Veeva MedTech

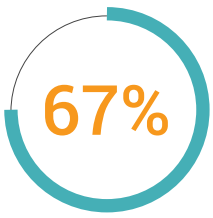
MedTech 2021 Regulatory Pulse Benchmark Report

The Veeva MedTech 2021 Regulatory Pulse Benchmark Report examines the medical device and diagnostic industry's progress towards modernizing regulatory operations by gathering 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.

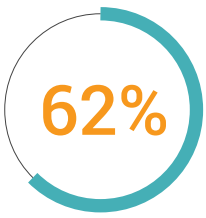
Although the research primarily focused on Regulatory Affairs, some learnings from this report may also be relevant to the Quality function.

Executive Summary

Findings show the medtech industry is taking action to modernize regulatory affairs with technology and streamlined processes. 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 life sciences. We still see medtech companies using manual processes, disconnected data, and siloed systems, that are neither scalable nor flexible, in most areas. We've also found that cross-functional areas, like quality, are leveraging technology to streamline processes much sooner than regulatory affairs.

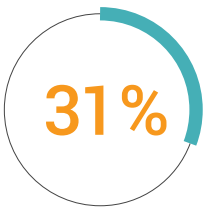


have identified areas where digital technology adds value



have already selected digital technology

already have harmonized global processes across regulatory operations



have a global RIM system in place

Global Compliance

Many device and diagnostics companies do not have oversight of what ultimately goes into the final submission to regional Health Authorities. The correspondence is often manually associated with the submission, making it difficult to track, trend, and leverage any learning from previous pre-market reviews.

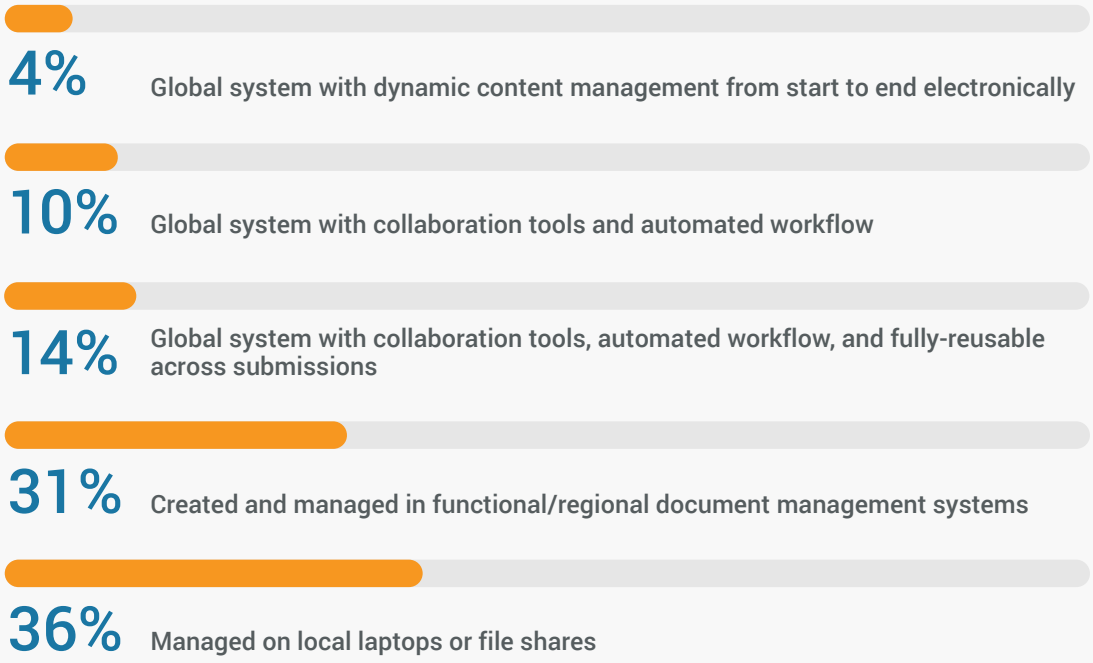
The sharing and re-use of documentation prove to be the primary challenge for medtech organizations in the context of submission and content management, with only 17% of respondents reporting a standardized, automated global process for submissions in place.

Submissions Content Management

More than 66% of respondents still manage submission documents on local laptops, file shares, or regional document management systems, resulting in increased proliferation of content duplication.

Recommendations: Companies can significantly improve content management by leveraging collaboration tools and automating workflows within a global system to create and manage content.

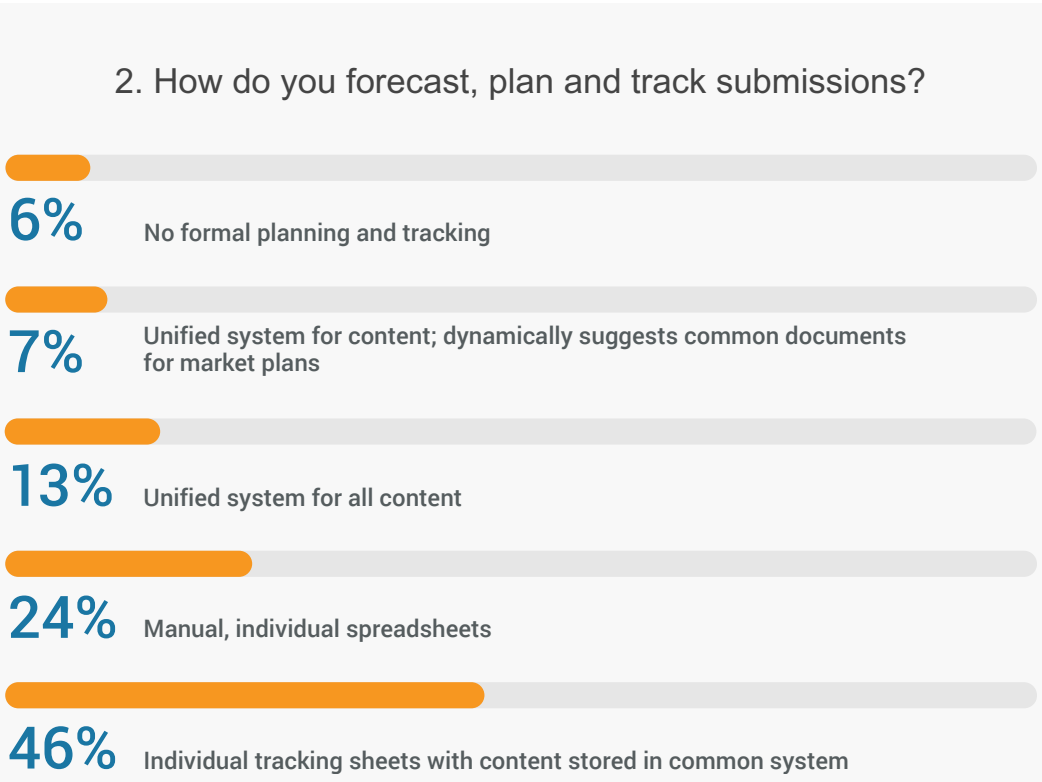
1. How do you create, store and reuse content across submissions?



Submissions Planning and Tracking

The majority of respondents, 76%, still use individual or manual tracking spreadsheets to forecast, plan and track submissions.

Recommendations: Companies can improve submission planning and tracking activities by unifying project management, submission planning, and submission tracking in a central, cloud system.

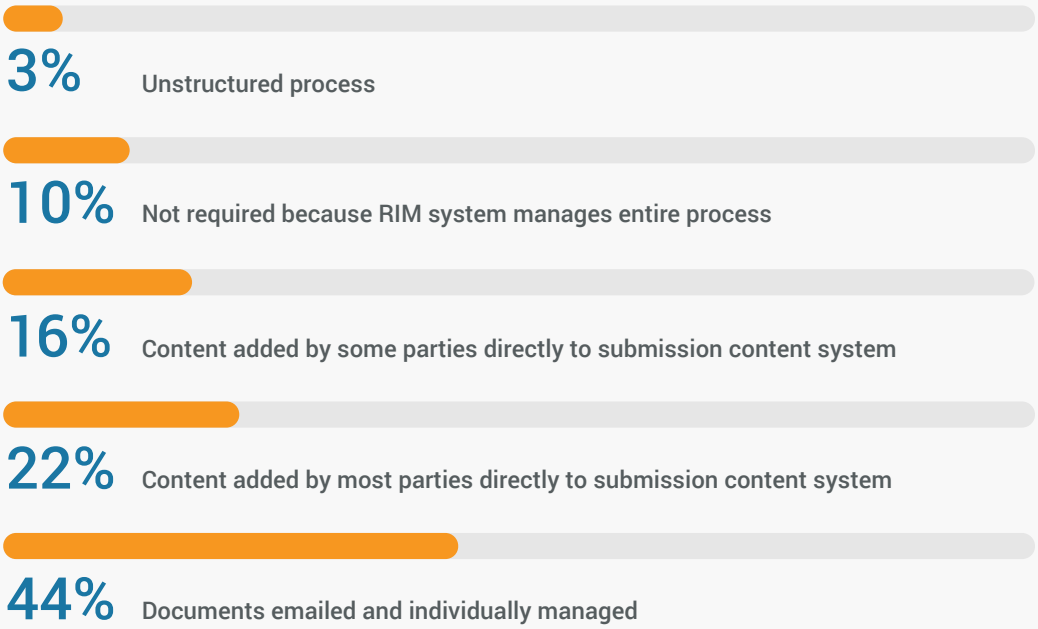


Submissions Production

40% of respondents review, approve and publish submission documents individually via email without a content system in place.

Recommendations: Companies can greatly improve submission compilation practices by establishing a single source of truth for source submission documents and creating a submission compilation workspace dedicated to regulatory affairs.

3. How do you review, approve and publish your submissions?

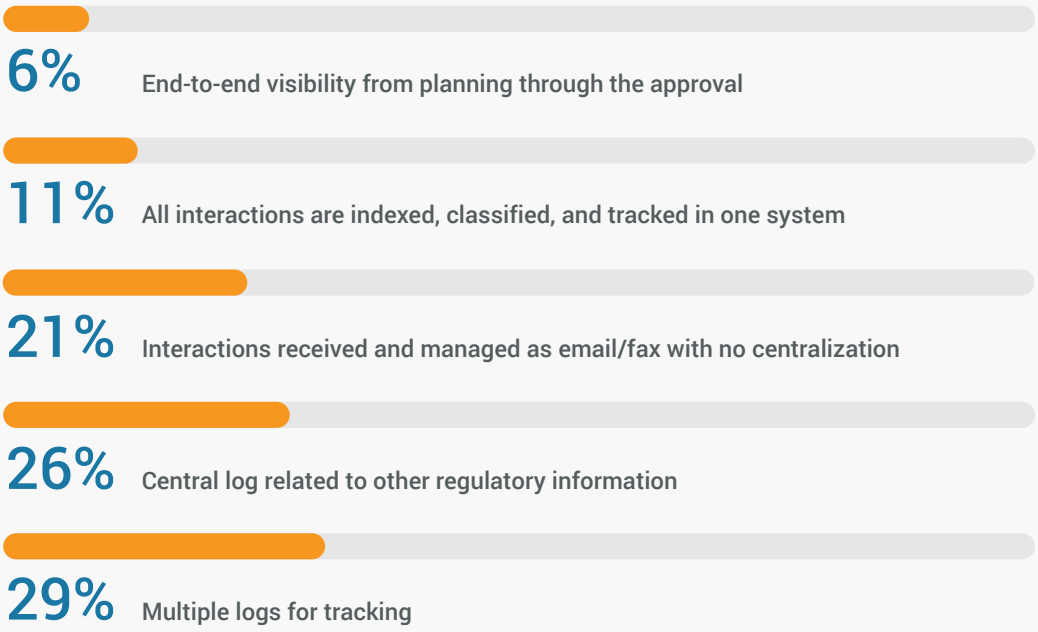


Health Authority Interactions

50% of respondents still receive and manage Health Authority commitments via emails or multiple logs with no common system in place.

Recommendations: Medtech companies can improve maintenance of Health Authority Interaction activities by considering indexing, classifying, and tracking interactions and storing these in context with the relevant submission.

4. How do you manage Health Authority commitments and track responses?

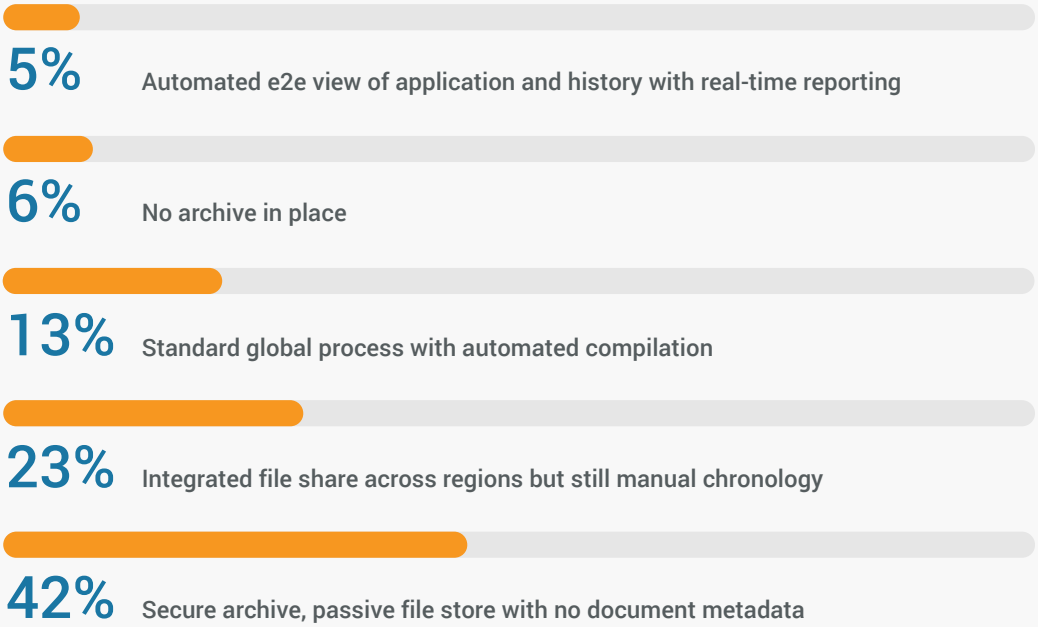


Submissions Archival and Viewing

While the majority (83%) of respondents have an archive to view and manage published output; a mere 18% have established a standard global process with automation.

Recommendations: To improve archiving and viewing historical submissions and related activities in your organization, companies should establish a standardized global process for archiving with the elimination of manual compilation and content duplication.

5. How do you archive and view published output?



Global 24/7 Visibility

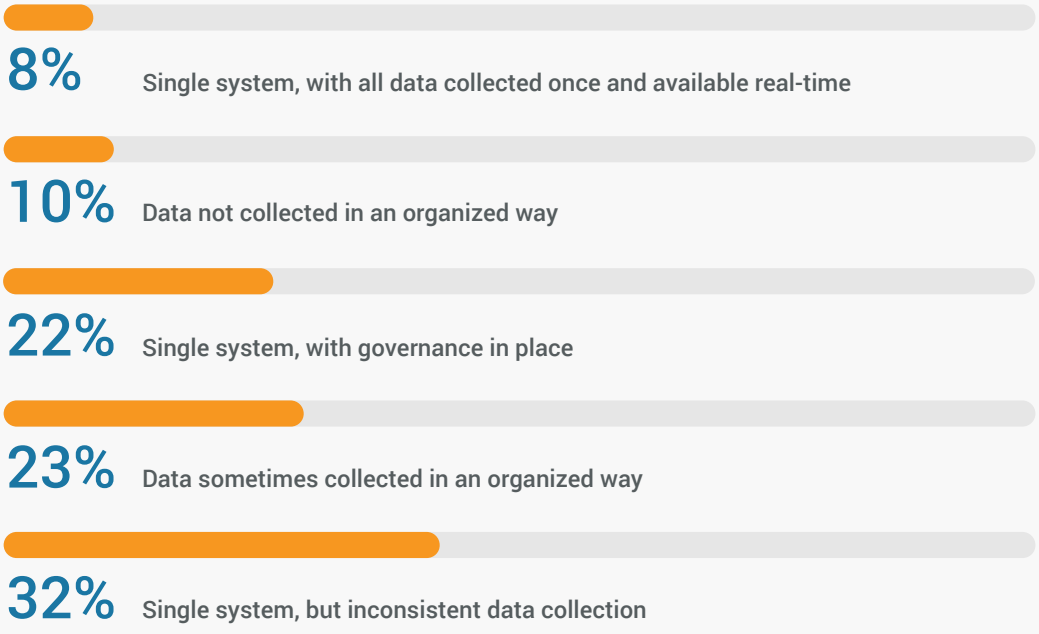
Following Global Compliance, the first focus area for products that are marketed is global 24/7 visibility. This includes the visibility into global product registrations - which products are registered per country - and the ability to report on pre-defined regulatory metrics that provide business insights and form the basis for decision-making.

Registration Tracking

While more than 60% of respondents have a single system to govern and track global registrations; 32% of those companies still experience inconsistent data collection.

Recommendations: To improve product registration tracking and inconsistencies, companies should implement a system and process where operational data is collected once at the source and re-used without recollection, making real-time data readily available through unified reports and dashboards.

6. How do you plan and track your global registrations?

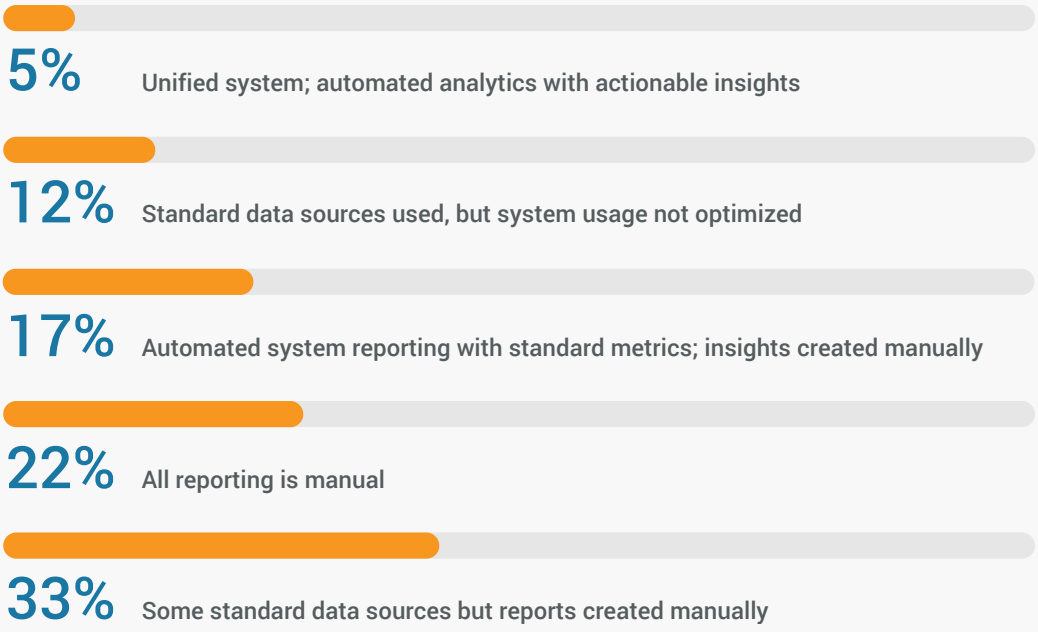


Metrics and Reporting

55% of respondents still create performance and KPI reports manually; with an additional 12% reporting that standard data sources are used but usage is not optimized.

Recommendations: To improve tracking metrics and report current regulatory status, companies should establish automated reporting from a system with standard metrics that provides analytic tools with actionable insights.

7. How do you track performance?



Speed to Market

Speed to market is critical for competitive advantage. It is also the area where regulatory teams are often challenged most as, to date, they are still considered the "last hurdle to the market" in many organizations. Having a centralized system in place increases the end-to-end visibility of regulatory operations and enables regulatory affairs to glean insight and gather necessary data information faster.

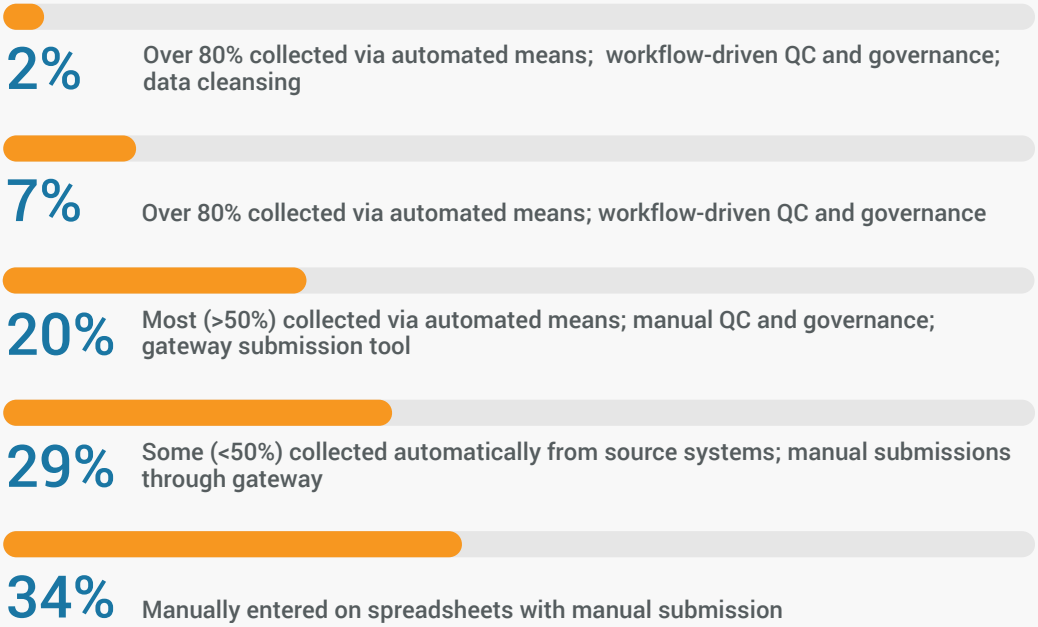
Data Governance

The majority of respondents (63%) report they are still using manual processes for regulatory submissions; 34% of which enter data manually using spreadsheets and the other 29% indicating manual submissions through a gateway.

Recommendations: Companies can significantly improve data governance by automatically collecting the vast majority of the data, supporting a workflow-driven QC and governance.

8. How do you collect and translate data into usable information?

(e.g. trends distilled from HA inquiries)

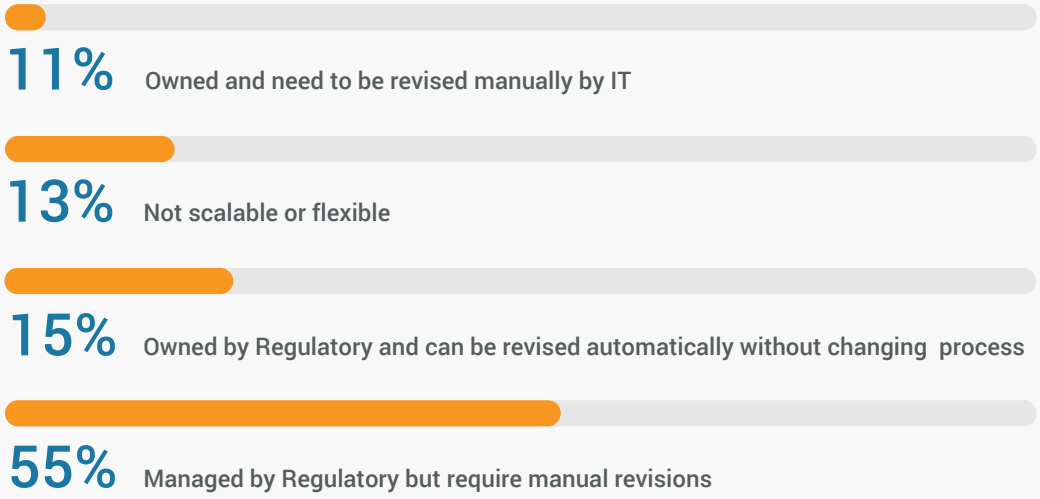


Flexibility and Scalability

The vast majority of respondents (79%) manually revise regulatory processes, 13% of which report complete process unscalability, potentially resulting in challenges when the company grows into other regions and countries.

Recommendations: Companies can improve flexibility and scalability by leveraging tools that can be revised automatically to support any change in scope without changing the process to scale up or down.

9. How flexible/scalable are your regulatory processes?

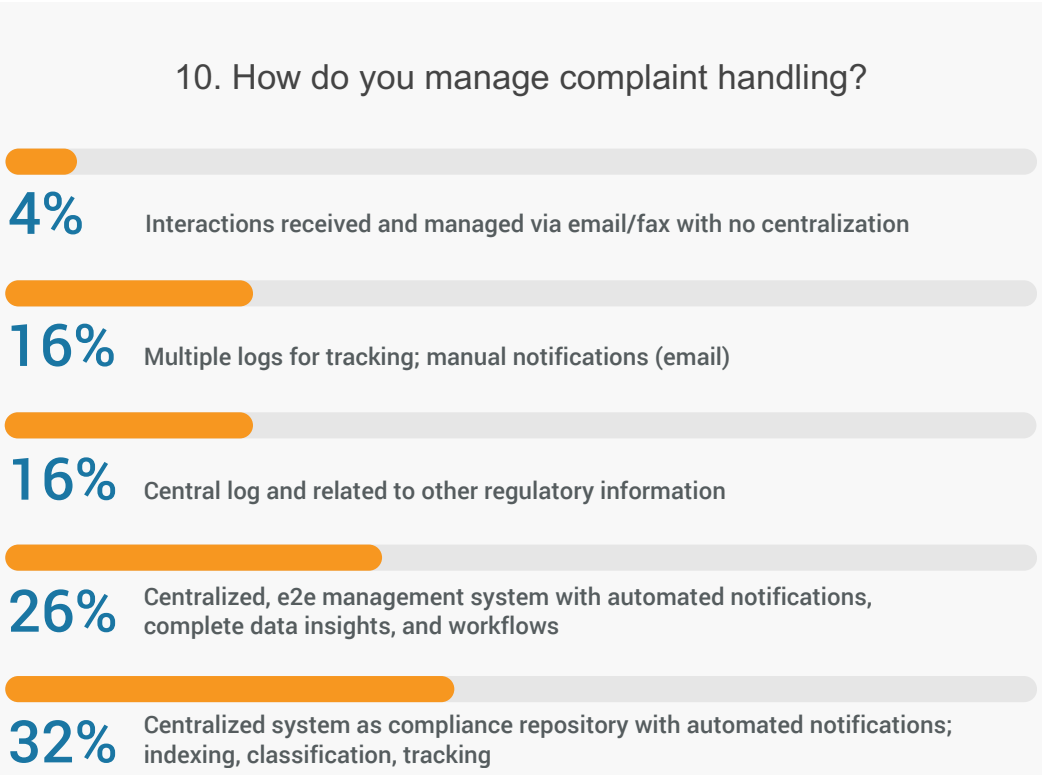


Post-Market Compliance

Post-market compliance is one of the key areas through which MedTech manufacturers ensure their products are safe, high-quality, and used correctly. Post-market compliance has already received a lot of scrutiny from regulatory authorities and will continue to increase under the new EU Medical Device Regulation (MDR) and EU In Vitro Diagnostic Regulation (IVDR). Our study focused on a few sub-elements of post-market compliance; vigilance reporting, trending and signaling, and change control.

Vigilance Reporting

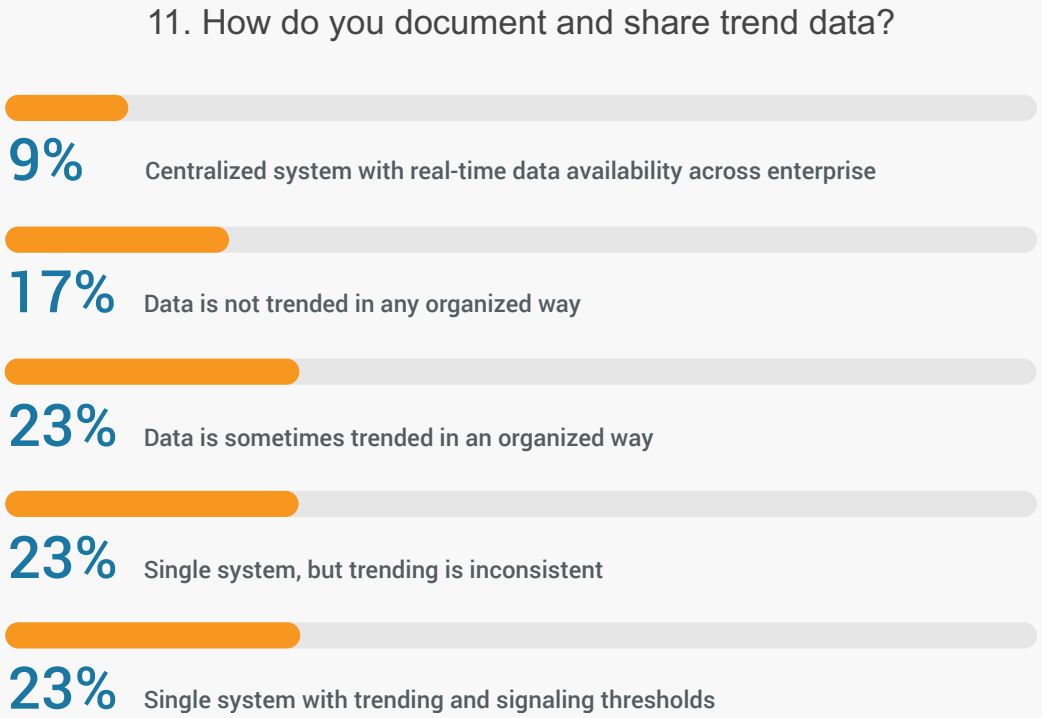
74% of respondents use a centralized log or system to manage the end-to-end complaints handling process, indicating steady progress towards unified compliant management.



Trending

64% of respondents indicate some level of inconsistency in data sharing through trending, 17% of which said data does not trend in an organized way at all.

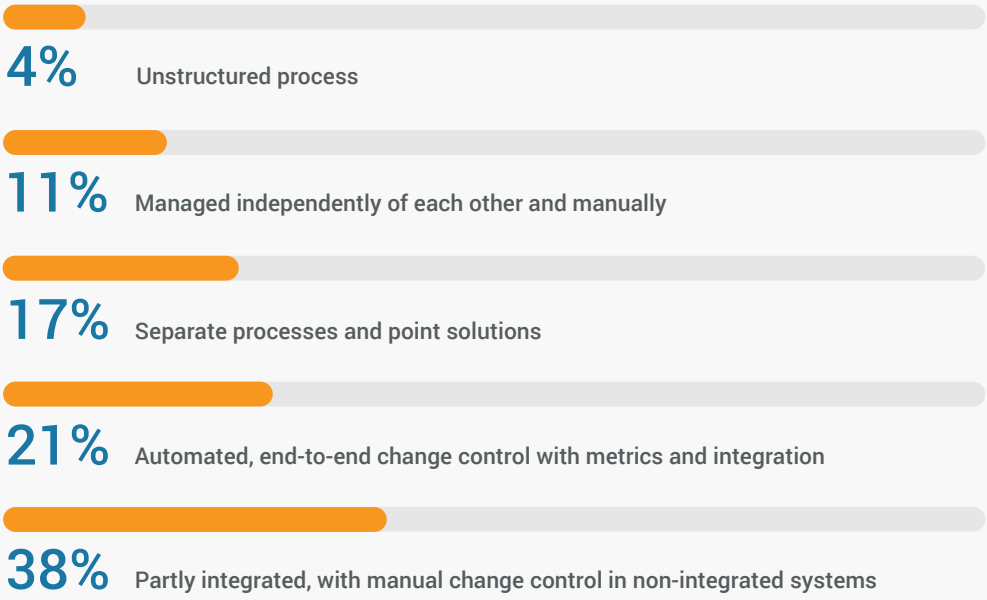
Recommendations: To improve trending, companies should consider setting trending and signaling thresholds that are leveraged in a single system. This would enable data to be collected once, in real-time, and consistently at the source.



Change Control

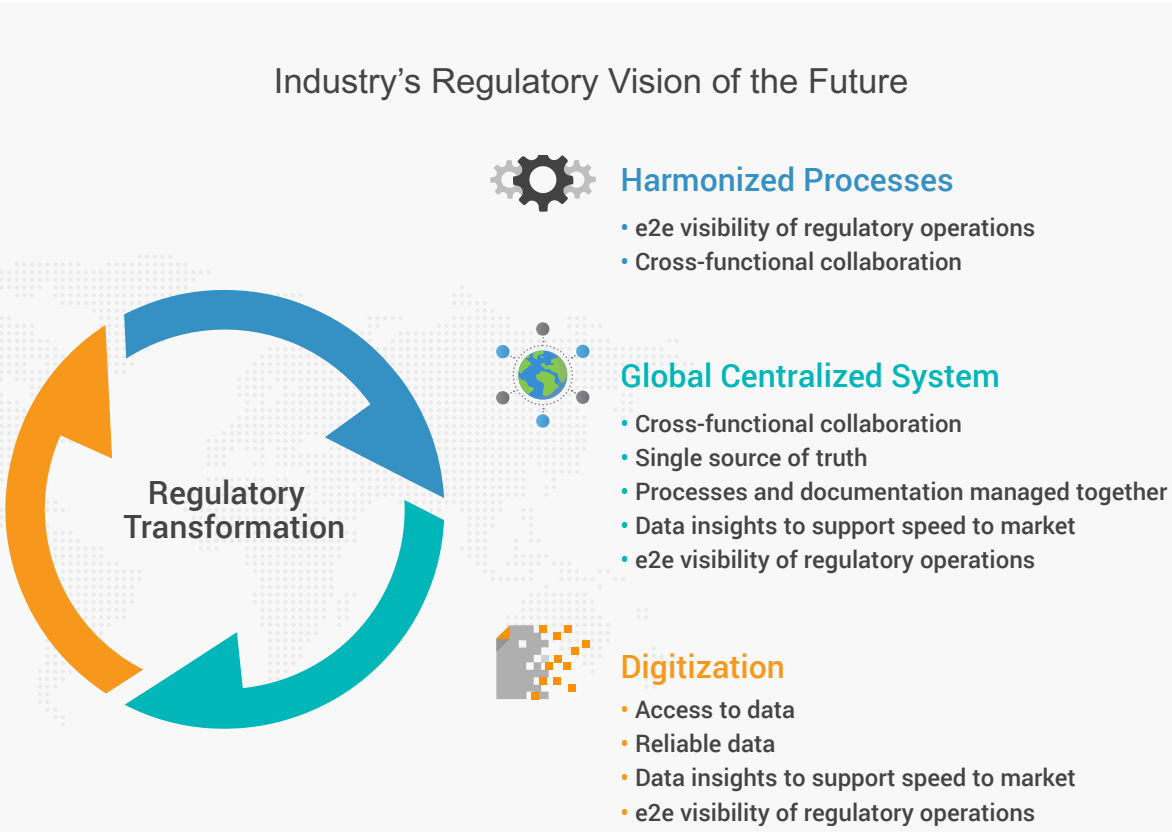
59% of respondents either partly integrated or completely automated the change control processes across quality and regulatory departments, allowing consistent data collection and proactive complaints management with an end-to-end view.

12. How do manage change control processes across quality and regulatory?



Industry's Regulatory Vision of the Future

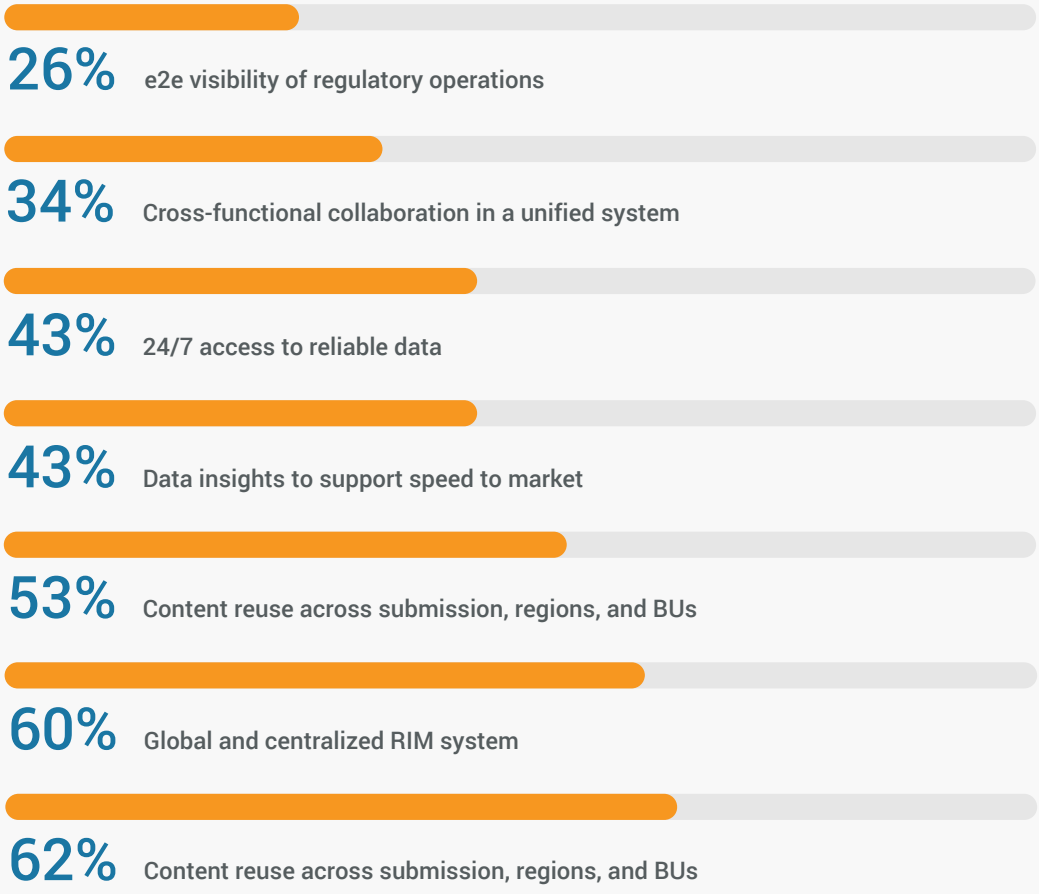
Post-market compliance is one of the key areas through which MedTech manufacturers ensure their products are safe, high-quality, and used correctly. Post-market compliance has already received a lot of scrutiny from regulatory authorities and will continue to increase under the new EU Medical Device Regulation (MDR) and EU In Vitro Diagnostic Regulation (IVDR). Our study focused on a few sub-elements of post-market compliance; vigilance reporting, trending and signaling, and change control.



Finally, the future vision is to have processes and documentation managed together for visibility in market approvals and submission changes throughout the product development lifecycle. To turn this vision of regulatory transformation into reality, many device manufacturers have put things in motion in their respective organizations, with 62% of respondents having already selected technology solutions to harmonize global processes across regulatory operations.

When asked which regulatory areas (multiple selection) respondents saw the industry prioritizing over the next two years — a globally centralized RIM system (60%) and a single source of truth for regulatory information (62%), scored the highest.

13. Which regulatory areas do you see the industry modernizing in the next two years?



Conclusion

This research shows that modernizing regulatory operations is a top priority for improving the access and quality of data to maintain compliance, decreasing the cost and impact on valuable resources.

The more reliable regulatory data, the more insights organizations can glean from it, enabling speed to market. The sooner regulatory affairs can identify which information is needed for commercialization in each target market, the sooner they can start collecting the appropriate data.

Having a centralized system in place also increases the end-to-end visibility of regulatory operations. It increases the ability to respond quickly to internal and external events that impact submission documentation and registrations.

The ability to move quickly also increases when cross-functional collaboration between regulatory, quality, R&D, and other functional teams is enabled through a centralized system. That would allow regulatory affairs to be proactive rather than reactive, allowing teams to focus on value-add activities rather than administrative tasks.

The centralized system also functions as a single source of truth to support consistent use and re-use of content, allowing for efficiency gains and reducing compliance risks. With increased scrutiny from regulatory authorities regarding the consistent use of content and information across documentation, reports, and other assets, having a single source of truth is vital for medical device and diagnostics organizations across all functions. Modernization across functional areas will drive speed to market, faster revenue generation, and competitive advantage.

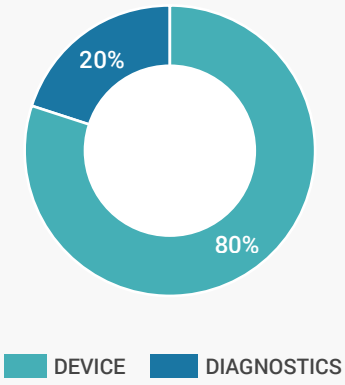
Survey Methods

The research consisted of 14 questions, some of which included sub-questions with response metrics. The survey questions were designed for medtech professionals with knowledge of regulatory operations processes and full responsibility for regulatory operations within their organizations. Completion of the survey was voluntary. All participants were offered a complimentary copy of a report upon the study's completion if indicated. No other compensation was offered or provided.

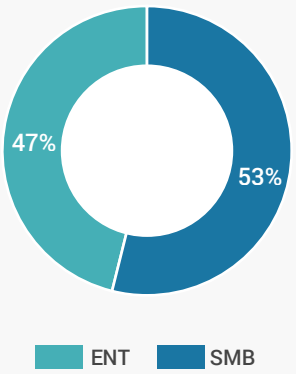
Survey Respondents

Of approximately 2,775 individuals invited to take the survey, a total of 94 surveys were initiated, yielding 92 qualified responses.

Type of organization



Organization business size



Region