2023 Medtech Regulatory Benchmark: The Strategic Role of Regulatory Affairs

The 2023 Veeva MedTech Regulatory Benchmark surveyed regulatory leaders from medical device and diagnostic companies regarding the strategic role of regulatory affairs.

While regulatory affairs should be a key cross-functional enabler of innovation and speed to market, results show that many regulatory teams are consumed by inefficient administrative tasks instead.

New Product Development

Medtech organizations remain vulnerable to errors and inefficiencies due to manual processes and communication methods, potentially slowing innovation.

Only 14% have a single-source-of-truth platform to exchange strategic plans across functions.

- 33% Individual functional plans, stored in disparate systems / locations
- 26% Individual functional plans, stored in a central repository
- 19% No single source, information exchanged ad-hoc
- 14% Single source of truth
- 8% None of the above

35% Rely primarily on status meetings to share plans cross-functionally.

- 35% Changes to functional area plans discussed during meetings
- 24% No formal process to share changes
- 21% Changes to functional area plans trigger impact assessment
- 10% Functional plans are collaborative – updates trigger notification to all areas
- 9% None of the above

Placing Products on the Market

Regulatory Affairs remains responsible for generating and maintaining critical product information, but often is not kept up-to-date by other functional areas.

75% report that key content, such as intended use or device description, is at least sometimes misaligned across functions.

14% say no notification process is in place to make RA aware of changes to the Design History File (DHF) or Clinical Evaluation Plan (CEP) impacting regulatory deliverables.

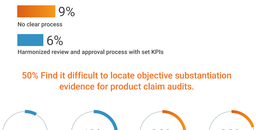
- 25% Integrated systems: new version of document triggers an alert and verification
- 20% RA manually subscribes to specific document and receives notifications
- 16% RA manually checks document repository for new versions
- 14% No formal notification process in place
- 25% None of the above

Expansion to Other Markets

In-country and global RA teams struggle to communicate in a way that ensures consistency and accuracy of product information across markets.

35% Report reactive process for exchanging critical documents.

Most report no access to a single source of truth for submissions.



Supporting Commercial Launch

RA often lacks access to the critical information it needs to support the launch of a new product.

34% State claims substantiation and review is undefined and lacks harmonization.

- 46% Defined and harmonized approval process
- 25% Siloed review of content and claims
- 14% Entire content lifecycle process is optimized across functions
- 9% No clear process
- 6% Harmonized review and approval process with set KPIs

50% Find it difficult to locate objective substantiation evidence for product claim audits.

Sustaining Regulatory Compliance

Much of RA's time within a medtech organization is monopolized by keeping abreast of regulatory developments and chasing down their impacts to the existing product portfolio, rather than supporting innovation.

60% Manually gather information to assess new regulations.

- 59% RA must reach out to each area individually, update, and store assessment locally
- 28% Central repository of all information but it's updated manually offline and re-uploaded
- 13% Collaboration in a system that is directly linked to all previous test reports and regulatory submissions to assess, annotate, and collaborate

Renewing Regulatory Approval

Renewals remain vulnerable to simplistic monitoring systems and processes that depend on key team members, rather than key systems.

69% State no system alerts exist for license expirations, or alerts are generic and don't account for complexities of an individual renewal.

19% Anticipate significant negative impact to business and renewals if a key person left the organization unexpectedly.

- 53% Medium impact – manual, individual spreadsheets are maintained – information shared only during regular meetings
- 20% No foreseeable impact – just reallocate some tasks in a central system
- 19% Significant negative impact to business – renewal process dependent on individuals
- 7% None of the above

Summary

Regulatory Affairs should play a critical, strategic role in a successful medtech organization, driving innovation and empowering its teams to bring new products to market faster. As organizations scale and the regulatory landscape becomes increasingly complex, internal systems, resources, and end-to-end processes become integral to RA taking its place as an innovation partner.

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