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New Research Finds 87% of Medtechs Lack Consistent Methods to Share Product Information Across Global Regulatory Teams

Growing regulatory complexity driving need for a single source of regulatory information

PLEASANTON, CA — Nov. 15, 2023 — Most medtech companies (87%) can't seamlessly exchange product information between in-country and global regulatory assurance teams, according to the 2023 Regulatory Benchmark Report from Veeva MedTech. Without a standardized and consistent way to share documents globally, organizations can't ensure the reliability or accuracy of product information across markets. This increases compliance risk and can delay the delivery of devices and diagnostics to patients.

A single source for regulatory documents can enable global teams to access real-time information and take proactive action. Yet, more than half of respondents (56%) say they don't have access to a single source for documents to support global submissions. As regulations — like EU Medical Device Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR) — continue to evolve, establishing centralized regulatory data and documents should be a top priority to accelerate approvals and speed up new market entry.

The report reveals additional opportunities for improving medtech regulatory affairs, including:

- **Cross-functional collaboration is still manual**: More than one-third (35%) of companies rely on status meetings to share regulatory plans across functions. This obligates individuals to communicate vital information, reducing visibility and data quality.
- **Misaligned content increasing risk**: The majority (75%) say key content, such as intended use or device descriptions, is misaligned across functions at least some of the time. With the variance in information, companies face an increased risk of inaccurate or incomplete regulatory submissions.
- **Greater need for harmonized claims management**: Just 14% of respondents say their entire content lifecycle process is optimized across functions. At the other end of the spectrum, over a third (34%) say they conduct siloed content reviews or have no clear review process. With this disconnected approach, regulatory teams report they often lack the evidence needed during product claim audits.

"As companies scale and expand into global markets, having real-time, accurate product information can significantly streamline in-country regulatory submissions," said Seth Goldenberg, vice president, Veeva MedTech. "The research reveals a significant opportunity for medtechs to unify global regulatory information, a shift that can empower regulatory affairs with data for faster approvals."

The Veeva MedTech 2023 Regulatory Benchmark Report examines the medical device and diagnostic industry's progress toward modernizing regulatory operations. Survey respondents include more than 100 regulatory affairs (RA) professionals from medtech organizations around the globe. See the complete annual study, which explores how medtech companies and RA teams work cross-functionally to manage new product development, global market entry, commercial launches, and renewal of product certifications.

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