Veeva MedTech

2025 Regulatory Affairs Benchmark

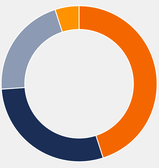
The 2025 Veeva MedTech Regulatory Benchmark explores how the industry is thinking about efficiency, data quality, and digital transformation. Although many medtech companies lack confidence in their data's accuracy and still rely heavily on manual processes to maintain compliance, there is a clear industry shift towards unified regulatory information management (RIM) systems, data, and AI tools while developing robust integrations between existing solutions.

Process Efficiency and Confidence

Regulatory teams can quickly retrieve global registration information, but they have lingering uncertainties about overall data completeness and organization.

45% Can retrieve global product registrations in a few minutes

Time to Determine Where a Product is Registered Globally



- 45% A few minutes
- 29% One day or less
- 21% A few days
- 5% A week or more

50% Somewhat or not confident in the completeness of underlying data

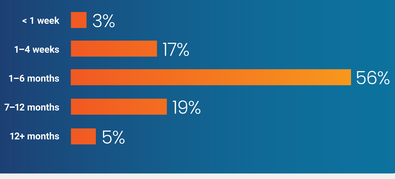
Confidence that Data Includes All Relevant Registration Information

- 50% Very confident
- 45% Somewhat confident
- 5% Not confident

Submission Preparation

Preparing a submission from data gathering to internal approval is still a substantial and costly undertaking for most organizations

Time to Prepare a 510(k) Submission



Operational Challenges and Gaps

Regulatory teams continue to struggle with excessive administrative tasks and fragmented workflows that hinder seamless collaboration and data flow

Methods for Monitoring Regulatory Metrics that Drive Time to Market

1. Adapting to regulatory changes
2. Consolidating data across platforms
3. Keeping data up to date

Looking ahead, regulatory professionals have clear intentions to adopt new tools and methodologies to enhance operational capabilities.

New Tools Planned for Adoption to Improve Efficiency or Compliance

- **56%** Regulatory Information Management (RIM) system
- **52%** Developing integrations between existing systems
- **48%** Automated submission tracking and reporting tools

Summary

There is a critical, unmet need for increased automation across medtech regulatory affairs teams, driven not merely by a desire for speed, but primarily by the need to alleviate heavy administrative burden, enhance data quality, and improve the overall reliability of regulatory processes. However, respondents indicated a strong and clear strategic intent to transition towards more integrated, proactive systems that can effectively handle the complexities of future regulatory changes and demands.

Veeva RIM enables medical device and diagnostics manufacturers to unify systems with a single source of truth for registrations, submissions, publishing, and archival to ensure global regulatory compliance and speed to market.

Learn more at veeva.com/medtech/regulatory | 925-452-6500 | +34 931 870 200 (Europe)

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