

Regulatory Strategy as a

Competitive Advantage



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The regulatory revenue opportunity

It is well known that medical technology (medtech) companies are highly regulated, given the potential risks their products present. Understanding and complying with the complex regulations in each country is, therefore, a necessary part of marketing and selling medical devices. To realize any revenue from a medical device, it must not only demonstrate compliance with all applicable regulations, it must also receive and maintain market clearance from each country in which it is to be sold. No market clearance means no revenue. Given the key role regulatory compliance plays in revenue attainment, regulatory teams, tools, and processes present a significant opportunity for differentiation for organizations willing to invest in them.

For the majority of medtech companies, however, regulatory departments have traditionally been treated as operational cost centers, with departmental improvements focused on cost reduction and efficiency improvements. Limited investment in people and tools, and limited interest in digital transformation, have left regulatory teams across the medtech industry underfunded and under-resourced.

This has led to great resourcefulness within the RA community, where most members can point to heroes within their team who worked long hours to meet a submission deadline, headed off a disaster by uncovering a pending expiration, created ad-hoc systems to organize information and streamline communication between the RA and QA teams for smoother audits, or have otherwise gone above and beyond their typical responsibilities.

Regulatory teams, however, have the potential to be a revenue-driving competitive weapon for companies that are willing to look at them a little differently and invest in regulatory performance above regulatory cost-effectiveness. Well-supported regulatory teams can provide a true competitive advantage by providing the resources and direction to:

- Capture market share by being first to market with novel devices.
- Avoid lost revenue by effectively tracking and planning for registration renewals/updates.
- Out-pace competitors and grow market share by adapting to regulatory changes more quickly and taking advantage of competitors' non-compliance or inability to enter a new market.

We believe we are entering a new era for regulatory affairs within the medtech industry. One in which RA teams have a seat at the table when go-to-market, competitive positioning, and strategic decisions are being made.

Regulatory responsibilities

In the medtech industry, regulatory affairs (RA) teams have a broad range of responsibilities across the product lifecycle:

Premarket regulatory strategy

Obtaining market clearance for a new medical device is the primary activity typically attributed to RA teams. It is not unusual for a regulatory team to be given market entrance projects with little warning, but ideally, the RA team would be brought in as early as possible to contribute to go-to-market discussions.

Premarket regulatory strategy, at a minimum, involves:

- Determining the most appropriate pathway to market approval. For example, a 510(k) or PMA submission in the U.S.
- Working with quality, product, and other teams to gather information needed for market submission.
- Establishing communication with applicable regulatory bodies and third-party approved auditors.
- Compiling and submitting required documentation for market approval. This includes managing follow-up activities, questions, and requests for additional information throughout the approval process.

Forward-thinking organizations often look to bring in RA teams even earlier in the process. As regulatory experts, RA professionals can provide unique insight into product development plans. In consultation with R&D teams, can help to refine product strategies, and steer development in areas that will reduce regulatory hurdles when new products are ready to be commercialized.

Maintaining regulatory compliance for existing products

While the primary focus of regulatory teams is often considered to be new market submissions, the majority of their time is actually spent on maintaining compliance for products that are already in-market. Even in situations where market registrations do not expire, constant vigilance is required to ensure that devices remain compliant with current regulations. These efforts take a considerable time for a typical RA team because information is often spread across disparate systems, where it can be difficult to find and confirm.

Maintaining regulatory compliance for approved devices includes:

- Staying on top of changing standards and making changes as required to existing technical files and other documentation.
- Submitting appropriate documentation updates when there is a change made that could potentially affect the efficacy or safety of the product, such as a material switch or facility change.
- Understanding pending regulatory changes and proactively addressing any that have an impact on devices currently in-market.
- Tracking registration expirations and preparing for timely re-submissions to ensure there is no lapse in market clearance.

Post-market activity

Post-market surveillance and vigilance activities are required by most countries and should involve the cooperation of the quality and regulatory teams. Ensuring that changing post-market reporting requirements are understood and complied with is an important regulatory responsibility.

Regulatory teams typically play a role in:

- Post-market surveillance of adverse events, complaints, and any issues associated with a device in the field.
- Assembling and submitting any required periodic safety reports to country/regional health authorities.
- Post-market vigilance and reporting of serious events to the appropriate regulatory agencies.
- Any required communication with regulatory authorities regarding adverse events or concerning trends in product quality.

Limitations of the “cost-center” approach to regulatory affairs

Ask any RA professional, and they are likely to tell you that they work long hours and are often scrambling to meet looming deadlines. Our 2023 Medtech Regulatory Performance report backs up this concern. Of the 200 medtech companies interviewed for the study, we found that:

- Most medtech companies must manage significant regulatory complexity



Almost half have more than 500 regulated products



40% distribute products to more than 50 countries

- Regulatory affairs teams are relatively small relative to their workload – even at very large companies



56% of all respondents have fewer than 10 full-time RA employees and 71% have fewer than 15



22% of large companies with more than \$500 million in revenue have 15 or fewer RA employees

Given that regulatory compliance is critical to not only gaining market access but maintaining the ability to sell a medical device in each market, it is striking how few regulatory professionals are employed in the industry. As a comparison, there are more medical sales representatives in the United States ([Zippia](#)) than there are regulatory professionals employed in the medical industry worldwide ([RAPS](#)). Some of the largest medical device companies employ more than 10,000 sales professionals, while only 6% of the companies in the study employed more than 100 regulatory professionals.

Positioning regulatory departments as key players in revenue generation provides sales and marketing teams with vital support in optimizing go-to-market strategies and competitive positioning. Without regulatory input, sales and marketing teams may select initial markets based solely on market size in situations where smaller markets may yield revenue sooner and smooth market entrance procedures in larger countries. Treating regulatory departments as cost centers denies the organization the strategic input that regulatory professionals can bring to discussions with a direct impact on the bottom line.

- Small RA teams end up being more costly as resource gaps are regularly filled with external consultants.



90% of survey respondents indicated that their company relies on external regulatory resources.



45% of larger organizations spend upwards of \$1 million per year on regulatory consulting, with 37% of them spending more than \$2 million.



40% of small and medium-sized medtech companies employ 5 or more full-time regulatory consultants.

Industry consultants serve an important role in the medical device industry. When used to provide specific expertise that a regulatory team is missing, consultants can provide guidance, improve project planning, and ensure that regulatory activities will strengthen compliance. However, heavy reliance on consultants, especially for more administrative work, can lead to inefficiencies and other issues.

Many medtech companies rely on consultants to augment staff and handle administrative and day-to-day tasks. This is understandable, given the relatively small size of internal RA teams highlighted earlier. However, an overreliance on consultants can result in:

- Lack of continuity – It is typical for consulting firms to change the employees assigned to specific projects. Consultants then need to re-learn an organization’s processes, product details, and unique issues and establish new relationships with internal teams.
- Loss of internal knowledge – As an organization becomes more and more reliant on outside resources to perform routine regulatory tasks, the ability of the internal team to perform these functions is diminished.
- Higher cost – Regulatory consultants are expensive. Using them to provide unique expertise in specific areas makes sense, but using them to provide services that an internal RA team should be able to handle is difficult to cost-justify. The average salary of all “intermediate level” Regulatory Specialist in the U.S. is \$81,300 ([salary.com](https://www.salary.com)), whereas the hourly rate for regulatory consultants with medical device expertise is upwards of \$400/hour. Even allowing for the additional costs associated with a full-time employee, consultants can cost up to 900% more than a regulatory specialist!

Significant non-compliance

As a result of understaffed regulatory teams struggling to keep up with critical tasks and constantly in “firefighting” mode, companies experience a concerning number of non-compliance events. Of the 200 study respondents, in the past two years:



These events can have a real and profound impact on medtech organizations. 75% of our survey respondents reported that the cost of noncompliance events in the past two years was greater than \$100,000, and 15% cited a cost greater than \$1 million. And these estimates likely don’t take into account the full cost of non-compliance, such as lost sales, and reputational damage. If a product has to be pulled from the market it can take 3 to 12 months or more to re-obtain market clearance.

Insufficient tools

The majority of regulatory teams continue to use spreadsheets and other basic tools to track regulatory projects and data. This leads to limited visibility into information such as upcoming renewals and expirations. Just as importantly, spreadsheet data can quickly become outdated, incomplete, or incorrect because it relies on individuals remembering to update information – and updating it correctly.

Spreadsheets and other disparate data can make it difficult and time-consuming to determine what products are affected by a standards or regulation update, what tasks remain on a renewal project, and even the answer to questions as simple as “what countries is this product sold in?”

The lack of a holistic regulatory tool, providing a “single source of truth,” also makes it difficult for other departments to access accurate and current information. For example, the sales team can likely view the latest customer communication in their CRM system and the current available inventory in their ERP system – but with no holistic regulatory system, they are unable to quickly view which products are approved for sale in which country.

Lack of strategic focus

Regulatory teams spend too much time finding and confirming information that should be readily available to them. As a result, they have little time to focus on strategic planning and process optimization where they can provide the most value.

In the following sections, we discuss the competitive advantages that a revenue-aligned regulatory team can provide. First, let's define "revenue-aligned" and what this type of regulatory organization looks like.

Regulatory as a revenue function

There is a strong case to be made for creating revenue-aligned regulatory teams. Unlike the necessary and valuable support functions, such as accounting and IT, there is a direct line between regulatory activities and revenue for the business. This means that alignment between sales, marketing, and regulatory affairs is necessary for go-to-market success. When these teams are truly aligned toward meeting revenue targets, organizations see a shift in regulatory planning and investment priorities.

When regulatory teams carry revenue goals, projects with the highest revenue impact are prioritized, and sales, marketing, and regulatory teams are aligned. This alignment allows regulatory teams to contribute directly to go-to-market decisions. For example, regulatory teams freed from metrics such as the number of submissions completed, may make different recommendations regarding the order of market entry. A country that has a more complex market approval process may be prioritized not only because of the revenue it represents directly, but because of the advantages it provides in obtaining market approval in other countries.

So, what does a revenue-aligned RA team look like?

 Optimized for performance	 Using purpose-built technology	 Intelligent staffing
Regulatory teams are optimized for performance with well-defined processes and clear goals that are aligned with the organization's objectives	Regulatory teams have access to software and tools designed to support their specific processes and workflows	Staffing levels are aligned with workload, and teams have visibility into upcoming projects in order to plan appropriately

Competitive advantage 1: Faster time to market

When brought in early, RA teams can provide valuable insight for product and quality teams that can eliminate the need to rework products and/or processes and increase the likelihood of quick approval. Regulatory teams that are aligned with sales, marketing, and product teams will be able to establish a strong global regulatory submission strategy that can decrease time to market by:

1. Fully understanding and taking advantage of harmonization efforts between countries.
2. Ensuring that the need for country-of-origin approval in certain markets is met.
3. Evaluating the impact of market approval complexities and costs market by market. And making informed decisions about which markets to enter and in what order.
4. Building and maintaining relationships with regulatory agencies, notified bodies, and other third parties involved in regulatory approvals, monitoring, and auditing. Understanding how to work with each agency can speed approval by minimizing requests for additional information and ensuring that the right processes have been followed and all required information obtained prior to the start of a submission or change process.

Some regulatory agencies are implementing programs that encourage more open dialog with industry. The FDA's Medical Device Discovery Appraisal Program (MDDAP), for example, provides a framework for continuous quality improvement that encourages medtech organizations to change the typical relationship between industry and the agency and to treat the agency as a partner. Participants in the program benefit from ongoing support for continuous improvement programs, modified inspection requirements, and a streamlined relationship with the FDA.

5. Optimizing business outcomes. Regulatory teams can help their organization gain a first-mover advantage in new markets and novel product categories. By choosing the correct path to market and ensuring that quality and product teams understand market-specific requirements as early as possible, a strong RA team will put their organization in a position to optimize revenue and market share.

Competitive advantage 2: Cost avoidance

In combination with the quality team, a strong regulatory team can guide product change submissions and interactions with regulatory agencies to avoid post-market events and limit the exposure when negative events do occur.

It is important to identify and address sources of regulatory risks that are separate and distinct from quality risks. Every medical device manufacturer has (or should have) a strong quality system because it is required to gain market approval. Once a device is on the market, however, regulatory risks become just as, if not more, important for medtech companies. The costs of non-compliance listed below should be addressed as diligently as the costs associated with a quality event in the field because those costs can be just as high and often have a bigger impact on the ability to market a device.

Cost of post-market non-compliance

1. Risk of expired registrations and certificates

A regulatory team that is constantly fighting fires is ill-prepared to plan for upcoming projects. Having the right processes, team members, and tools in place to proactively identify and manage expiring registrations and certificates should be a priority for medtech regulatory teams. Missing an expiration can mean pulling a product from the market and a new, time-consuming and costly, submission request to reinstate the product. Once a device expires, it not only needs to undergo a completely new certification process but may be required to meet new, more stringent standards. For example, devices with expired registrations in the EU will need to meet new MDR requirements, which in many cases require the involvement of a Notified Body (NB) whose backlogs are up to 2 years.

In the [2023 Regulatory Performance Report](#), 24% of respondents indicated that they had to withdraw products from a specific country due to an expired registration, and 19% accidentally sold or marketed products into countries without proper regulatory clearance.

2. Risk of missing updates to standards and regulations

Some of the most time-consuming activities for medtech RA teams involve compiling a gap analysis when a regulation changes and determining the impact of a change in global standards. There are two parts to this risk:

- Missing the update - When an RA team is unaware that one of the many standards they reference has been updated, they are not only unable to update existing technical files and information, but may reference outdated information in audits or new submissions.
- Not finding all references to outdated standards - RA teams typically will go through technical files line-by-line and use text searches to find references to outdated standards. This manual process provides plenty of opportunities for missed references that should be updated.

The risk that products will become non-compliant when documentation references become outdated can lead to costs associated with audit findings, rushed rework, and consultant fees associated with researching and updating documentation.

3. Lost business opportunities

Regulatory risk is often assessed based on fines or enforcement actions from health authorities. A much larger cost, however, is having to withdraw products from the market or being unable to enter a market when it is most advantageous for the company. Registrations and renewals comprise the majority of regulatory work performed by today's medtech RA teams, and without focused and organized plans based on corporate goals, medtech organizations cannot optimize revenue.

Competitive advantage #3: Out-pacing competitors

Regulatory can be used as a competitive advantage. However, this is only true for organizations that embrace the concepts discussed in this book. When regulatory teams are assigned revenue-aligned goals and given the resources they need to move beyond “firefighting” mode, they are able to help position their company for success and surpass their competitors.

Achieving a competitive advantage through regulatory positioning can come about in a number of ways:

1. Proactively addressing regulatory changes

In situations where the majority of competitors are waiting until the last minute to comply with regulatory changes, there is an opportunity to differentiate your organization by obtaining and promoting compliance with new regulations and standards. Being able to show adherence to a new regulation in one country may not only be a benefit from a marketing perspective but can also simplify regulatory approvals in other countries.

While the EU has extended MDR deadlines for many products, MDR compliance may smooth submissions in other countries which recognize CE-marked products.

It is not uncommon for countries to mirror another’s regulations in the name of “harmonization,” while almost always introducing their own changes and specific requirements. Companies that can adapt to one set of regulations quickly will be able to move into additional markets ahead of competitors.

In addition, the MDR example also highlights an “early-mover” advantage in that companies who have already established relationships with Notified Bodies will be able to bring compliant products to market more quickly than competitors who are waiting for NB resources. In some cases, the competitors have, or are considering, removing products from the market altogether.

2. First-mover advantage

A strong RA team will be able to help identify the best market(s) to enter first to improve the speed and likelihood of quick approval in additional markets. It is also important that RA teams navigate the submission process so that all teams are working together to create an optimal market submission with the best chance of quick approval. For example, before entering China with a new product, the RA team can ensure that a “product expert” is fully briefed on how to answer questions and that a strategy is in place for what information to share, and not to share, with Chinese authorities.

3. Product positioning and classification

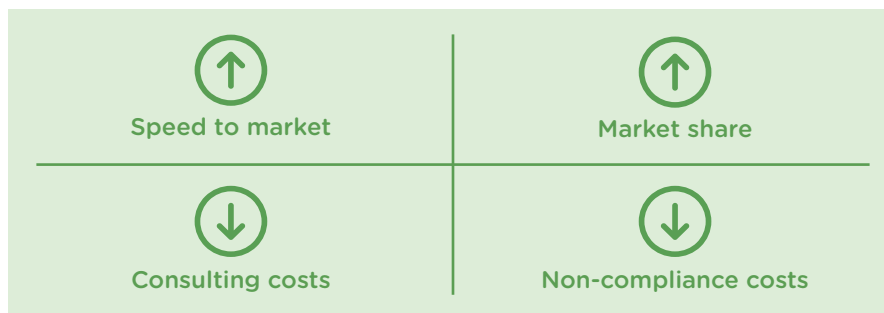
It is tempting to “down-classify” a device whenever possible to reduce the amount of work involved in gaining and maintaining market approval. However, when medtech organizations have the right regulatory resources, they may determine that taking a more complex regulatory path to market helps differentiate their product. Classifying a device in a higher risk-category can also prevent competitors with fewer resources from using your device to gain clearance for their device (ex: a Class III device in the U.S. cannot be used as a predicate device to gain FDA clearance for a Class II device using a 510(k) submission).

4. Maintaining a regulatory advantage

It is always likely that some competitors will suffer a non-compliance event or even have to pull products from the market. Right now, this is an issue particularly in the EU as new MDR requirements come into force. Simply maintaining regulatory compliance can allow an organization to take advantage of mistakes by the competition and capture market share. Once competitors re-enter the market (if they choose to do so), they will be operating at a disadvantage and have to expend resources to regain the lost share.

Why invest in regulatory/revenue alignment?

In a market as highly regulated as medical devices and IVDs, all companies are subject to varying levels of scrutiny by health authorities and regulatory bodies. And in an environment where most medtech companies still treat regulatory functions as an operational expense, there is a significant opportunity for organizations to use regulatory as a competitive advantage.



There is a clear return on investment (ROI) case that can be made for investing in a strong, proactive, and revenue-focused regulatory team. Companies that do so can expect the following results:

1. Increased revenue
 - Products reaching market more quickly (faster ROI on R&D).
 - Products remaining in market longer and without interruption.
 - Revenue from growing market share when competitors stumble or have to remove products from market.
2. Cost savings
 - Decreasing the use of consultants to perform daily regulatory activities.
 - Decreasing the use of consultants required when last-minute projects and regulatory “emergencies” arise.
 - Optimize staffing levels through the use of better processes and technology.
 - Reduce direct and indirect costs associated with non-compliance issues.

In order to realize these improvements, medtech companies must invest in resources and processes:

1. Improved processes – Regulatory processes that prioritize collaboration between departments and prioritize identification and notification of pending changes will allow an RA team to optimize their activity and proactively contribute to revenue attainment.
2. Digital transformation – Moving away from manual processes and information stored in spreadsheets and separate systems is critical to optimizing processes and providing accurate data to the organization as a whole. Regulatory teams need to be able to find information quickly and have visibility into upcoming expirations, renewals, and standards/regulatory changes to plan and execute effectively.
3. Purpose-built tools – Regulatory teams need regulatory software that is purpose-built to handle the processes and data that are required for market submissions, maintenance of regulatory compliance, and post-market reporting requirements. Asking them to use generic productivity tools or systems built for quality teams, product teams, or other purposes leads to inefficient processes that can lead to less-than-optimal outcomes and a dissatisfied workforce.

Getting started – 3 steps to move towards a revenue-aligned RA team

1. Establish revenue-centric team goals

Align regulatory goals with those of the sales, marketing, and product teams so that all teams are working together towards organization-wide objectives that are clearly understood by everyone. High-level objectives should link to departmental and cross-departmental goals that focus on optimizing market entrance and post-market activities.

2. Identify opportunities for improvement

Process improvements should be categorized and prioritized based on:

- Revenue impact – For example, implementing notifications for the regulatory team that allows them to begin market submission projects earlier, thereby allowing products to enter markets more quickly.
- Cost optimization – For example, implementing a medtech RIM system that removes administrative burden from the RA team, improving employee retention and decreasing reliance on consultants.
- Ease of implementation – For example, automated notifications from the PLM system to the RA team may be quick and simple to implement and even though this change doesn't provide the greatest impact on revenue or cost, it is a "quick win" that is worth prioritizing over process improvements with longer lead times.

3. Obtain an executive sponsor and make a case for change!

A change as significant as modifying departmental goals and updating inter-departmental processes will typically require buy-in from go-to-market (sales & marketing) leaders as well as senior leadership within the organization. The good news is that the case for modernizing your regulatory team is an easy one to make. An analysis of the costs that could be minimized, such as those associated with non-compliance events and consultant use, is often enough to demonstrate a positive ROI. Add in the potential revenue benefits provided by improved market activities and competitive positioning, and the numbers will speak for themselves!

About Rimsys

Rimsys is improving global health by accelerating delivery and increasing availability of life-changing medical technologies. Rimsys Regulatory Information Management (RIM) software digitizes and automates regulatory activities, helping medtech regulatory affairs teams to plan more effectively, execute more quickly, and confidently ensure global regulatory compliance. Unlike complex, color-coded spreadsheets, or expensive external consultants, Rimsys centralizes all regulatory information, automates submission processes, and provides detailed visibility into product registrations, expirations, relevant standards, and global regulations. Traditional approaches to regulatory affairs can't keep pace with the growing complexity of the global landscape, and overburdened teams face increasing compliance risks. Rimsys is designed around medtech regulations and workflows and supports a full breadth of regulatory activities including registrations, submissions, UDI, essential principles, standards management, and regulatory intelligence in a single, integrated platform.

For more information, visit www.rimsys.io.

The logo for Rimsys, featuring a stylized 'R' icon composed of a pink triangle and a blue square, followed by the word 'Rimsys' in a dark blue sans-serif font with a registered trademark symbol.