Veeva MedTech

# Modernizing Medtech Regulatory Affairs

**Veeva MedTech recently surveyed regulatory affairs leaders from 100 global medical device and diagnostics companies on compliance, visibility, collaboration, and change control. Here's what we found:**

## Overall Status of RIM

### 69% do not have global RIM in place

While medtech is progressing towards regulatory transformation, there is still more work to be done


**67%** identified where technology adds value

**62%** selected technology to begin harmonization

**56%** harmonized regulatory processes globally

## Global Compliance

**84%** lack standard automated submission archival process

**76%** use manual tracking methods

**66%** manage submissions in silos

**50%** manage Health Authority commitments manually (emails, logs)

**40%** don't have central submission content system

## Global 24/7 Visibility

**60%** single registration tracking system

**5%** fully automated KPI reports & insights

## Speed to Market

**63%** manual submission data collection

**79%** manual regulatory process revision

## Post-Market Compliance

**74%** centralized complaints handling system

**59%** partly integrated or automated change control

## Priorities for Future Regulatory Affairs

(respondents indicated one or more top priorities for the next two years)

**62%** single source of truth for regulatory information

**60%** global and centralized RIM system

**53%** content reuse across submission, regions, and BUs

**43%** 24/7 access to reliable data

**34%** cross-functional collaboration in a unified system

**26%** end-to-end regulatory operations visibility

## Summary

**The study revealed that manual processes and data governance, disconnected data, and siloed systems that are not scalable nor flexible, are still present in most organizations. While 56% of respondents have completed or begun modernizing global regulatory operations, the industry is still behind in digital transformation compared to the rest of the life sciences.**

Veeva MedTech provides cloud solutions that enable medical device and diagnostics companies to speed clinical studies, improve quality, ensure global regulatory compliance, and streamline scientific and commercial content management.

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