in regulatory practice

The growing use of AI in regulatory practice has created opportunities to improve efficiency while raising concerns about oversight, data integrity, and accountability.

In **Building AI literacy for medical device regulatory affairs professionals** (p. 5), **Geethapriya Setty** and **Jay Vaishnav** examine the competencies regulatory professionals need to evaluate and use AI tools responsibly. The authors distinguish AI literacy from broader digital literacy and consider how AI-assisted workflows alter the responsibilities traditionally associated with document-centered regulatory work. Regulatory professionals must understand not only what AI tools can do, but also how their outputs are generated, where errors or limitations may arise, and when additional scrutiny is required.

In **AI in regulatory writing: Examining critical pitfalls and implications** (p. 16), **Red Thaddeus D. Miguel, Rami Ali**, and **Manal El Joumaa** focus on the application of generative AI to regulatory writing. The authors draw upon studies that highlight potential risks, including inaccurate representation of source material, incomplete summaries, and statements that are not adequately supported by evidence. These deficiencies can be difficult to identify without deliberate and systematic review. The authors therefore recommend establishing governance controls, safeguarding confidential information, verifying content against original sources, and maintaining meaningful human involvement throughout the writing process.

Navigating product development and global regulatory pathways

The next two articles examine how regulatory requirements across jurisdictions shape product development and market-entry strategy.

In **Understanding iterative medical device software development in the US and EU** (p. 25), **Wybe Hoffmann** and **Patrick Mahoney** compare how the regulatory systems in these jurisdictions accommodate, or potentially constrain, iterative software development. Software may be updated frequently in response to technological advances, user needs, cybersecurity considerations, or new

clinical and performance information, creating challenges when development cycles outpace conventional regulatory processes. The authors examine differences in risk classification, intended use, regulatory consultation, evidence expectations, data reuse, and the assessment of software changes.

In **Regulatory pathways for approving foreign drugs in China: A global integration perspective** (p. 42), **Wenny Du, Hamish King**, and **Xiao Michelle Meng** describe China's changing regulatory environment and the pathways available for bringing foreign drugs to the Chinese market. Regulatory reforms have created opportunities to integrate China into global development programs, but sponsors must consider differences in development timing, evidence requirements, patient populations, and regulatory strategy.

The authors discuss approval pathways for different drug types and factors that can determine how China is incorporated into global clinical development.

Postmarket evidence and regulatory outcomes

The final two articles in this issue use regulatory data to examine medical device recalls and the outcomes of oncology indications granted accelerated approval.

In **Trends in FDA Class I medical device recalls over an eight-year period** (p. 61), **Tabitha Y. Shen, Autumn J. Bullard, Ekaterina Galkina Cleary, Alex Peer**, and **Marta L. Villarraga** analyze publicly available FDA data on Class I medical device recalls during fiscal years 2018 through 2025. The authors identified 579 recall events involving 2,202 recalled products. They distinguish a recall event, meaning a firm's recall action, from the individual products associated with that action. Recall events increased over the eight-year period, while recalled products peaked in 2023. Class II devices were recalled most frequently, and cardiovascular devices were the most common medical specialty.

In **Accelerated approval pathway for oncology: Summary of approvals and withdrawals, 1992-2026** (p. 73), in which **Sarah Sejoro** and **Karl E. Peace** analyze oncology indications approved through the FDA accelerated approval pathway. The authors identified 347 indications approved through the pathway, of which 243 were oncology indications. Among the oncology indications, 124 subsequently received full approval, and 34 were withdrawn. The authors examine reasons for withdrawal, timelines to withdrawal or full approval, and reforms affecting the pathway. The analysis illustrates the balance inherent in accelerated approval: providing earlier access to therapies while ensuring that anticipated benefits are verified through timely and adequate confirmatory evidence.

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