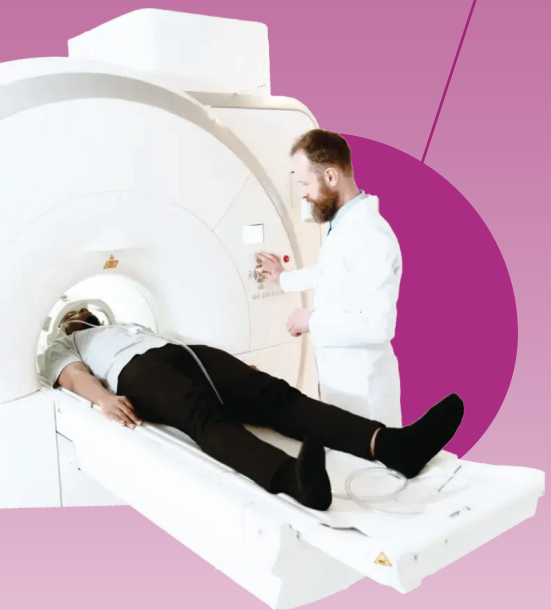
2023

Medtech Regulatory Performance Report



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2023 Medtech Regulatory Performance Report

Insights and process benchmarks from 200 medtech regulatory professionals.

Introduction

Welcome to the inaugural Medtech regulatory performance report. This ebook explores key findings from a new survey of 200 regulatory professionals across the medical technology industry including medical devices, in vitro diagnostics, software as a medical device, and combination products.

Why a performance study?

This report is intended to be a usable reference for medtech regulatory organizations, meaning that it should provide truly helpful information that organizations can use to assess the effectiveness of their teams and processes. While numerous studies explore the state of the regulatory profession, or areas of specific technology adoption, fundamental questions remain unanswered. What does it mean to work efficiently? What is the right level of resources for a regulatory affairs team? How long should it take to complete a registration or license renewal? Is my organization ahead or behind?

This study tries to address these questions by looking at the specific performance of regulatory teams and processes in the medtech industry. It covers team setup and size, common regulatory activities, issues and compliance, and, yes, technology. Beyond adoption, it looks to the impact of technology on productivity and performance, helping teams see the real outcomes associated with their investments.

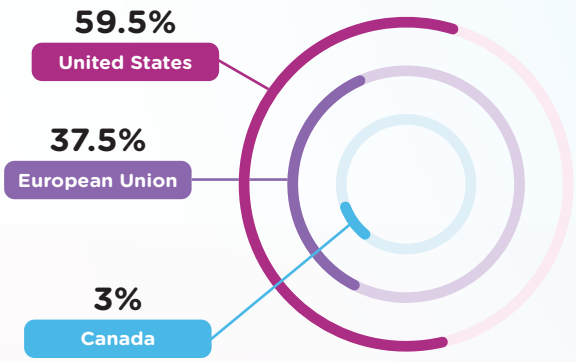
What did we find?

- Medtech regulatory teams are often understaffed relative to their workload. 22% of enterprise companies (with revenue greater than $500 million) have 15 or fewer regulatory employees. 38% of front line RA employees feel under-resourced. Resourcing decisions and headcount are rarely allocated based on planned workload. Consultants are (over-) used to make up the gaps.
- Regulatory teams (especially leadership) self-assess their capabilities and performance highly. A majority believe that they outperform their peers in both planning and execution. Yet over 60% reported a major non-compliance issue/incident in the past 2 years. There's clearly a disconnect between perceived and actual performance.
- Technology can make a difference, but not all tools add value. 64% of companies that specifically invest in regulatory information management report significant productivity gains, and all complete projects more quickly.

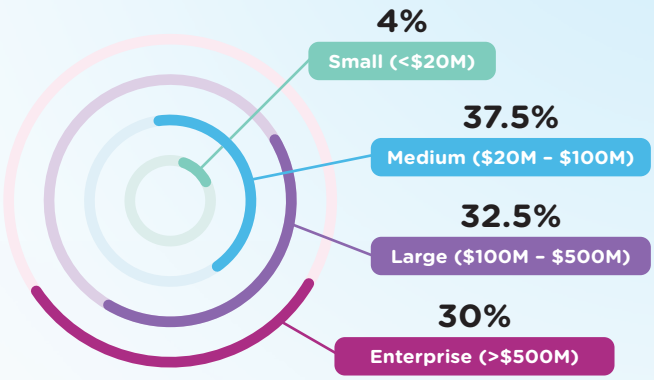
Survey Approach and Respondent Demographics

Data in this study was collected through phone interviews with 200 regulatory professionals at medical technology companies across North America and Europe. Respondents represented companies headquartered in 14 different countries, with annual revenue ranging from $10 Million to more than $5 Billion.

Headquarters location

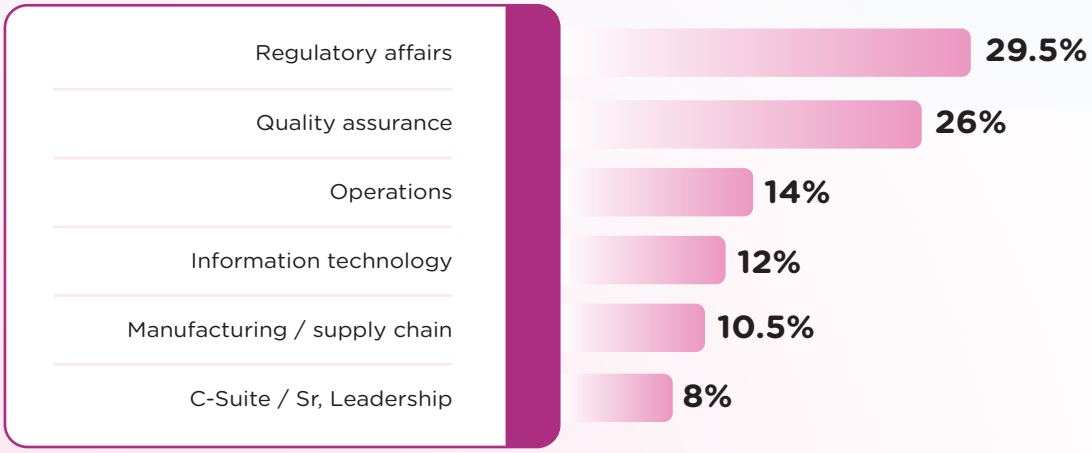


Company size



Respondents work in multiple departments within their companies including Regulatory Affairs, Quality Assurance, Information Technology, and Operations. Why not focus exclusively on Regulatory Affairs departments? Not all companies have dedicated regulatory departments (the function is often bundled with quality), and members of other teams often spend a significant amount of their time on regulatory activities. All survey respondents included in the results reported spending more than 50% of their time on regulatory projects or processes.

Respondent departments



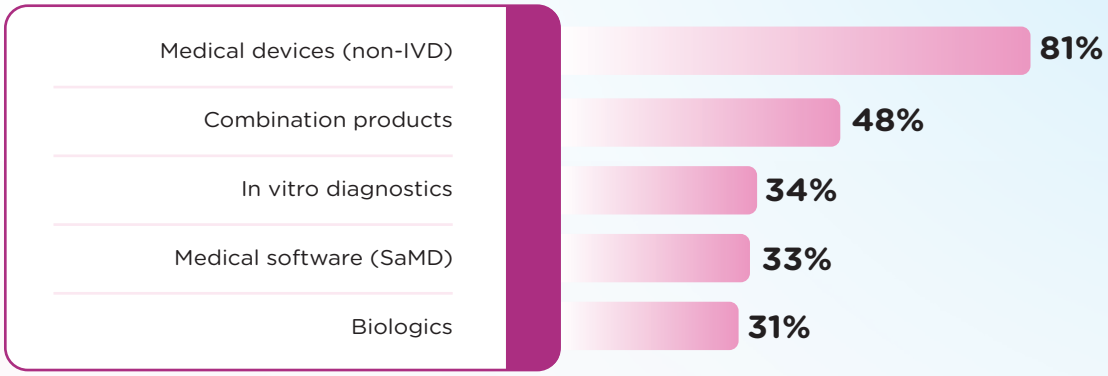
Respondent seniority

Respondents varied in seniority from front-line professionals (individual contributors and managers), executives (VP and Director-level), and C-Suite leadership.

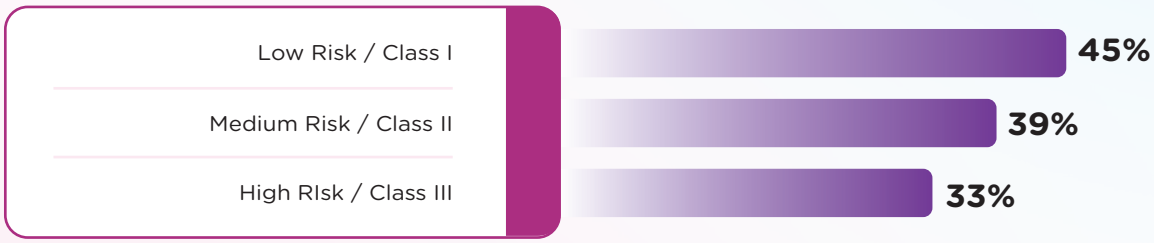
Product Profile

All companies represented in the survey are primarily medical technology companies (those that produce medical devices in-vitro diagnostics or medical software). Of those, most were device manufacturers, with about a third producing diagnostic and software products respectively. 71% produce medium or high-risk products, meaning they are subject to regulatory approval before they can be marketed or sold in a given market.

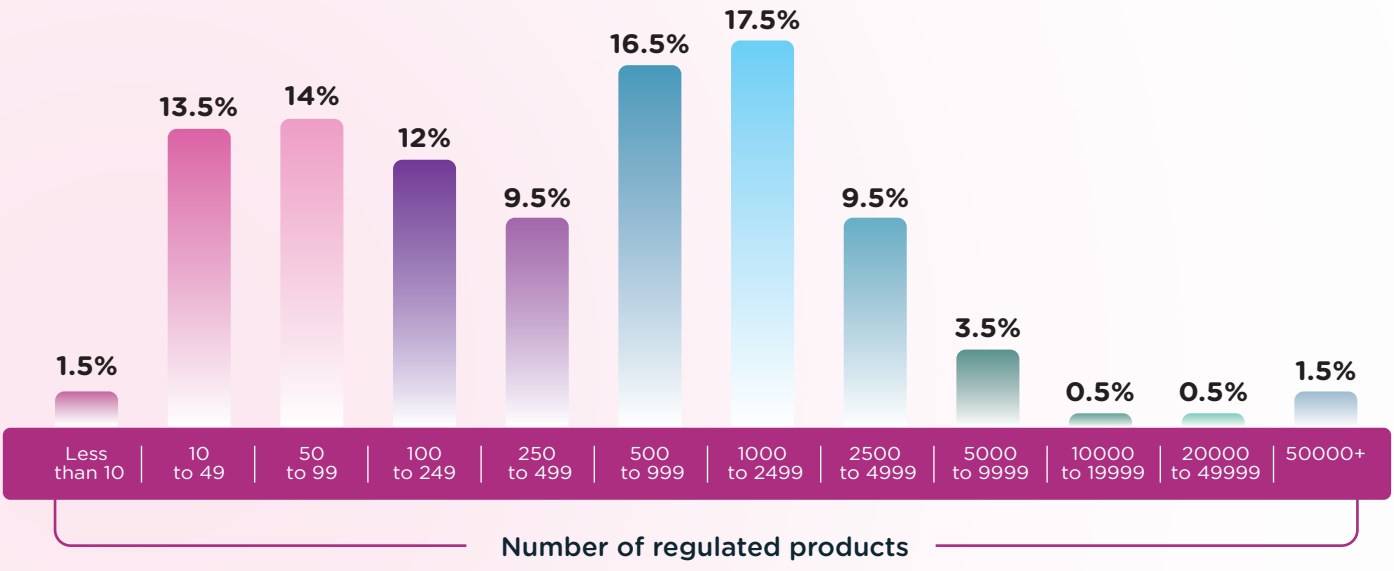
Product types

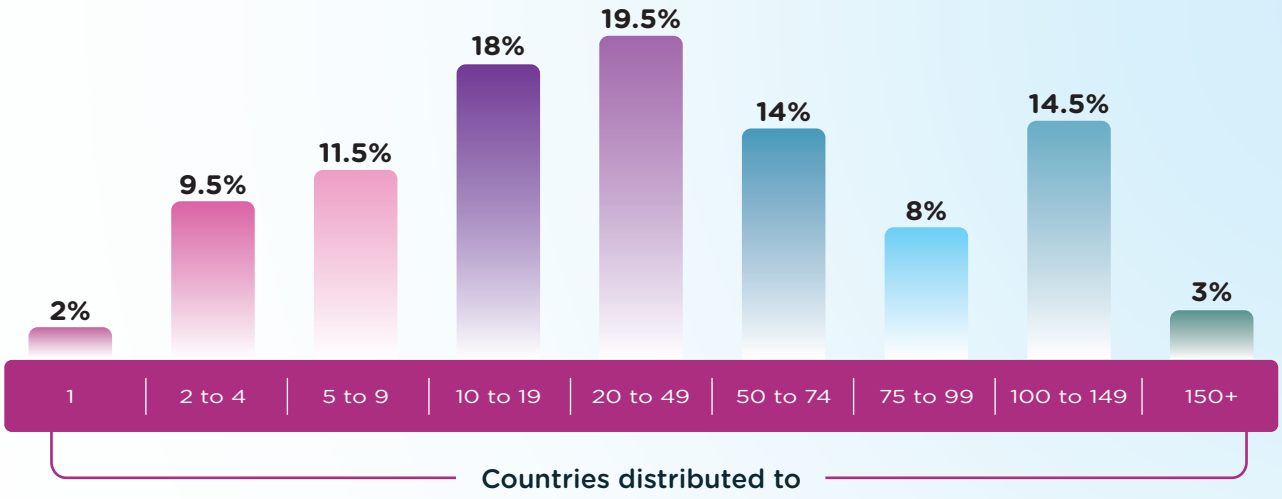


Risk class



Most companies manufacture a pretty broad array of products. Nearly half of respondents have more than 500 regulated products, and 16% have more than 2,500. These products are distributed broadly. 40% of respondents' companies distribute their products to more than 50 countries.

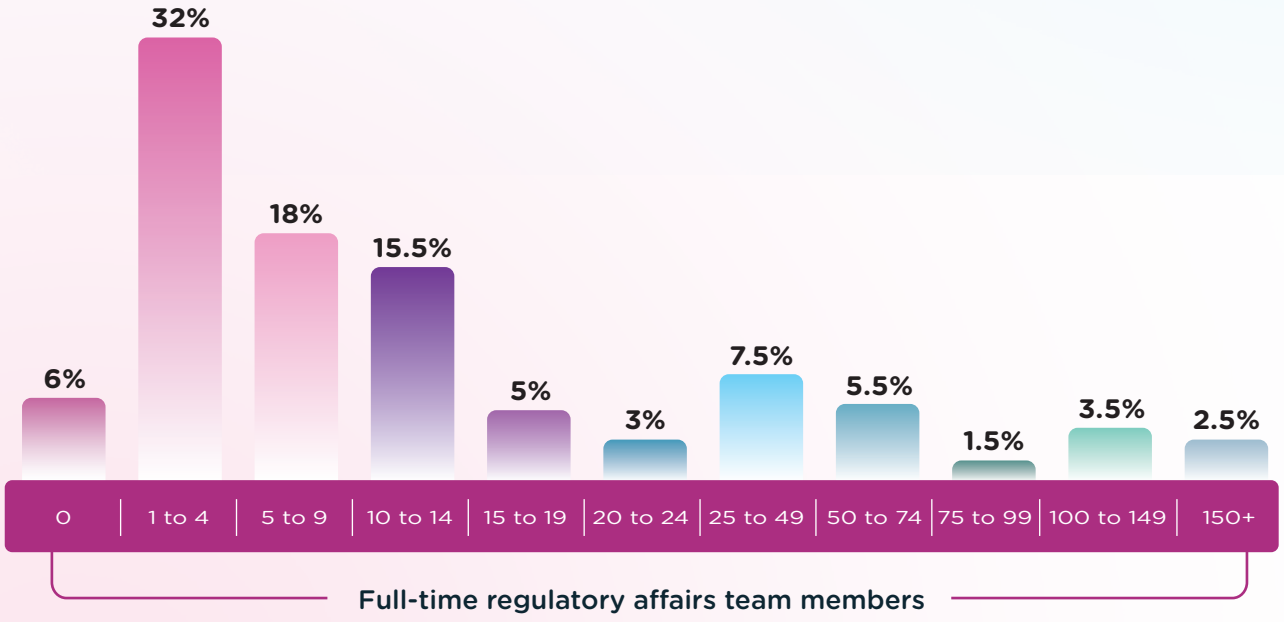




Regulatory Team Size and Staffing

The number of products and breadth of distribution that survey respondents reported indicate a lot of complexity, and a significant amount of regulatory work. And teams definitely reported having a high workload, which is covered in more detail in the next section. Yet at the same time, most respondents reported that a fairly small number of employees within their organizations were dedicated to regulatory activities.

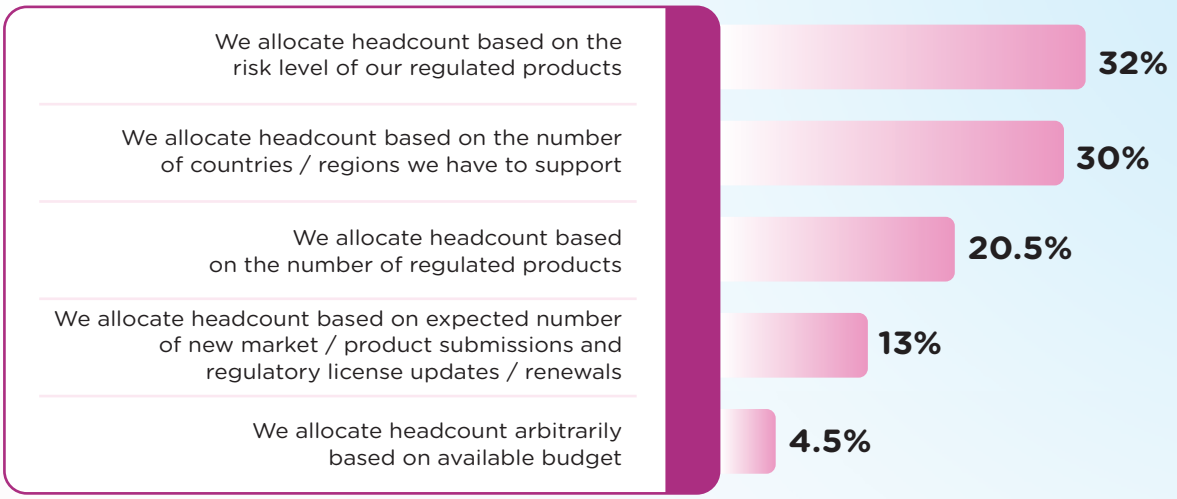
56% of respondents indicated that their companies had less than 10 full-time employees focused on regulatory affairs. 71% had less than 15.



Naturally, the number of regulatory employees grows with company size, but even the largest companies reported a relatively small number of full-time regulatory employees. 22% of enterprise companies (with more than $500 million in revenue) have 15 or fewer regulatory employees.

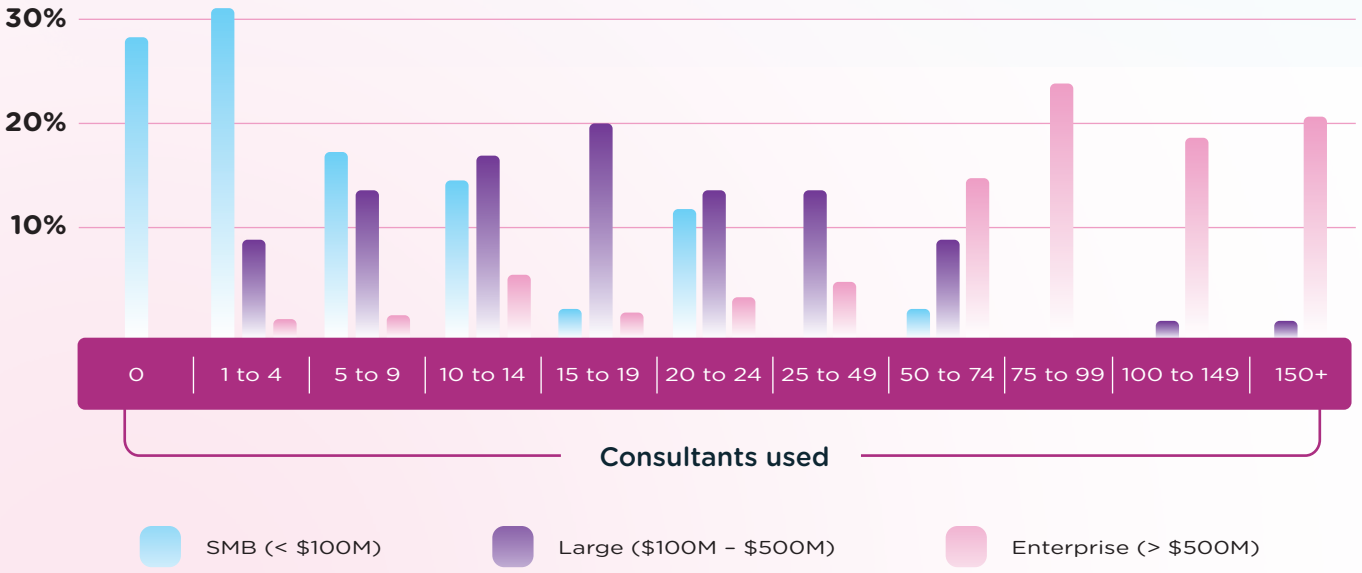
Why the discrepancy between staffing and workload? Part of the reason seems to be how regulatory headcount are allocated within organizations. Headcount planning and resource allocation rarely take into account the actual anticipated workload. Instead, teams are assigned primarily based on device class or markets served. This approach may be due in part to a lack of visibility into upcoming projects or needs on the part of regulatory leadership.

How regulatory affairs staffing is allocated

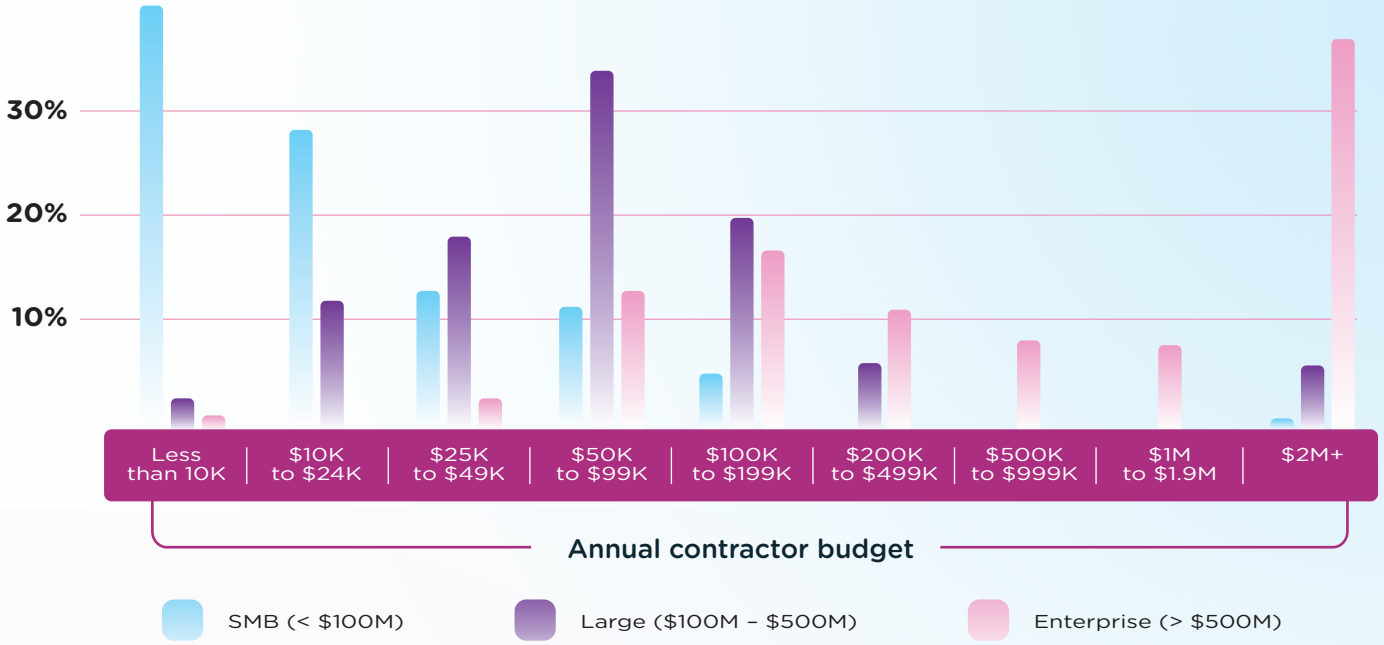


Filling the Gap with Consultants

Consultants play an outsized role across the life-sciences industry, and they're especially prevalent in medtech regulatory affairs. 90% of respondents indicated that their company relies on external consultants to complete regulatory work, and those that didn't were overwhelmingly small companies. Naturally, the number of consultants used grows with company size, but they're not only heavily used by large organizations. 40% of small and medium medtech companies employ 5 or more full-time consultants to support regulatory affairs.



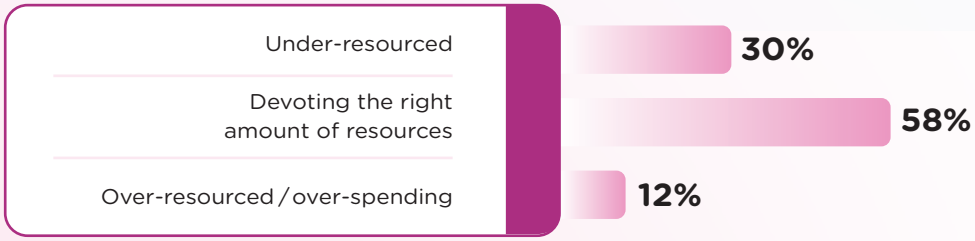
Consultants are a fairly expensive way to get regulatory tasks completed. With hourly rates running from $150 to $300, the cost of using consultants can pile up quickly. Survey respondents reported pretty significant annual expenditures on consultants—especially in large and enterprise companies. 45% of enterprise companies spend more than $1 million per year on consulting, and 37% spend more than $2 million.



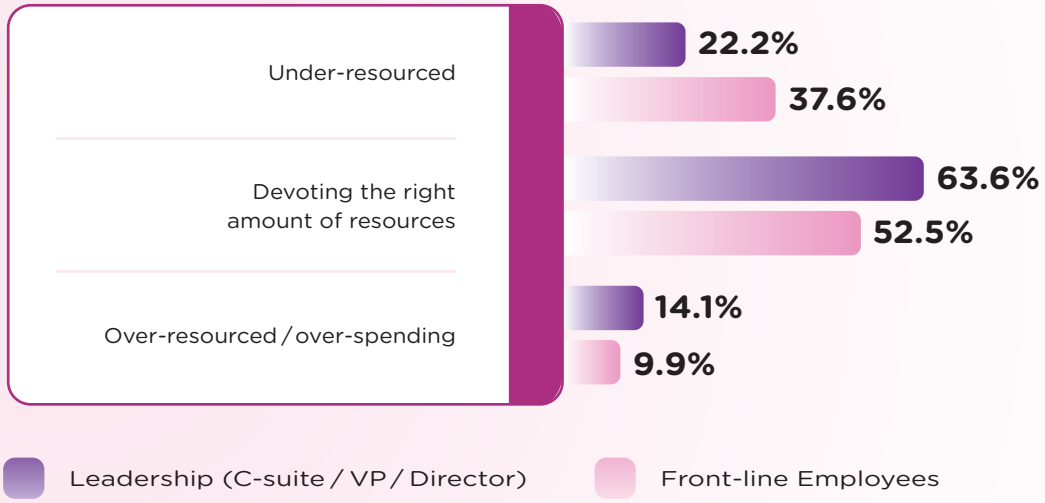
Future Staffing Expectations

Despite what seems to be understaffed regulatory teams, respondents were generally satisfied with resourcing within their regulatory departments. 58% of respondents felt that their companies were investing the right level of resources (including budget, staffing, and tools) in regulatory affairs. However, there is a satisfaction gap between regulatory leaders and front-line employees. Front-line employees were much more likely to report feeling under-resourced than those in leadership roles.

Current regulatory resources – all respondents

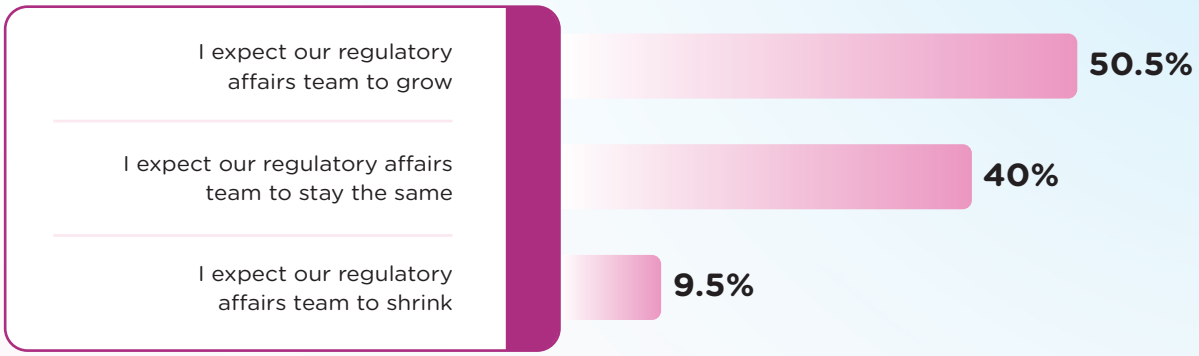


Current regulatory resources – leaders vs front-line employees



It may be that leaders are seeing the results that come with extensive spending on consultants, while front-line employees are managing the added complexity of trying to staff projects, and managing information hand-offs with consulting teams. And perhaps there is some understanding that current full-time staffing levels may not be sustainable. The majority (50.5%) of respondents expect that their regulatory teams will grow in the coming year.

Regulatory team growth in 2023



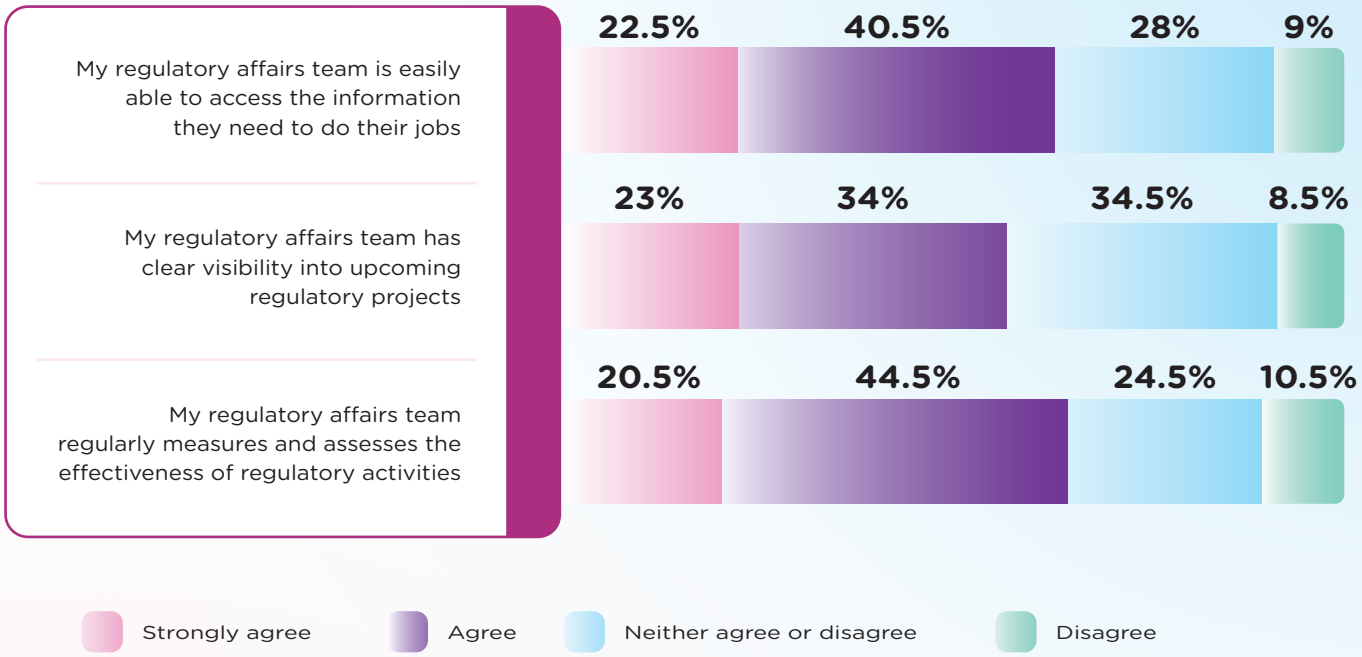
Regulatory Activities and Performance

The study looks at regulatory performance from 2 dimensions. Respondents were asked to self-assess the performance of their regulatory teams compared to their peers. They were also asked to detail their regulatory activities, how they complete their jobs, and issues faced. The results showed a significant discrepancy between how teams perceived themselves and how they actually perform.

A strong self-assessment

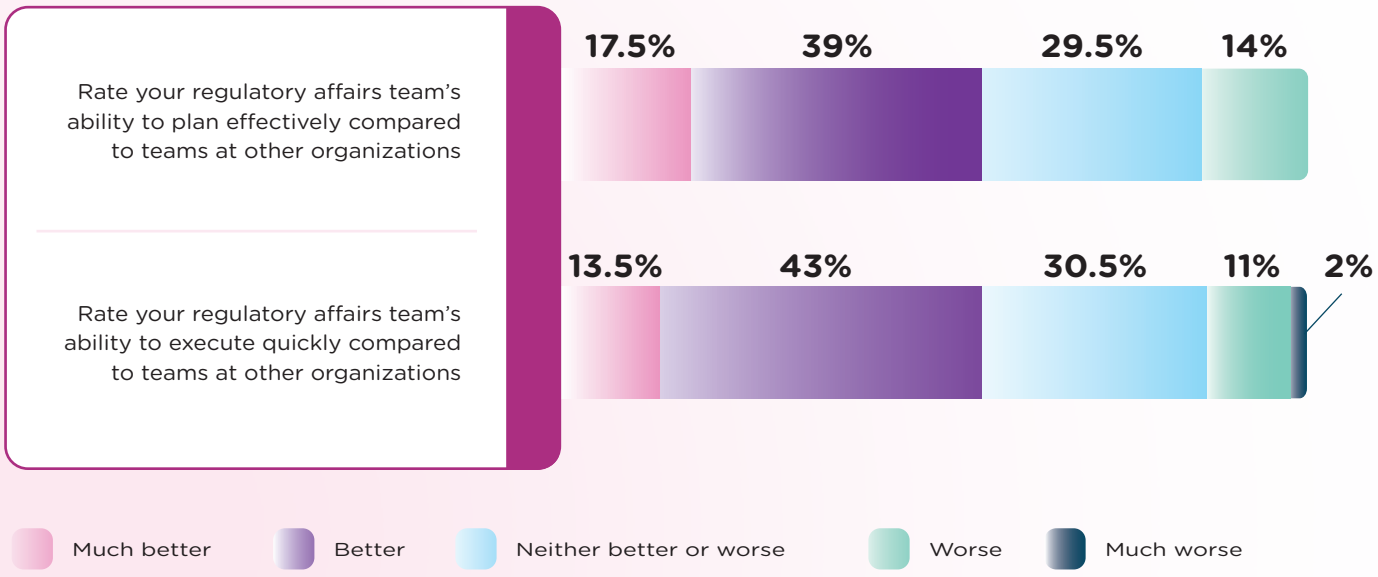
Respondents were generally confident in all aspects of regulatory performance, believing that they have the capabilities and processes in place to execute effectively. Over 50% of respondents felt that they were easily able to access the information they need, had adequate viability into upcoming expirations, and did a good job of measuring and assessing the effectiveness of their regulatory processes.

Regulatory self-assessment



When asked to compare their regulatory performance to peer organizations, respondents were similarly confident. Over 50% of respondents believed that their regulatory affairs team was able to plan more effectively and execute more quickly than teams at similar organizations. Apparently everybody in regulatory affairs is above average.

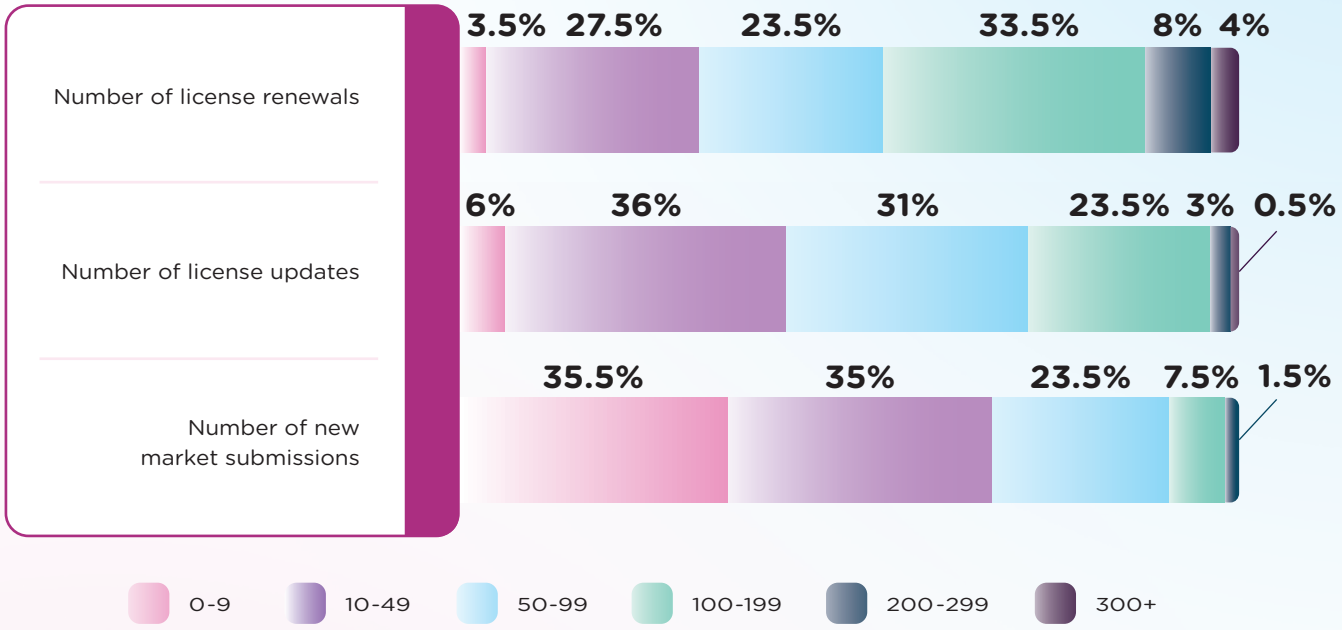
Performance compared to peer organizations



Regulatory Workload

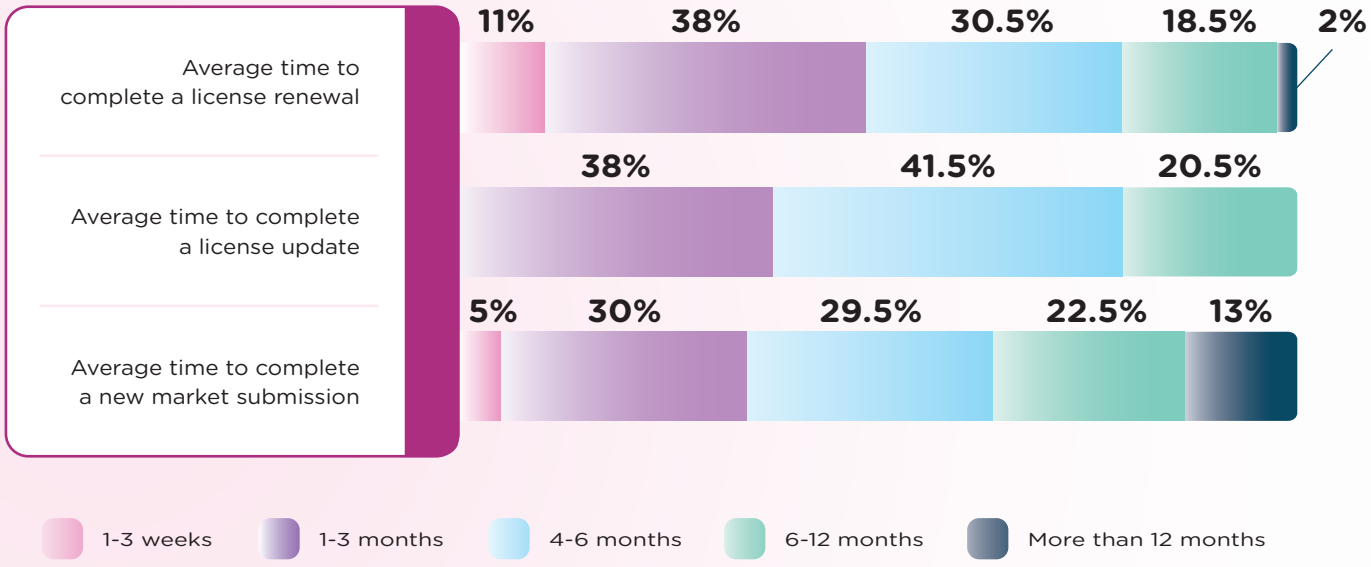
Despite the relatively small team size, respondents reported completing a large amount of regulatory work in the past year. On average companies completed 50 license renewals, 50 license updates (notifications and amendments due to design, software, legal entity, or manufacturing updates), and 10 new market submissions (market clearance or approval applications).

Activities completed in the past year



The volume of workload relative to team size would seem to validate the strong self-assessment, but did their processes allow them to complete these activities efficiently and without errors? On average new submissions took the most time, with 65% of respondents saying it takes their organizations more than 4 months to complete a submission, and 36% reporting more than 6 months per submission. However more than half indicated that it also takes their regulatory teams more than 4 months to complete a license renewal or update.

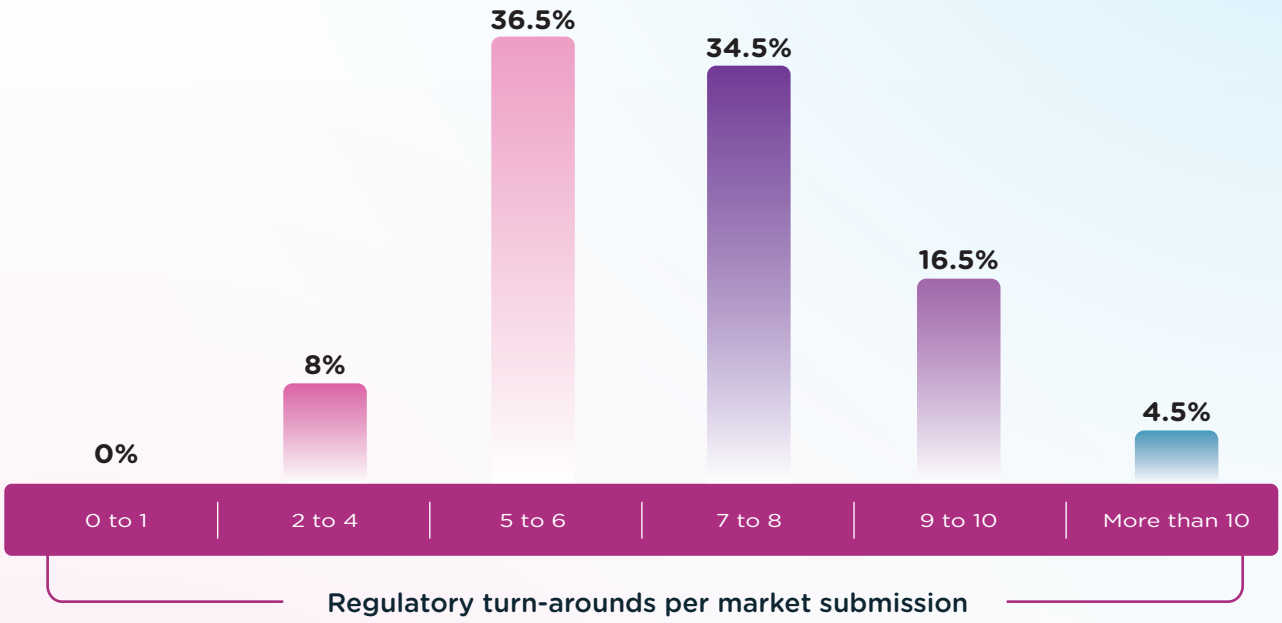
Time to complete regulatory activities



Process Inefficiencies

What drives the long completion times for regulatory activities? Naturally these are complicated processes, so it's not surprising that there's a significant amount of work involved. However, there were some clear process inefficiencies that surfaced in the survey results. First, much of the work is manual. 70% of respondents said that their regulatory affairs team spends nearly half their time on repetitive, administrative tasks.

Secondly, poorly managed or incomplete information requires a lot of back and forth with health authorities. Half of all new market submissions require more than 7 turn-arounds (correspondence, requests for additional information, etc.) with regulatory authorities.



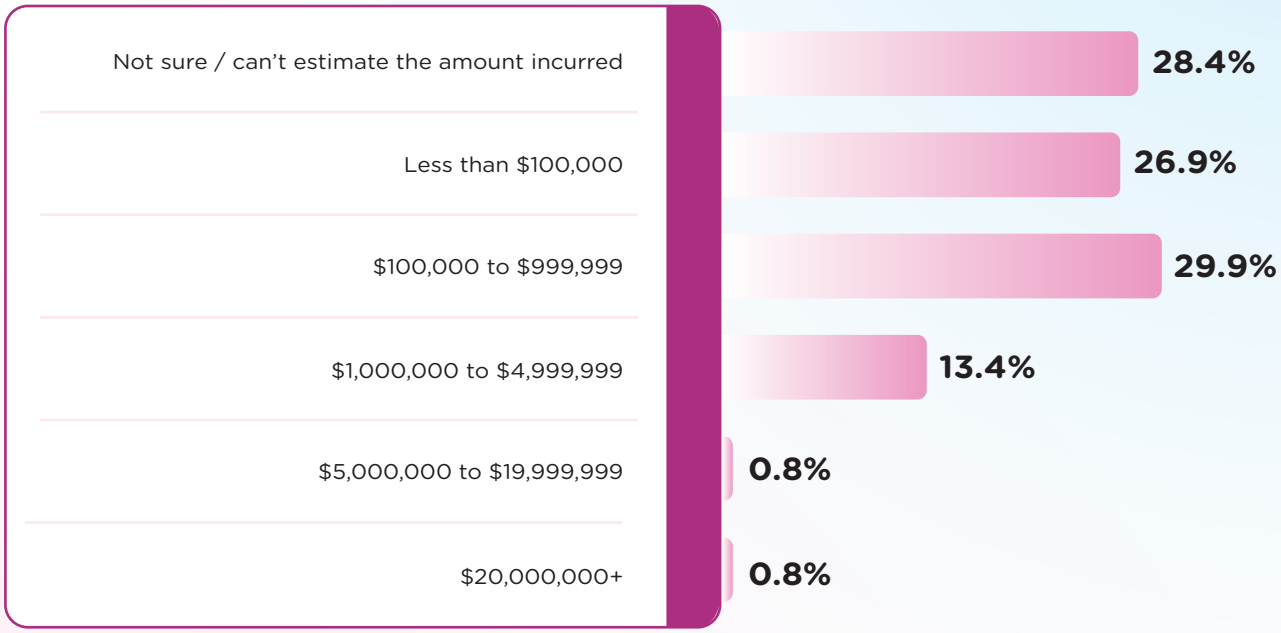
Non-Compliance

Survey respondents also reported a surprising number of non-compliance issues. 61% reported that their companies had received a CAPA or audit result showing significant process issues from health authorities, had withdrawn products from a specific market due to an expired registration, or accidently marketed products into a region where they did not have clearance in the past 2 years.

Non-compliance issues in the past 2 years

While 30% of those that reported non-compliance issues indicated that they couldn't estimate the associated costs, 75% indicated that the cost was greater than $100,000 and 15% said that the costs their organization incurred were greater than $1,000,000. These estimates likely don't take into account the full impact of non-compliance issues. In addition to fines and penalties imposed by health authorities, companies also lose significant revenue if products have to be pulled from a market. Plus, there are general costs associated with business disruption, or additional work required from the regulatory team to re-establish compliance.

Costs associated with non-compliance issues

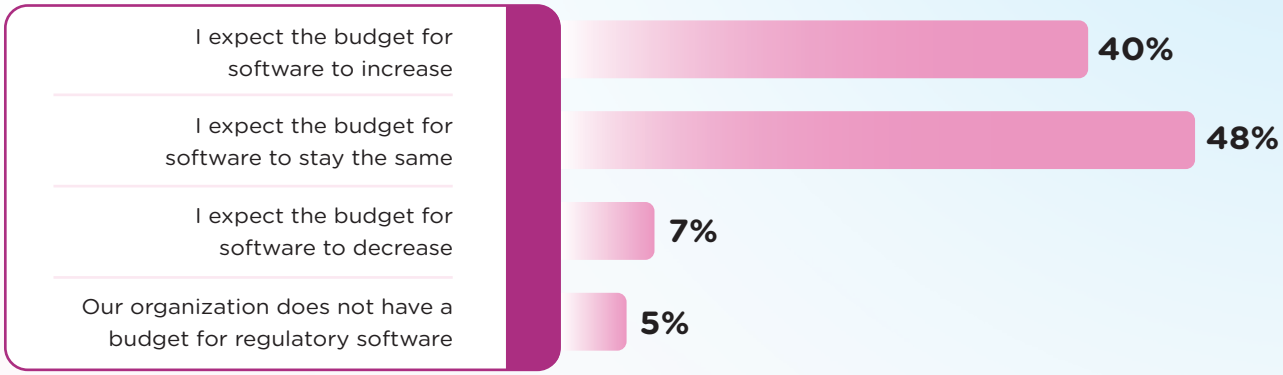


So while regulatory teams are generally satisfied with their processes and performance, there are clearly opportunities for improvement. Highly manual processes and information gaps are driving long execution times, repetitive work, and leaving regulatory teams and their businesses at risk of non-compliance.

Technology Adoption

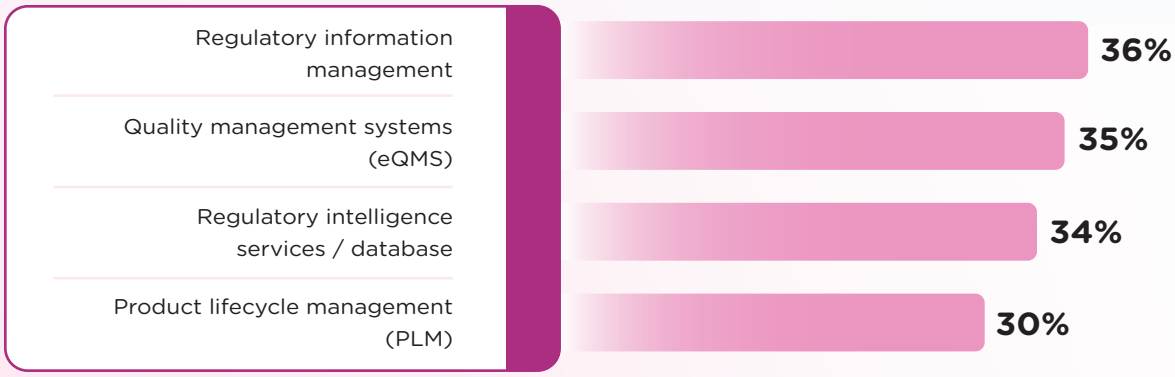
It seems likely that medtech regulatory affairs teams do have an awareness of their process shortcomings, and are increasingly investing in technology as a result. 40% of respondents expect their budget for regulatory software to increase in the coming year, with another 48% expecting it to stay the same.

Software budget for 2023



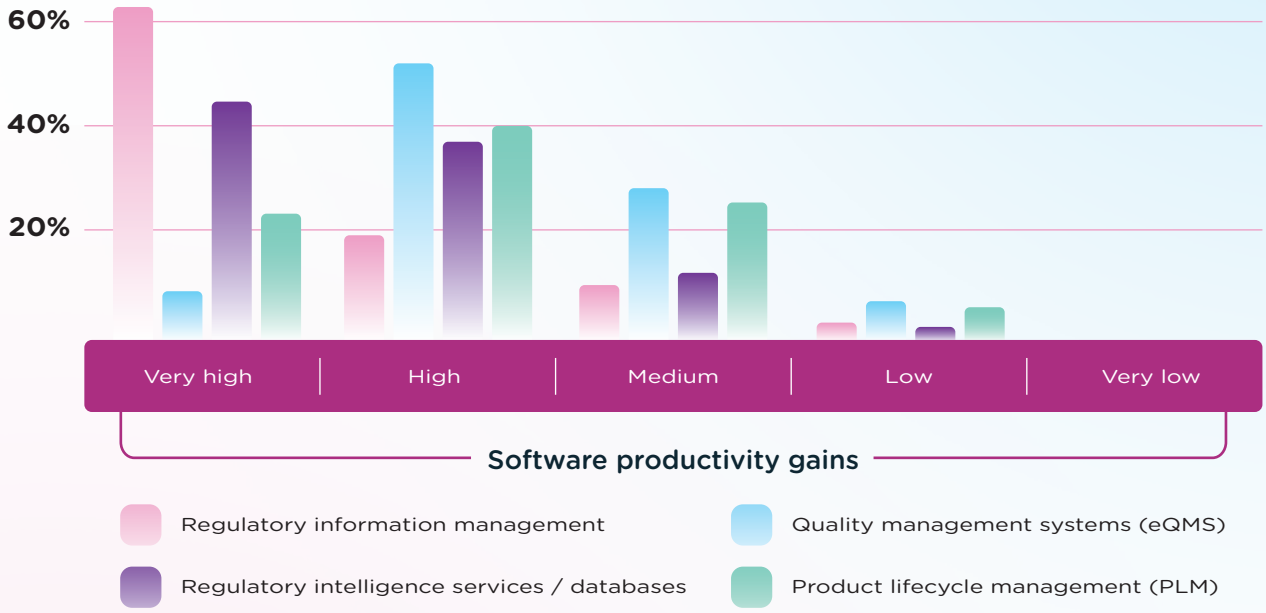
Regulatory affairs teams are increasingly moving away from traditional productivity tools (documents, spreadsheets, email, file-sharing systems, etc.) and adopting tools that are designed to support regulatory and regulatory-adjacent processes such as regulatory information (RIM), quality (eQMS), and product lifecycle (PLM) management systems. 88% of respondents indicated that their regulatory teams use one or more of these specialized software tools.

Software tools used



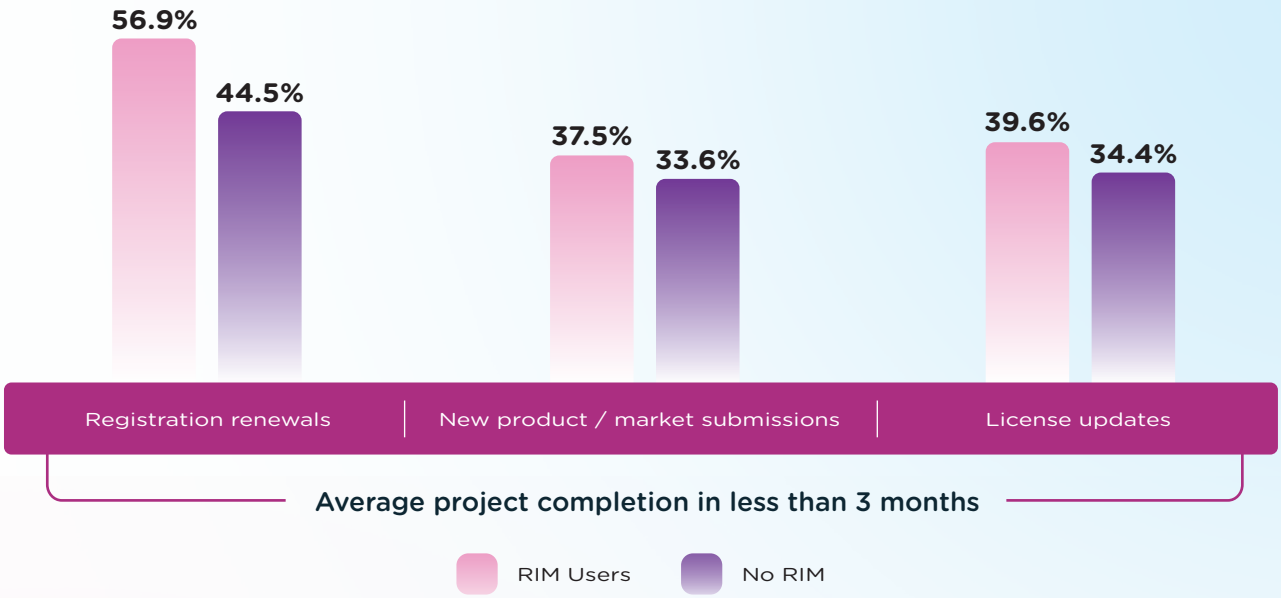
Uneven Productivity Gains

While adoption across different tools is fairly even, the productivity gains from those tools are not. Respondents were asked to rate the improvements they saw from very high to very low. While all tools provided benefits, those that are specifically designed for regulatory affairs (RIM, and regulatory intelligence) provided the greatest results. RIM systems delivered the highest productivity gains, with 64% of respondents reporting very high gains, and another 20% reporting high gains.



These results make sense. RIM systems help to centralize and organize regulatory information, making it easier to assemble complete submissions and other regulatory applications that don't require as many turn-arounds with health authorities. And they can automate a number of what would otherwise be repetitive, manual tasks, improving the efficiency of regulatory teams.

The impact of regulatory information management productivity gains was clearly visible in the performance of regulatory activities. Companies that use RIM systems reported completing license renewals, license updates, and new market submissions more quickly than those that do not. RIM users were much more likely to report an average completion time of 3 months or less for all projects.



Implications and Recommendations

The regulatory performance study ultimately shows mixed results. Medtech regulatory affairs teams clearly punch above their weight, with relatively small teams completing a very large body of work each year. This performance volume leads teams to generally believe that their processes are highly effective. At the same time, companies reported a significant amount of manual work, and information management issues that require a lot of turn-arounds with regulatory authorities.

Even more concerning was the rate of reported non-compliance issues. Over 60% of companies had a serious issue in the past 2 years. It's hard to believe that these results are congruent with highly functioning regulatory processes. Ultimately it does seem that companies are aware of, and attempting to address some of these issues. The growing adoption of regulatory-specific software shows that companies are looking to technology solutions to improve execution.

Recommendations and next steps

- **There's no reason to understaff regulatory teams.** Yes, respondents indicated that their organizations can accomplish a lot with small teams, but much of that work relies on expensive external consultants. Maintaining staffing levels that are aligned with expected workload will allow teams to work effectively, and reduce costs in the long run.
- **Track and report on upcoming workload.** Regulatory leaders aren't always aware of resourcing needs, and don't take upcoming projects into account when putting together hiring plans. Better visibility into upcoming expirations, updates, and new product launches would help leaders to plan more effectively.
- **Re-evaluate regulatory performance.** It's easy to develop complacency with status-quo processes, and there are clearly areas of improvement for regulatory affairs. Leaders should look past self-assessments and make sure that they're clearly measuring and benchmarking regulatory activities compared to their peers (data in this study is a good starting point).
- **Be thoughtful with technology investments.** Not all tools provide the same productivity gains. Regulatory leaders should assess their biggest areas of need, and prioritize tools that can address these gaps. Solutions that are purpose-built for regulatory processes provide the greatest gain, so attempting to use general productivity software or product/quality management tools to automate regulatory processes may not provide the best return.

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, and global standards. 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, and standards management in a single, integrated platform.

For more information about Rimsys or to get a free demo of our platform, please visit rimsys.io.

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