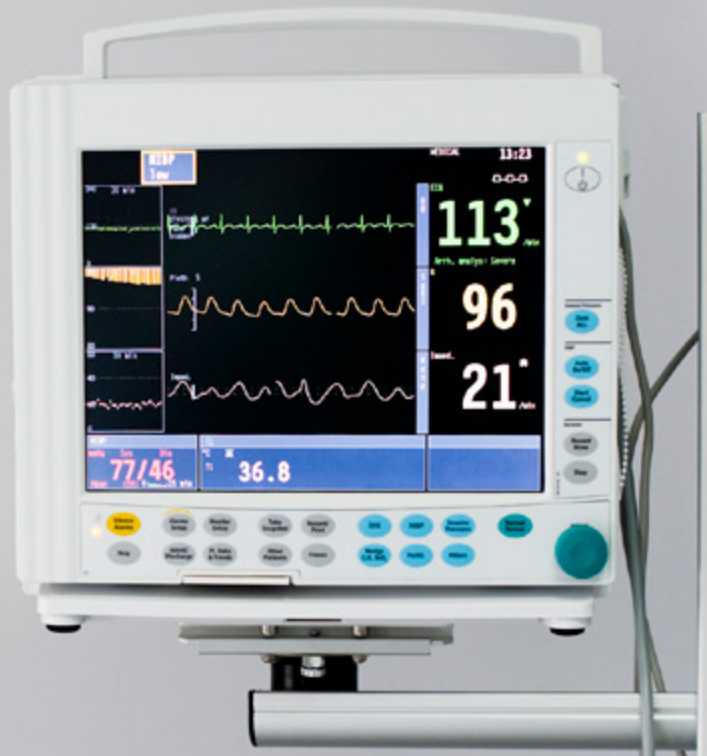
Operational transformation within the Regulatory Affairs function of medical device companies

Key insights and opportunities to unlock additional value by streamlining Regulatory Affairs operational activities



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Medical device companies are facing an increasingly complex and evolving global regulatory environment, driven by factors such as globalization and patient safety concerns. Manufacturers are consistently trying to balance regulatory requirements with commercial viability of products, in addition to taking advantage of unprecedented opportunities to better serve patients with innovative products. Regulatory Affairs in medical device companies play a pivotal role in balancing these competing priorities. An efficient and strategic Regulatory Operations function is critical to addressing the challenges and opportunities within the industry.

KPMG's survey of global medical device companies provides insights into the maturity and readiness of Regulatory Operations teams to drive additional value in their organizations. While it is now common for companies to have a Regulatory Operations function, the survey indicated that many still have a long way to go to drive operational transformation within their regulatory teams. Gaps remain related to roles and responsibilities, governance, metrics, and adoption of digital technologies.

About the survey

KPMG conducted a survey of leading medical device companies. The survey was designed to provide industry participants with collective insight into some of the trends in this Regulatory Operations area. In total, 13 companies participated in the survey, a majority of which were larger companies (greater than $5B revenue).

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Organizational design and responsibilities

Most major medical device companies have established a Regulatory Operations group, but the roles and responsibilities of these groups are not consistent across the industry. Further, in many cases, they are still focused on administrative support (e.g., system oversight) rather than more direct product value chain functions (e.g., submission publishing). There is an opportunity for Regulatory Operations groups to move quickly up the maturity curve and provide a greater impact to the broader organization.

1. 85% of companies surveyed have established a Regulatory Operations group.

2. A majority of these groups comprise 25 FTEs or less (69% of those surveyed).

3. Regulatory Operations groups vary in their levels of maturity: the most common responsibilities include system oversight, data management, and metrics management, while areas like submission publishing and submission archiving are lower in maturity.

Technology

Most medical device companies have foundational systems of record to manage regulatory data and documents and are actively working to improve these capabilities. However, the portfolio of these solutions is still inconsistent across the industry, and there are ongoing challenges when it comes to global adoption of the tools across all business units and geographies. There are significant opportunities for both companies and vendors to mature Regulatory technology solutions for medical device companies and utilize technology to drive transformation in this space.

1. A majority of companies have some formal instances of Regulatory Information Management (RIM) (77%) and Document Management systems (85%), but the scope and usage of these systems can vary across business units and geographies.

2. The solution vendor landscape is very fragmented – a wide variety of systems/tools are being used by the companies surveyed, with no clear market leader in any Regulatory Affairs (RA) system category.

3. The technology approach is still evolving – a majority of companies surveyed indicated plans to make a change to their RIM (62%) or Document Management (54%) capabilities in the next 12 months.

Governance and metrics

Medical device companies are actively capturing metrics for the Regulatory Affairs function, many of which are focused on volume of activity and compliance-related activities. However, many organizations are challenged when it comes to utilizing metrics to capture the value generated by the function, e.g., bringing products to market more quickly or increasing the productivity of the broader organization. There is an ongoing opportunity to further leverage metrics to articulate the value and criticality of the Regulatory Affairs organization, and more specifically the Regulatory Operations function.

1 There are a wide variety of metrics being collected by Regulatory Operations teams, but minimal consensus on key metrics, apart from submission volumes (69%).

2 Data governance approaches seem to be still maturing: the only activity reported by a majority of companies was reoccurring training (69%), whereas process audits (46%), data audits (38%), and standard data models across systems (31%) were less common.

Background on survey demographics

The survey was conducted in December 2018. Participating companies varied in size from small to large, but a majority (62%) were larger companies (>$5B in annual revenue). 69% of the companies surveyed had greater than 100 FTEs in the overall Regulatory Affairs organization. The product portfolio of participating companies varied across product classes, with "Class 2" products most common across all participants.

Detailed observations

The following sections will further elaborate on these key findings and provide additional insights from the survey.

1 Organizational design

Based on the survey results, the presence of a Regulatory Operations group within medical device companies is now common. However, the size, geographic footprint, and responsibilities of the group tend to differ across companies. In general, most seem to be relatively small in scale, which presents opportunities to build out further capabilities in the future.

85% of responding companies indicated that they have established a Regulatory Operations group. The most common size threshold for these groups was reported as 10 FTEs or fewer (46% of respondents), with an additional 23% indicating a size of 11-25 FTEs.

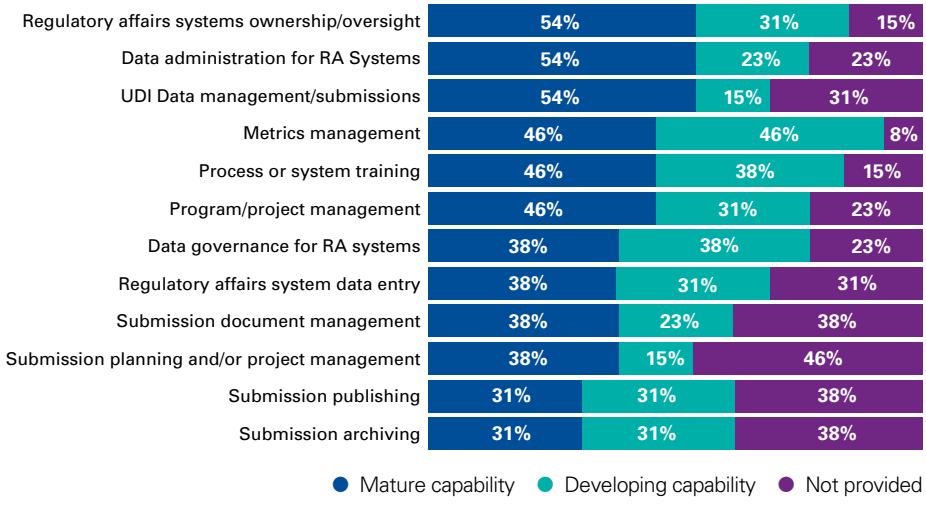
In terms of geographic footprint, a majority of the groups are situated in a variety of physical locations, rather than co-locating their resources. The most common model comprises one global group (54%) vs. groups that are specific to a given region (31%) or business unit (7%). The survey also demonstrated that almost all Regulatory Operations groups are composed of in-house resources that are not located in low cost countries. Based on these results, it seems there are significant opportunities to further leverage lower cost resources for Regulatory Operations activities and to explore outsourcing.

The survey results revealed a wide variety of services offered by Regulatory Operations groups, but there were not many "mature capabilities" across the industry (see the graph for full details).

Of the 12 services included in the survey, there were only 3 where more than 50% of respondents reported a mature capability. These included: Regulatory Affairs System Ownership/ Oversight, Data Administration for RA Systems, and UDI Data Management/ Submissions. Overall, the most common services were "indirect" work like Metrics Management and Process/System Training, in addition to the items previously listed.

More "direct" work categories like Submission Publishing, RA Systems Data Entry, and Submission Archiving were designated as mature capabilities by fewer than 40% of respondents. So there appears to be a significant opportunity for Regulatory Operations groups to expand their portfolio of services to include more "direct" activities to help drive value and efficiency in the organization. In the pharmaceutical space, many of these more direct activities are fairly common responsibilities for Regulatory Operations groups, so there is a precedent among life sciences companies to consolidate and mature these internal services.

Services the regulatory operations group provides for medical devices?



2 Technology

In addition to looking at the organizational structure of Regulatory Operations groups, we also gathered information about the Regulatory Affairs technology landscape within medical device companies. As regulations become more complex and present stricter data management and reporting requirements (e.g., EUDAMED), there is a critical need for more robust systems to support the Regulatory Affairs department. Based on the survey results, many companies already have formal systems to support Regulatory Affairs. A majority of companies have reported some formal instances of RIM systems and Document Management systems. However, the scope and usage of these systems can vary across BUs and geographies. Overall, it seems like there is an opportunity for vendors to capture greater market share in this space by offering solutions that are tailored to medical device Regulatory Affairs.

Regulatory Information Management*

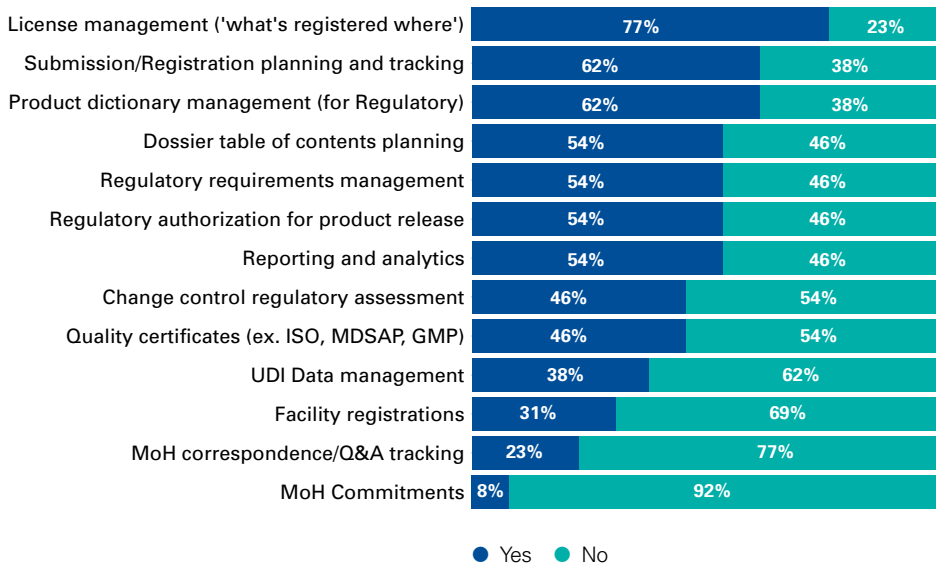
77% of companies responded that they are using some instance of a formal RIM system. Of these companies, half indicated that they have a single global system, while the other half indicated that systems can vary by BU and/or product line.

License Management, Submission/Registration Planning, and Tracking and Product Dictionary Management are the most common activities covered by RIM systems. Meanwhile, activities like Facility Registration Tracking, Correspondence Tracking, and Commitment Tracking were much less common. See graph below for additional details:

In order to help gauge the effectiveness of these systems, we also asked companies to report the approximate turnaround times for answering key regulatory questions. Based on the results, it seems that companies are still challenged by the need to quickly generate high-confidence data for key regulatory topics. For instance, none of the topics surveyed had a majority of responses indicate that the question could be answered in less than 1 hour. Of the topics surveyed, "Product License Renewal/Expiration Dates per Country" and "Registered Products per Country" had the shortest turnaround times; "Summary of In-Process Submissions" and "Pending Product Change Control Assessments" had the longest turnaround times. Based on these results, it seems that companies are having more success using their systems as data repositories for license information. However, key planning and tracking areas appear to be more challenging, i.e., it is likely that the systems are not often used to drive real-time decision making and enable regulatory team effectiveness.

The vendor landscape of RIM solutions within the medical device industry appears to be very fragmented. MS Excel use was reported by several companies and was the leading tool for the "Submission/Registration Planning" category. The "License Tracking" and "UDI" categories seem to have lower reliance on MS Excel, but results were

Activities included within your primary RIM system



* "RIM" refers generally to systems/tools focused on tracking regulatory submissions and licenses (and any related information critical to Regulatory Affairs day-to-day work)

still very fragmented across custom solutions, SharePoint and off-the-shelf vendors. Overall, it looks like there are opportunities to further leverage more formalized solutions in the RIM space, and it will be interesting to see if there is a further concentration of vendors in the near future.

Implementing changes to RIM systems does seem to be a focus for many medical device companies. Our survey indicated that a majority of the companies (62%) are considering some form of change to their RIM capabilities in the next 12 months. Examples of "significant planned changes" include increasing headcount and dedicated resources/development, establishing a formal system, and implementing new integrated system/processes. Examples of planned "incremental changes" include increasing RIM system capability, executing required software updates, and advancing maturity of data, governance, systems integration, and overall analytic capabilities.

Regulatory Document Management

85% of companies responded that they are using some instance of a formal Regulatory Submission-Related Document Management System (DMS). Of the companies with a Regulatory DMS, slightly more than half indicated that they have a single global system, while others indicated that systems can vary by BU and/or product line.

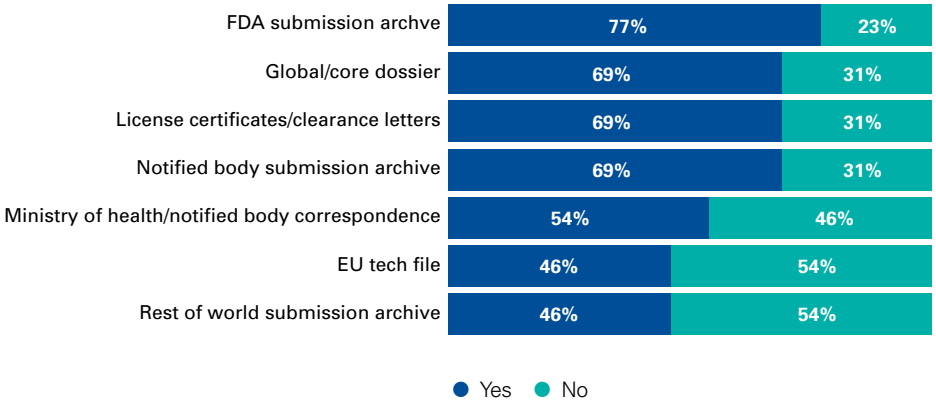
In terms of the scope of these systems, there is some inconsistency across the industry – which is to be expected based on the nuances of each company's organizational design and the fact that not all documents entered into submission are actually authored by Regulatory Affairs. The most common survey response (38% of respondents) was: The Regulatory DMS is the authoritative source for documents authored by Regulatory; all other source documents are linked/pulled from a different authoritative source.

Regulatory Document Management systems are being used to manage a variety of document types. (See embedded graphic for more details.) Utilizing a DMS to store some form of a "Global Dossier" seems to be a well-established practice (69% of respondents). Many also use the DMS for "FDA Submission Archive," "License Certificates / Clearance Letters," and "Notified Body Submission Archive." While EU Tech Files were reported in scope for fewer than half of participants, it will be interesting to see if this number increases with upcoming EU MDR / IVDR requirements.

Much like RIM, the Regulatory Document Management vendor landscape seems to be very fragmented. However, compared to RIM, there does seem to be a higher usage of off-the-shelf solutions. As this market matures, it will be interesting to see if certain vendors can gain more market share by offering solutions tailored to medical device companies.

For Regulatory Document Management, nearly half of the companies surveyed are considering some change in the next 12 months. Significant planned changes include establishing a new system and replacing an existing DMS with an off-the-shelf solution. Planned incremental changes include improvements across a spectrum of data and systems.

Documents managed in your primary Regulatory Submission-related document management system



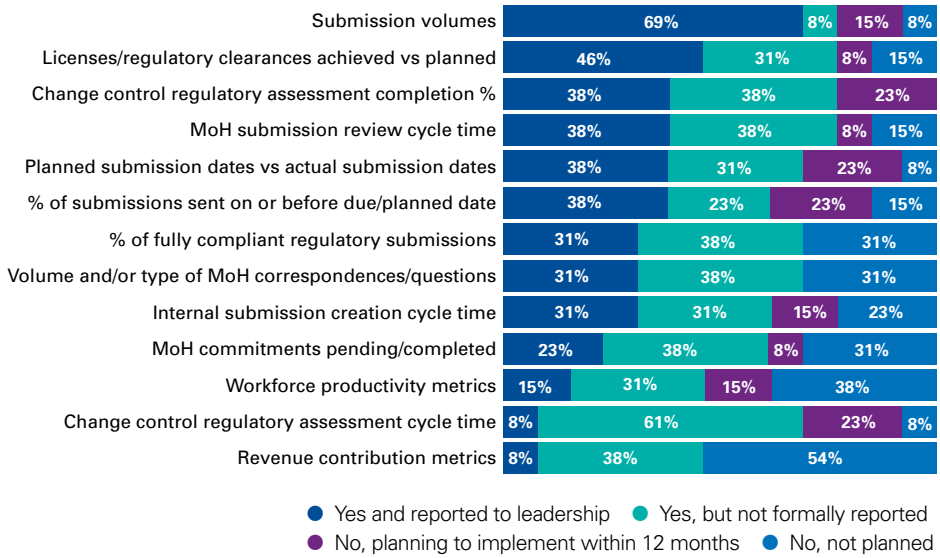
3 Governance and metrics

It is clear that Regulatory Operations teams help manage a large volume of data and documents. As part of these responsibilities, they often manage metrics for the Regulatory Affairs organization. Teams are capturing a wide variety of metrics, but the survey data did not demonstrate a clear consensus on key metrics across the industry (see chart below for more details).

"Submission Volumes" was the clear leader in terms of metrics tracked by respondents that are reported to Leadership (69%). After that, the results were somewhat fragmented, with many metrics tracked, but not necessarily reported, to leadership. More complex measures, such as "Workforce Productivity Metrics" and "Revenue Contribution Metrics," had much lower adoption. Overall, there is an opportunity to achieve greater alignment across the industry on key Regulatory Affairs KPIs and to further adopt more complex metrics that help articulate the value and benefits delivered by RA to the broader organization.

We also asked companies about activities they execute to maintain high-quality data in the Regulatory Affairs systems. "Reoccurring Training" was the most common, with 69% of the respondents. Meanwhile, process audits (46%), data audits (38%), and standard data models across systems (31%) were less common. Based on these results, there is an opportunity to use different approaches to more proactively support high-quality data in RA systems.

Do you measure the following metrics?

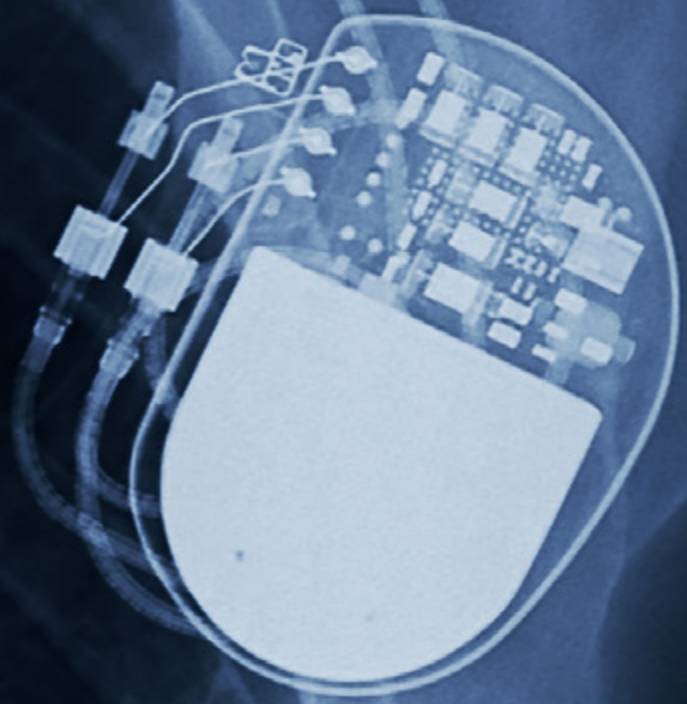


EU MDR Considerations

Given upcoming regulatory changes in the EU, we also sought information about any process or system changes being planned specifically for EU MDR. The majority of respondents said they are planning some changes to support the regulation. Example responses included: "Updates to SOPs and templates to support new file structures," "Dedicated clinical writing group," "Some sort of a product information management tool for Eudamed," and "Integrations; consolidation of data to exchange between internal and Eudamed." So it seems that most participants are mindful of the potential impacts of EU MDR and are starting to plan initiatives to support the regulation. On a broader scale, various aspects of EU MDR / IVDR may help drive transformational change in the industry.

Conclusion

Our experience working with medical device manufacturers suggests that, as regulatory complexity increases, companies are rethinking their operational strategies to maximize the value delivered by Regulatory Affairs to the broader organization. This has led to a focus on further developing Regulatory Operations groups to help deliver tactical and systems-related activities. It has also meant an increased emphasis on metrics and articulating the benefits and outcomes generated by Regulatory Affairs. Based on the survey results, there are still many opportunities to drive further efficiencies in Regulatory Affairs and continue to mature the Regulatory Operations groups supporting the function. These improvements are critical to managing the increasing volume of data and documents required to meet growing regulatory demands for bringing a medical device product to market. Optimizing operational infrastructure is of critical importance. Companies that lack focus on this optimization will likely find it challenging to keep pace with the day-to-day regulatory activities that are central to the success of medical device organizations.



About KPMG

KPMG is a leading professional services firm with senior healthcare and life sciences practitioners dedicated to regulatory affairs, data & analytics, R&D and commercial strategy, risk consulting, and M&A.

Our one firm approach to client engagements results in an enterprise-wide view from strategy through results. In particular, our life sciences advisory team focuses on providing strategic support to pharamceutical and medical device companies seeking to comply with regulatory initiatives and assists them in anticipating, navigating and balancing the myriad of issues that arise when undertaking a compliance project.

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