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Introduction: *Journal of Regulatory Affairs*, July-August 2026

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Welcome to the *Journal of Regulatory Affairs*, featuring articles on global regulations governing orphan drug designation, regulatory science considerations for live biotherapeutic products (LBPs), the role of technology in medtech regulatory affairs operations, and cross-regional pediatric study plans.

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.

Orphan drugs and live biotherapeutics

In **Global regulations governing orphan drug designation** (p. 4), **Mauro Placchi** and **Adriaan Fruijtier** compare rare disease definitions and orphan drug designation (ODD) frameworks in the US, EU, UK, Japan, and China and consider how differing regulatory constructs shape global orphan drug development strategies. The authors also explore how jurisdiction-specific ODD frameworks influence development feasibility and strategic decision making, providing a practical understanding of how regulatory design affects downstream patient access.

LBPs are an emerging class of biological medicines that rely on viable microorganisms to treat or prevent disease. In **Regulatory science considerations for live biotherapeutic products: Insights from early FDA approvals** (p. 14), **Jahnavi Patel and colleagues** examine regulatory expectations for these products in the US and EU, with an emphasis on safety evaluation, clinical development strategies, and manufacturing controls. Patel and co-authors **Piyush Modi, Jigneshkumar Modasiya,** and **Dhaval Desai** note the recent US Food and Drug Administration (FDA) approvals of Rebyota and Vowst, the first microbiota-based LBPs for avoiding recurrent *Clostridioides difficile* infection, to show how these therapies can progress through regulatory frameworks if appropriately supported and to highlight the related challenges. They also address ongoing efforts by the EMA to establish a more harmonized approach to microbiome-based medicines.

Technology, pediatric study plans

In **The role of technology in evolving medtech regulatory affairs operations** (p. 23), **Diogo Geraldes** assesses the ensuing challenges regulatory affairs teams face in bringing new products to market and how using technology to manage regulatory information can help centralize information, structure documentation and data, and standardize and streamline workflows. Geraldes emphasizes the importance of training and upskilling programs and shifting from reactive, manual processes to integrated, proactive systems that fully leverage technological infrastructure, process automation, and optimization to ensure strong data quality and governance and proactive regulatory management.

Pediatric plans are regulatory frameworks ensuring that the well-being of the pediatric population is adequately considered during the development of new medicinal products. With global harmonization, regulatory writing becomes critical in drafting compliant, ethical, and scientifically robust pediatric study strategies. In **Pediatric study plans: Requirements and regulatory writing considerations for FDA, EMA, and PMDA submissions** (p. 33), **Heta Mehta** provides an overview of the differences in pediatric plan requirements across the European Medicines Agency, Japan's Pharmaceuticals and Medical Devices Agency, and the FDA. She highlights the regulatory submission process, writing considerations, and common challenges encountered during plan development. The article serves as an introductory guide, summarizing the regulatory and legal requirements governing pediatric plans, and is intended for professionals involved in regulatory writing, drug development, or clinical strategy.

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