

# Introduction: Journal of Regulatory Affairs, May-June 2026



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Welcome to the JOURNAL OF REGULATORY AFFAIRS, featuring articles on in vitro diagnostic (IVD) medical devices and the associated workflow between notified bodies and reference laboratories in the EU, the Eurasian Economic Union (EAEU) regulatory pathway, comparability protocols, commercial investigational new drug (IND) applications in the academic setting, and regulatory intelligence on cell and gene therapies.

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.

## Notified bodies, reference labs, and the EAEU

In **From IVDD to IVDR: The interplay between notified bodies and EURLs** (p. 4), **Jennifer Rosendahl** and colleagues, **Marta Carnielli**, **Panna Vass**, **Karin Agrenius**, **Alex Laan**, **Tom Patten**, **Olga Tkachenko**, and **Aisha V. Sauer**, track the transition from the former EU In Vitro Diagnostic Directive, under which notified bodies (NBs) verified devices, to the EU In Vitro Diagnostic Medical Device Regulation and its associated EU reference laboratory (EURL) legal framework for confirming the performance of high-risk, Class D IVDs through laboratory testing. The authors

present the EURL designation and technical areas and discuss the development of harmonized agreements and workflows between NBs and EURLs. The harmonization efforts have streamlined processes and standardized testing templates, ensuring improved consistency and efficiency during testing and delivery of a safe and effective final product. Rosendahl and colleagues also present key operational steps, manufacturer obligations, and batch testing criteria.

The transition to unified EAEU registration rules was completed on 31 December 2025, resulting in a new regulatory environment for pharmaceutical manufacturers in the member countries of Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russia. In **The EAEU regulatory pathway: A practical guide for global applicants** (p. 14), **Natalia Tsygankova** provides a practical guide to the key regulatory institutions, the hierarchy of normative documents, registration procedures, and electronic common technical document dossier requirements and preparation. The author highlights common applicant mistakes and offers strategies for optimizing the regulatory process, noting that the focus of regulatory work in 2026 will be on registering new products and the lifecycle management of medicines that have already been authorized. Longer-term, the union will address further digitalization of document flow, continued harmonization with international standards, pharmacovigilance, and oversight of postmarketing obligations.

## Comparability protocols and academic drug development

Comparability protocols rooted in strong scientific reasoning, proper analytical comparability, and clear acceptance criteria can provide structured, pre-approved plans for managing postapproval chemistry, manufacturing, and controls (CMC) changes, resulting in lower reporting categories and faster implementation while ensuring product quality. In **Comparability protocols as a strategic tool for postapproval CMC changes** (p. 27), **Piyush Modi, Jigneshkumar Modasiya, and Dhaval Desai** highlight the protocols' usefulness when they are incorporated into the pharmaceutical quality system through risk assessment, ongoing process monitoring, and management review to maintain consistency in quality control. The authors note that the protocols should be used for quality changes only and not for changes that might affect clinical outcomes. They also detail how to create and implement a protocol and address the benefits and limitations of using a protocol, suitable and unsuitable chemistry CMC changes, lifecycle management, and the differences between the US Food and Drug Administration and the European Medicines Agency's approaches in regulating and guiding these valuable tools.

In **Regulatory roadmap for NCE commercial IND submissions in academia: A case study** (p. 37), **Sebastian Biglione and Chad Bennett** draw on their experience as academic drug developers to document the regulatory pathway from academic discovery to IND submission and the unique challenges in development in that setting. Their brief introductory discussion about the differences in drug development between industry and academia provides a helpful context for their case study, which includes valuable takeaways for other academic institutions pursuing similar ventures. The authors emphasize the importance of thorough preparation, regulatory strategy, interdisciplinary collaboration, regulatory expertise, and the ability to swiftly respond to feedback.

## Regulatory intelligence and CGTs

Two articles by **Padma Priya Togarrati**, focusing on cell and gene therapies (CGTs), highlight the importance of incorporating regulatory intelligence into strategic decision making throughout the CGT product lifecycle while remaining responsive to regulatory fluctuations and scientific

and technological advances. In the first article, **Strategic regulatory intelligence on cell and gene therapies** (p. 51), Togarrati notes the prevailing gaps between product approvals and patient access despite significant advances. She contends that integrated strategies addressing CMC robustness, the generation of real-world evidence, collaboration among stakeholders, and region-specific market access could help address these gaps and underscore commercial viability. The second article, **Strategic regulatory intelligence on pricing and reimbursement models for CGTs** (p. 65), Togarrati examines regulatory intelligence across China, the EU, Japan, South Korea, and the US, specifically, health technology assessments, payer expectations, and reimbursement scenarios defining commercial access for approved CGT products.

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- **Nov – Dec** Global clinical trials
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All Journal articles

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- REGULATORY FOCUS monthly articles (2012-2025)

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- Style guidelines for authors

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