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New Medtech Survey Reveals Urgency to Harmonize Regulatory Processes and Streamline Submissions

Medtech accelerating regulatory transformation to ensure global compliance with changing regulatory requirements

PLEASANTON, CA — Dec. 8, 2021 — Modernizing regulatory operations is a top priority for medtech companies to accelerate submissions and reduce market entry barriers, according to the MedTech 2021 Regulatory Benchmark Report conducted by Veeva MedTech. The new research shows that more than half of medtech organizations are taking action by unifying regulatory operations across departments and geographies to eliminate data silos and ensure compliance.

While the shift to streamline regulatory operations in medtech is underway, the survey indicates more work remains to eliminate manual processes, drive speed, and meet evolving regulations like EU MDR and IVDR. Only 17% of respondents say they have standard processes for managing content and global regulatory submissions, highlighting the industry-wide need to harmonize regulatory operations on a single, global digital system.

Two-thirds of respondents manage submission documents on local laptops, file shares, or regional document management systems, creating challenges with duplicate content and unreliable data. These issues can delay new product introductions and post-market compliance, challenges that impact the bottom line. The heavy reliance on manual processes for submission planning, tracking, and health authority interactions also increases compliance risk by limiting visibility into status and archives.

"The new EU MDR and upcoming IVDR changes require strict adherence for compliance. The more reliable regulatory data is, the easier it will be to adapt to this and future industry changes," said Seth Goldenberg, Ph.D., vice president, Veeva MedTech. "Transformation is underway as organizations adopt a single, digital regulatory solution to ensure consistency and compliance across global markets while speeding product development."

The Veeva MedTech 2021 Regulatory Benchmark Report examines the medical device and diagnostic industry's progress towards modernizing regulatory operations. The report gathers the experiences of regulatory affairs professionals from nearly 100 organizations around the globe, ranging from enterprise to midsize businesses. The study explored how MedTech companies manage global compliance and visibility, speed to market, post-market compliance, and regulatory modernization. The full report is available online here.

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