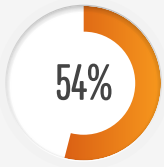
2022 Year-end Regulatory Benchmark Report

The Veeva MedTech 2022 Year-end Regulatory Benchmark Report examines the medical device, diagnostic, and digital health industry's progress towards modernizing regulatory operations by gathering the experiences of regulatory affairs professionals from nearly 100 medtech organizations around the globe, ranging from enterprise to midsize businesses. The study explores how medtech companies manage global compliance and visibility, speed to market, postmarket, and regulatory modernization.

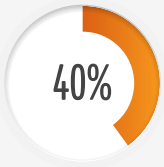
Although the research primarily focused on regulatory affairs, some learnings from this report may also be relevant to quality professionals.

Executive Summary

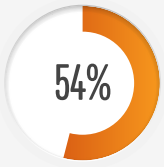
Findings show the medtech industry is continuing to modernize regulatory affairs. Many organizations have initiatives in place to harmonize the function across divisions and geographies where they have typically been siloed.



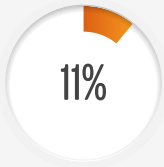
identified areas where digital technology adds value



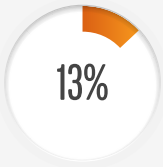
selected digital technology



harmonized global processes across regulatory operations



have a global RIM system



implemented a digital global RIM system for end-to-end regulatory management

While 54% of respondents indicate having harmonized processes across global regulatory operations, we still see medtech companies using manual processes, disconnected data, and siloed systems, that are neither scalable nor flexible, in most areas.

Year-Over-Year Progress

When comparing the results from 2022 to 2021, there are a few key areas in which we see positive shifts from industry including global data collection, content reuse, file sharing, and unified systems for submissions.

2021 **2022**

report that they collect global registration data in a single system, with all data collected once and available real-time

2021 **2022**

state that global content reuse across submissions, regions, and business units is an area where they see industry modernizing in the next two years

2021 **2022**

report that they have an integrated file share across regions to archive and view published submission output

2021 **2022**

now have a standard global process for archiving with automated compilation

2021 **2022**

indicate having a unified system for forecasting, planning, and tracking submissions

Though we see growth in these areas across the industry, a majority of companies continue to rely on outdated, manual, duplicative, and error-prone processes in key areas. It is crucial for the medtech industry to focus on leveraging technology and modernizing processes to ensure compliance and increase speed to market.

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, or leverage any insights from previous pre-market reviews.

The sharing and re-use of documentation proves to be the primary challenge for medtech organizations in the context of submission and content management, with only 16% of respondents reporting a standardized, automated global process for submissions.

Submissions Content Management

More than 37% of respondents still manage submission documents on laptops, file shares, or regional document management systems, resulting in increased proliferation of content duplication. A mere 1% report having dynamic content managed from start to end electronically.

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

- 37% All documents are managed on local laptops and/or file shares
- 33% Documents are created and managed in functional/regional document management systems
- 16% Content managed in a global system with collaboration tools, automated workflow, and fully-reusable across submissions
- 8% Content managed in a global system with collaboration tools and automated workflow
- 1% Content is dynamic and driven by a global system, managed from start to end electronically
- 5% None of the above

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

This improves efficiency in the management of global registrations and ensures accuracy of content reused across multiple submissions. It also streamlines the workflow and access to data in submissions by multiple stakeholders, including in-house regulatory teams, consultants, and distributors.

Submissions Planning and Tracking

The majority of respondents, 66%, still use individual or manual tracking spreadsheets to forecast, plan, and track submissions. While this is an improvement over 2021 – 76% were manually tracking – there is still significant room for improvement.

2. How do you forecast, plan, and track submissions?

- 33% Individual tracking sheets are used, but content is stored in a common system
- 33% Manual individual spreadsheets
- 16% Unified system used for all content
- 7% No formal planning and tracking
- 5% Unified system used for all content; system dynamically suggests common documents into local market plans
- 6% None of the above

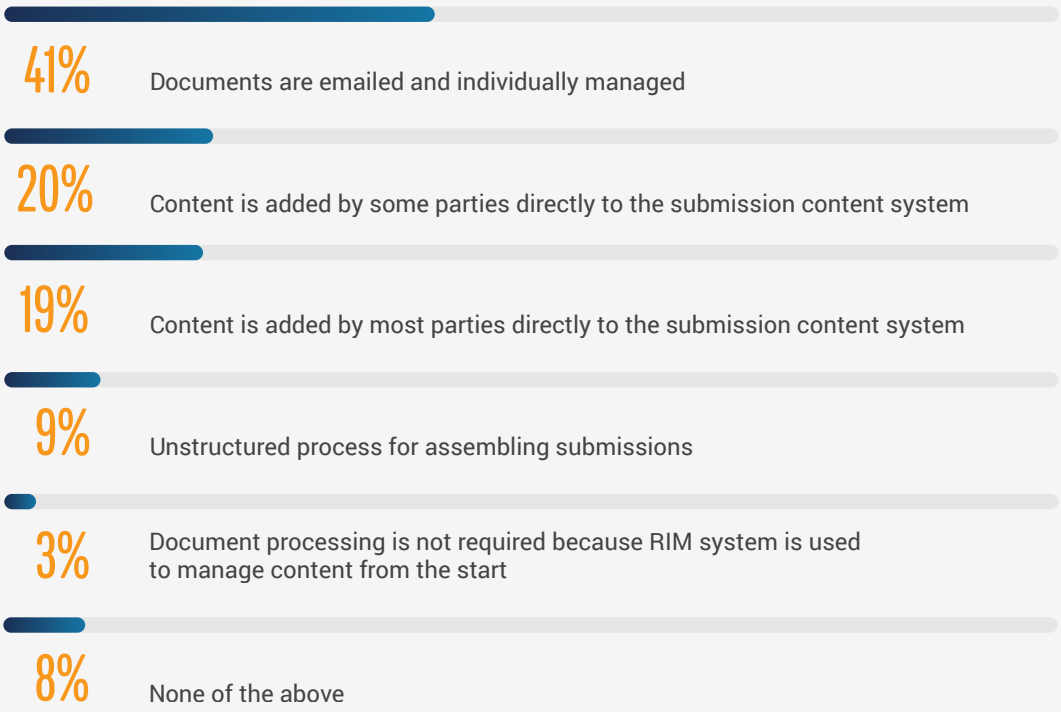
Recommendations: Leveraging a single, unified system to manage submissions planning and tracking will drive efficiency across regulatory, ensuring compliance and allowing the team to focus on other activities.

Submissions Production

Submissions production has remained nearly flat year-over-year – 41% of respondents (versus 40% in 2021) indicated they review, approve, and publish submission documents individually via email without a content system in place.

This approach can lead to unnecessary and expensive reworks due to data inconsistencies. In addition, difficulties accessing data on the part of multiple stakeholder groups routinely delay submission timelines and ultimately time to market.

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



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. This drives efficiency for all parties involved in the submissions process and reduces the risk of error.

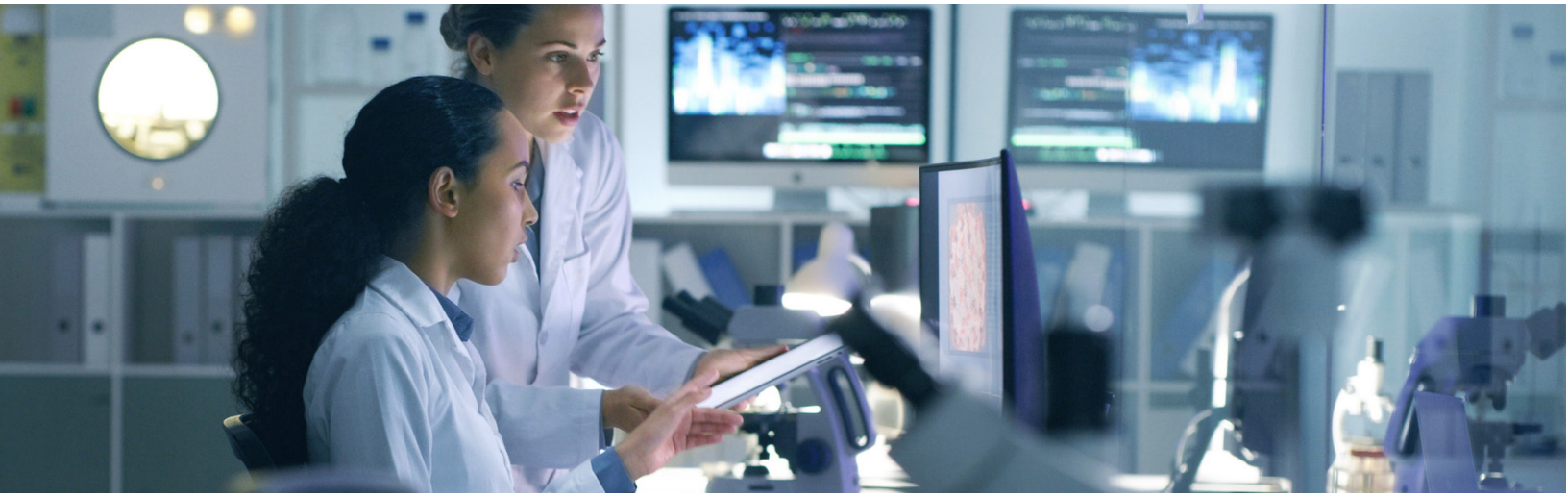
Health Authority Interactions

A startling 58% of respondents either still receive and manage Health Authority commitments via email with no central repository or maintain multiple logs. Without a common system in place, medtech companies risk losing track of interactions, missing deadlines, and allowing compliance issues to slip under the radar.

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

- 33% Multiple logs are used for tracking
- 25% Interactions are received and managed as email/faxes with no centralization
- 21% A central log is used and related to other regulatory information
- 11% All interactions are indexed, classified, and tracked in one system
- 3% There is end-to-end visibility of the entire process from planning through approval
- 7% None of the above

Recommendations: Medtech companies can improve maintenance of Health Authority Interaction activities by implementing a central repository for indexing, classifying, and tracking interactions and storing documents in context with the relevant submission.



Submissions Archival and Viewing

While we see a fairly even split between the archive being a secure, passive file store with no document metadata (35%, down from 42% in 2021) and the archive being an integrated file share across regions but still using manual chronology (31%, up from 23% in 2021), a mere 15% (up from 13% in 2021) have established a standard global process with automation.

5. How do you archive and view published output?

35% Archive is a secure, passive file store with no document metadata	6% Automated end to end view of application knowledge and history; with real-time reporting
31% Archive is an integrated file share across regions but still manual chronology	5% No archive in place
15% Standard global process for archiving with automated compilation	8% None of the above

Recommendations: The lack of automated and secure archiving with real-time file sharing leads to inefficient methods of sharing data with internal stakeholders and introduces information security risks when sharing data externally.

To improve archiving and historical submissions record and activity retrieval, companies should establish a standardized, global process and use technology to automate to eliminate manual compilation and content duplication.

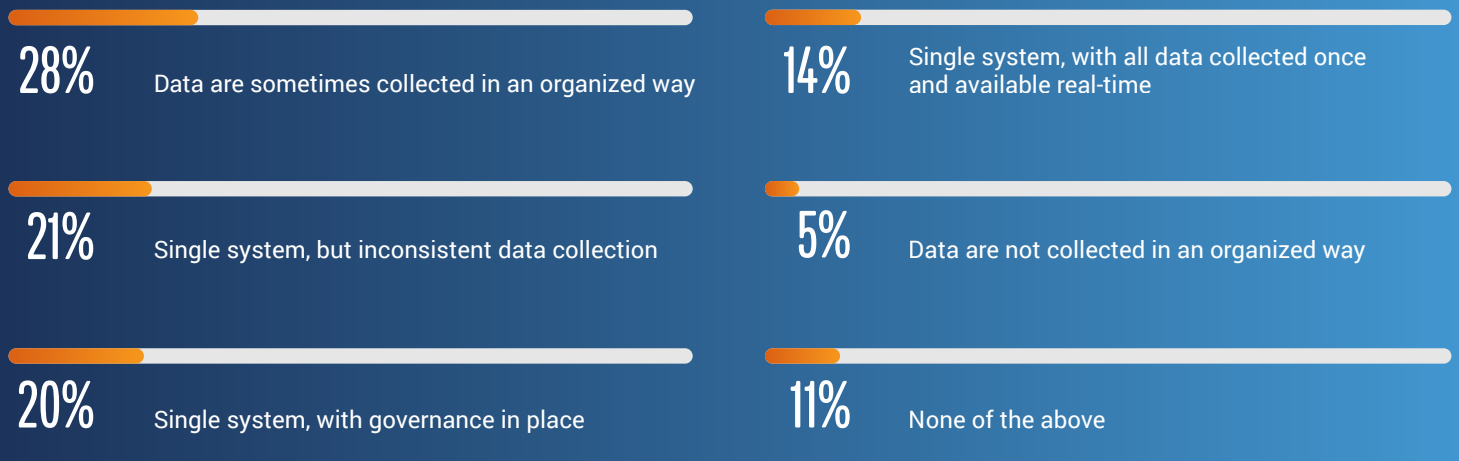
Global 24/7 Visibility

Following global compliance, the first focus area for products that are marketed is global 24/7 visibility. This includes 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 55% of respondents have a single system to govern and track global registrations, 21% of those still experience inconsistent data collection. The remaining 34% of respondents only sometimes collect data in an organized way or still lack an organized collection process.

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



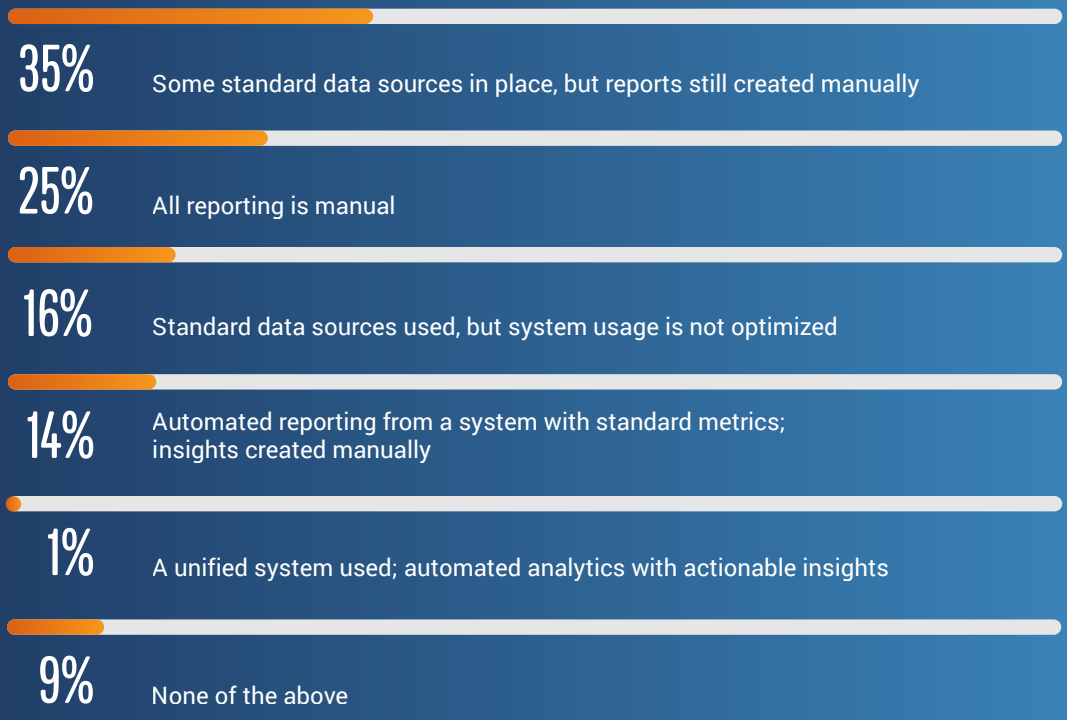
Recommendations: To improve product registration tracking and ensure accurate data is available, medtech companies should implement a system and processes where operational data is collected once at the source and reused without re-collection, making real-time data readily available through unified reports and dashboards.

These improvements provide better visibility to product registration status (e.g., does this product have approval to ship in a given market?) and easy, quick access for all stakeholders to critical data. A centralized system also provides a single source of truth for data required to assess product change impacts.

Metrics and Reporting

35% of respondents (33% in 2021) have some standard data sources. An additional 16% (12% in 2021) report that standard data sources are used but usage is not optimized. A mere 1% report having a unified system with actionable insights.

7. How do you track your performance and KPIs?



Recommendations: A system with standard metrics providing automated analytics tools with actionable insights is crucial for medtech organizations to ensure overall organization health in key areas. These include the ability to quickly identify issues and delays in regulatory processes and streamlined processes for reporting and metrics review.

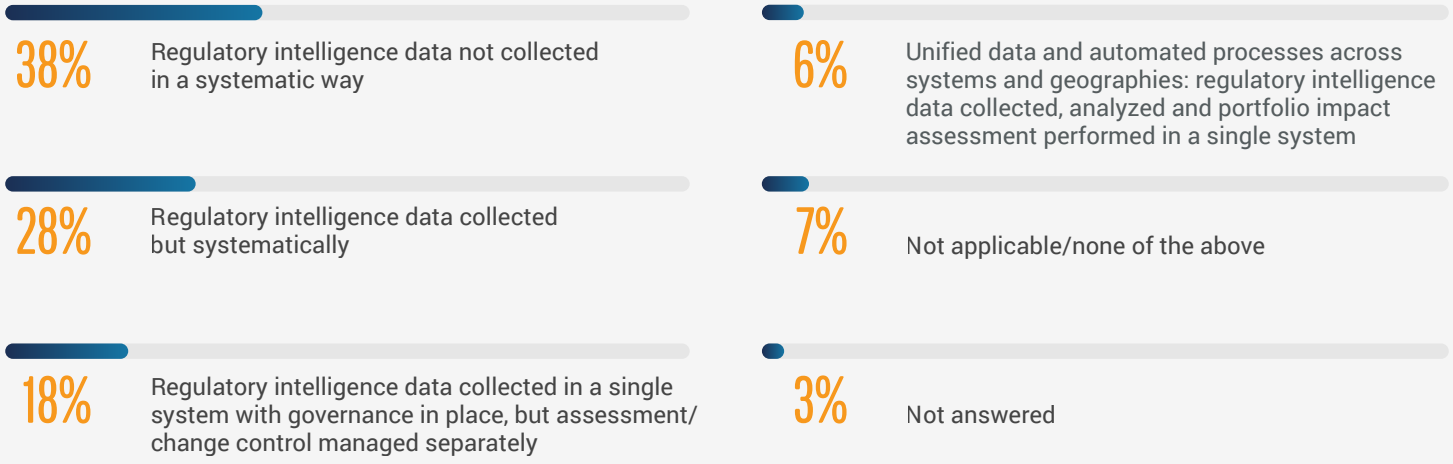
Speed to Market

Speed to market is critical for competitive advantage. It is also the area where regulatory teams are often challenged most as they are still considered the "last hurdle to the market" in many organizations. Additionally, with the increasing amount of changes in the global regulatory landscape, the need for accessing and managing data such as UDI and regulation changes has never been more important. 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 – Regulatory Intelligence

A significant percentage of respondents (38%) report that regulatory intelligence data is not collected in a systematic way. Only 6% of respondents have unified data and automated processes across systems and geographies. This data is becoming more and more important across medtech to make meaningful decisions about the product portfolio and ensure continued compliance of all products on the market.

8. How do you currently manage your regulatory intelligence data/regulatory requirements for each of your target markets?



Recommendations: Companies can significantly improve the regulatory intelligence workflow (data collection and analysis) by utilizing a single system to both capture and systematically analyze the data. This allows companies to immediately assess the impact of a regulation change on the product portfolio and take necessary actions to ensure continued product compliance or modify marketing status.

Data Governance – UDI

When evaluating the Unique Device Identification (UDI) data, we see there is somewhat of a split between how the data attributes are collected and managed. 51% of respondents collect UDI data from multiple data sources; however 21% of those respondents don't have a governance structure in place once that data is collected. Only 8% have global UDI data attributes imported and processed in a single scalable data management platform with an electronic machine-to-machine export/submission method. Slowness to collect and centrally store global UDI data slows the ability of companies to register UDI data and assess the impact of product changes to UDI attributes.

9. How do you manage all the data required for your UDI submissions globally?

30% Global UDI data attributes imported from multiple data sources and processed into a single system with a governance structure in place to ensure high data quality

Export/submission managed manually

17% Global UDI data attributes not collected in a central way

Affiliates in each affected geographies are responsible to manage their data

21% Global UDI data attributes collected from multiple data sources (PLM, MasterData, ERP) without a governance structure in place

8% Global UDI data attributes imported and processed in a single scalable and flexible data management platform, with an electronic machine-to-machine export/submission method

20% No processes or procedures in place to gather UDI data and manage submission

4% Not answered

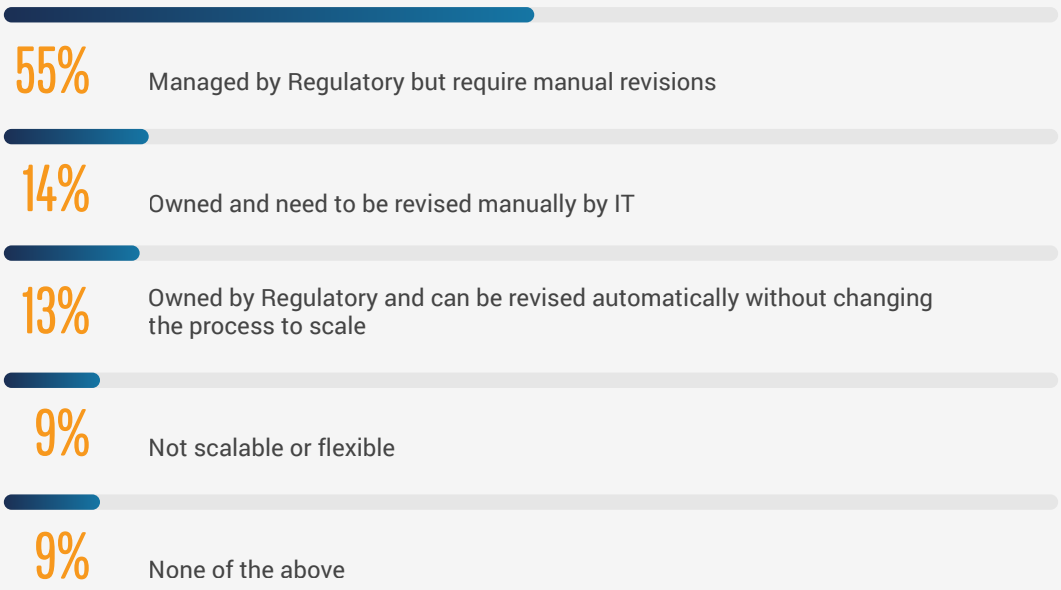
Recommendations: Companies can significantly improve the UDI data management workflow by implementing a single system that contains all the UDI data attributes and can scale to manage the end-to-end workflow from initiation to change assessment to end of life.

Flexibility and Scalability

The vast majority of respondents (55%) still manually revise regulatory processes, which remains flat from 2021. Nine percent report a lack of process scalability, resulting in potential challenges during periods of growth, especially into additional regions and countries.

10. How flexible and scalable are your regulatory processes?

(For example, if your company grows and expands into other regions/countries, can the regulatory activities scale with that growth?)



Recommendations: Medtech companies can save significant time, improve compliance, and increase speed to market by leveraging scalable technology. Implementing tools that are flexible and scalable enough to support changes in scope, without having to change the process, is a must-have.

Postmarket Compliance

Postmarket compliance is one of the key areas in which medtech manufacturers ensure their products are safe, high-quality, and used correctly. Postmarket 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 postmarket compliance; vigilance reporting and change control.

Postmarket Reporting

38% of respondents have data in a centralized location for postmarket reporting, but the information is still gathered manually. While only 5% have information presented proactively in predefined outputs from enterprise systems. In addition to the risk posed by these practices to postmarket reporting compliance, quickly accessible postmarket data remains one of the most critical sources of timely insight into the safety and efficacy of a company's currently marketed product portfolio.

11. How do you coordinate, gather, and compile information required for periodic reports like the Post Market Surveillance Report (PMSR), Periodic Safety Update Report (PSUR), and Post Market Clinical Follow-up (PMCF) Report?

- 38% Processes or procedures are in place and information is gathered manually and stored in a central location
- 22% Processes or procedures are in place and information is gathered manually and stored locally
- 18% Processes or procedures are in place and information is made available through queries of enterprise systems
- 12% No processes or procedures in place to gather information for periodic reports
- 5% Processes or procedures are in place and information is presented proactively in predefined outputs from enterprise systems
- 5% Not answered

Recommendations: To improve efficiency and speed with developing and submitting periodic reports used for postmarket surveillance companies should consider implementing an enterprise system that can proactively present data required for submission to health authorities. This would enable data to be collected in real-time, and consistently at the source, ultimately leading to more efficient development of periodic reports.

Change Control

53% 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.

Only 13% of respondents have an automated end-to-end change control process with metrics and integration across regulatory and quality. The remaining 83% have partial integrations, point solutions, or manual processes. This introduces risk of ineffectively assessing changes to product portfolio, leading to potential compliance issues. In addition, inefficient processes for assessing and processing product changes lead to rework and slow the ability of companies to adapt to regulation changes, engineering design changes, postmarket insights, etc.

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

- 40% Partly integrated, with manual change control across Quality and Regulatory in non-integrated systems
- 26% Separate change control processes for documents, process, and product changes managed in point solutions
- 13% Automated end-to-end change control with performance metrics and integration across external and internal stakeholders
- 13% Change controls are managed independently of each other and manually
- 1% Unstructured process
- 7% None of the above

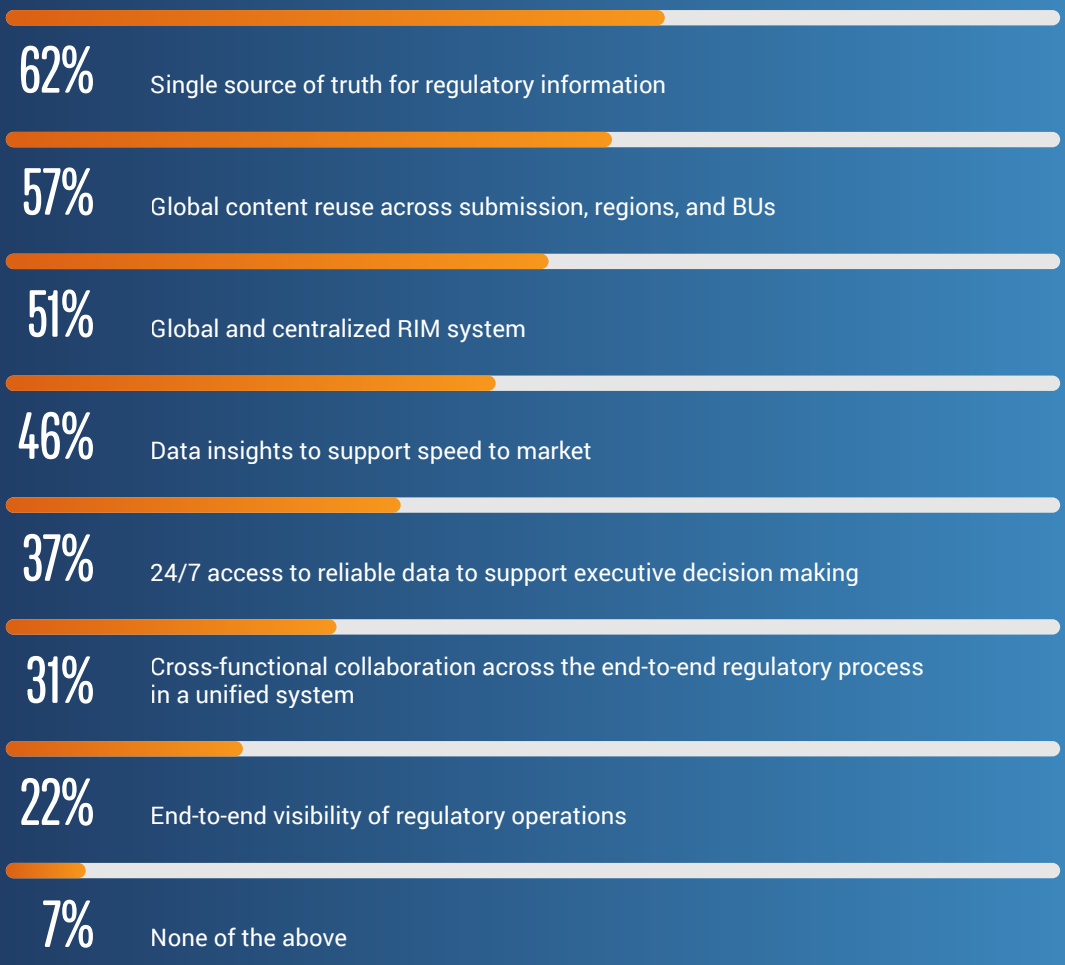
Recommendations: To improve the speed and efficiency with which change assessments are conducted, it is recommended that organizations implement a system capable of managing the end-to-end lifecycle of a change assessment. This would allow for a single source of truth for change control visibility, assessment, and impact as well as the ability to derive metrics and KPIs around the change control process.

Regulatory Vision of the Future

Finally, the future vision of the medtech industry is one in which processes and documentation are managed together for visibility in market approvals and submission changes throughout the product development lifecycle. Many medtech manufacturers are working to make this vision a reality – 62% of respondents have already selected technology solutions to harmonize global processes, provide access to a global RIM system, establish a single source of truth, and integrate regulatory intelligence processes across their organizations.

When asked which regulatory areas (multiple selection) respondents saw the industry prioritizing over the next two years – a globally centralized RIM system (51%) 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

The 2022 year-end research shows that modernizing regulatory operations remains a top priority for improving the access and quality of data. These efforts are crucial to maintain compliance and decrease the cost and impact on valuable resources.

The more reliable regulatory data becomes, 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.

A centralized RIM 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.

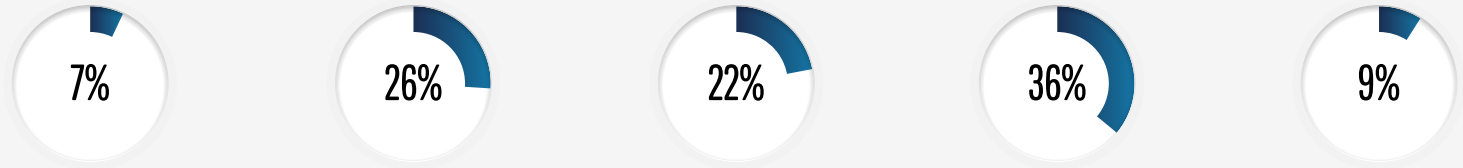
Survey Methods

The research consisted of 15 required core questions, some of which included sub-questions, along with additional optional demographic questions. 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 contact information was provided for delivery of the report.

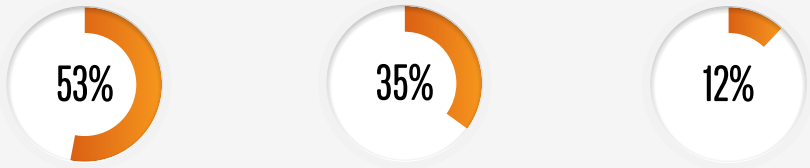
Survey Respondents

134 survey responses were initiated, yielding 100 qualified responses (i.e. completed surveys from professionals currently employed in a regulatory or quality function at a medical device, diagnostics, or therapeutics manufacturer).

What size is your company (global revenue in USD)?



Where is your global headquarters located?



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Veeva MedTech provides purpose-built solutions to unify the total product lifecycle, from ideation to commercialization, for medical device, diagnostics, and therapeutics companies.

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