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Driving Regulatory Excellence™

The race to EU MDR compliance

KPMG/RAPS survey illustrates the ground medical device companies still have to cover

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In June 2018, KPMG and the Regulatory Affairs Professionals Society (RAPS) conducted a comprehensive survey of more than 200 regulatory and quality leaders at major medical device companies to evaluate where individual organizations stand on the road to MDR compliance. The results yielded several key, and sometimes surprising, insights:

78% of medical device companies stated that, as of today, they do not have a sufficient understanding of the EU MDR legislation.

58% of all respondents noted that they had no strategy in place to remediate gaps in their clinical data or processes for collecting data.

When asked what they believed to be **the greatest barriers** to MDR compliance, respondents highlighted **the understanding of the regulation itself**, followed by the bandwidth of designated notified bodies, as their greatest concerns.

39% of organizations have yet to identify, define, or document the roles and responsibilities of a Person Responsible for Regulatory Compliance (PRRC).

This paper looks at several key areas on the road to MDR compliance and:

- **Highlights where companies of different sizes and types fall when it comes to the issues detailed in this paper by assessing the challenges they face.**
- **Recommends immediate actions by diving into what to do now.**
- **Provides insight into how these changes are likely to play out in the long run.**

The first imperative:

Understanding the law

The challenge

With less than two years until the clock runs out, it may be surprising to learn that 78% of medical device companies surveyed by KPMG and RAPS do not yet believe they have a sufficient understanding of the EU MDR legislation. Most of the hurdles companies are facing start here: At a high level, industry must accept the fact that the roll-out and interpretation of any broad-based regulation will contain elements of "gray area." The journey to compliance will not happen overnight, and mistakes will be made by any organization striving to comply with the long list of MDR requirements. Having a cross-functional plan in place that not only captures lessons learned, but also articulates remediation and compliance efforts will best position an organization for long-term success.

What to do now

The current Medical Device Directive (93/42/EEC) has 20 Articles and 12 Annexes, and the Medical Device Regulation (EU 2017/745) has 123 Articles and 17 Annexes. It is, therefore, critical to build a cross-functional team and assign appropriate staff members to read and analyze different aspects of the law. Further, since most of these individuals will likely be regulatory or quality professionals, they must be able to "translate" regulations into language that resonates with different audiences, particularly when it comes to gaining understanding and securing commitment from C-suite leadership.

The long run

EU MDR is not a standalone regulation but is integrally entangled with other required certifications. It is, therefore, of concern that most companies seem to be challenged by the need to manage multiple compliance efforts at the same time. For example, since EU MDR certification is easier to obtain when compliance with certain aspects of ISO 13485:2016 have been achieved, it is wise to pursue compliance with both requirements in tandem. And yet, almost half of survey participants have not yet achieved ISO certification to the current standard, of which 42% were mid-sized companies and 43% were small companies.[1] The reality is, there are enough overlapping requirements between the two—e.g., business procedure and process modifications, as well as language and reference adjustments—that pursuing them simultaneously will likely be more efficient in the long-term.

The same holds true for the Medical Device Single Audit Program (MDSAP). Although large companies seem to be relatively far along in this compliance effort, 30% of mid-sized companies and 52% of small companies have yet to initiate their MDSAP programs. It may be sensible to make headway on this requirement, for Canada in particular, before proceeding full steam into EU MDR compliance. This will ensure efficient application of resources and avoid duplication of work and/or unnecessary revisions to the procedures supporting Quality Management Systems (QMS). In turn, MDSAP compliance will allow organizations to better utilize their resources not only to support EU MDR and ISO compliance, but also to ensure that new product development and post-market requirements are not neglected while pursuing this compliance effort.

1 Small companies are defined as having revenue of less than US$10M; medium-sized companies are defined as having revenue of between $US10-999M; and large companies are defined as having revenues over $US1B.

The match game:

Aligning cross-functional resources and teams

The challenge

Forty-one percent of organizations have not taken a long-term view to planning for budget considerations, potential organizational and business process changes, and resource requirements. This lack of foresight could hinder successful execution if it reflects an absence of cross-functional engagement. Survey results demonstrate that, although larger companies are more likely to have formed cross-functional teams than small ones, 28% of all companies do not have such a program in place at all.

What to do now

Although companies with an established program may have a robust overall EU MDR compliance budget, it is critical that they stratify requirements by functional area, e.g., regulatory affairs, quality assurance, research & development, supply chain, and information technology. A cross-functional team is indispensable when it comes to reviewing and discussing dependencies and impacts of the regulation across functions. Further, documentation should include new organizational structure changes, including details of the PRRC role, the individual's role in the organizational structure, and appropriate training curricula. Finally, companies should seek insight from the supply chain organization into how their business continuity and product portfolio management efforts could be impacted by changes in other functions.

The long run

In the near term, companies may allocate the majority of funds to quality assurance and regulatory affairs. However, a truly prepared organization will ensure that there is sufficient funding for issues with longer-term, cross-functional impacts, such as MDD recertification and MDR certification, relationship management with newly designated notified bodies, and efforts to ensure that economic operator entities are compliant (as detailed in the following section). Without adequate planning, EU MDR compliance efforts could have the unwanted impact of jeopardizing post-market surveillance (PMS) plans, labeling, and product cutover timelines.

The big picture:

Navigating systemic challenges related to notified bodies and economic operators

Notified bodies

The challenge

The "bandwidth of notified bodies" was cited as the most pressing concern by most survey respondents. Due to more stringent requirements, only 19 notified bodies have applied for re-designation under MDR, which is in sharp contrast to the 80+ notified bodies that are currently designated under the MDD. Not only has the number of potential notified bodies dropped by more than 75%, but there are competing priorities between MDD re-certification activities, ISO 13485:2016 certification, and MDSAP audits. These competing interests could create resource constraints, limit the availability of the requisite notified body auditors to maintain current products on the market, and, ultimately, hinder companies as they seek to schedule required MDR certification audits.

What to do now

In addition to devising MDR certification strategies, organizations should take advantage of the grace period under MDR when they tackle MDD recertification. It is important to consider that some reusable Class I products and unclassified software must be compliant by May 2020, and that some products will need to incorporate significant changes after notified bodies' MDD recertification application deadlines. Since MDR compliance must include significant changes made after the May 2020 deadline, requirements should be considered as early as possible during product development.

The long run

Based on the expected intensity of their workloads, many notified bodies have begun informing their client(s) of cutoff dates for MDD recertification applications, prior to the May 2020 deadline, so that they can begin to transition their focus to MDR certifications. Companies should communicate with their notified bodies to understand what is expected of them regarding MDD recertification versus MDR certification.

Economic operators

The challenge

The supply chain function has several significant new requirements to address under EU MDR. This explains why 45% of companies surveyed rank supply chain as one of the most challenging areas to manage.

What to do now

Companies are finding it helpful to establish cross-functional teams that include substantial representation from the supply chain function as they seek to accommodate new requirements. One of the most far-reaching provisos is the need to have all economic operator entities (importers, distributors, authorized representatives, and contract manufacturers) that were not previously registered under the MDD comply with traceability requirements, post-market obligations, and required inputs into the EUDAMED database. Additionally, companies must account for the likelihood that "original equipment manufacturer" (OEM) will no longer be a valid operating model in the near future.

The long run

Forward-reaching companies can get ahead of this reality by rethinking their relationships with economic operators through revised Quality Agreements and preparing for the fact that labeling requirements will be much more prescriptive in the future, e.g., important information will be required on the label or accompanying documentation and must be updated on the manufacturers' website. Many are undertaking the detailed long-term planning needed to ensure that all devices are fully traceable through a Unique Device Identification (UDI) system. And, where applicable, OEMs are planning for conversion to contract manufacturers by establishing visibility into the design and PMS of the OEM, buying the design completely, becoming product distributors, or discontinuing product sales altogether.

The need for balance:

Assessing impacts on quality measures for both new and legacy devices

The challenge

Quality requirements— for both new and legacy products—was ranked as one of the most difficult barriers to achieving EU MDR compliance by 62.5% of survey respondents. It is likely that this challenge stems from quality's cross-functional impact—from clinical data requirements to PMS obligations. There are some differences, however, between the impacts on new breakthrough innovation versus legacy products.

– Innovation

When asked if their organization had determined a strategy for evaluating clinical evidence and preparing clinical evaluation reports (CERs) to meet EU MDR requirements, 58% of respondents said they had no strategy to remediate gaps in their clinical data or processes for collecting data. Although many manufacturers are still taking the equivalency route for their Class IIb implantables, clinical data will soon be required on their own devices, due to equivalency restrictions introduced in MDR. Many organizations do not currently have a resource model in place to manage their devices' clinical data, nor do they have sufficient clinical expertise and systems to manage the data. Finally, post-MDR compliance, there will be an additional burden on manufacturers when it comes to sustaining the required frequency of updates.

– Legacy products

EU MDR efforts seem to be particularly daunting when it comes to legacy products, with 64% of respondents stating that their organizations would discontinue manufacturing some products due to stringent new requirements dictated by EU MDR. Given these findings, a thorough evaluation of legacy products should be conducted immediately to ensure that strategies are in place for continuation or rationalization. It is important to note that, even when a product has been discontinued, there may still be a need for periodic collection and analysis of risk data under the new legislation.

What to do now

Since EU MDR requires organizations to consider risk management across all aspects of the device lifecycle, PMS systems must be structured to allow data to be communicated back to the risk management team. For example, any risk that arises in a clinical setting must be addressed by post-market clinical follow-ups and evaluations. And, adverse event reporting must occur within 15 days of an event and include all product risks.

These shifts require a comprehensive plan specifying schedules, resources and budgets to ensure that all products on the market—both new development and legacy products—are compliant. Finally, these new processes require a concerted people and change effort to clarify the evolving interrelationship between post-market and risk functions, and to ensure that CERs include regularly updated PMS data.

The long run

To meet the EU MDR deadline, it is critical that organizations accelerate strategic decision-making on issues with long lead times, such as headcount and staffing, labeling, product rollout, clinical guidelines, and documentation. Specifically, since more frequent updates and maintenance of technical documentation will be required post-2020, organizations may want to simultaneously evaluate their tech file structures for consolidation opportunities. This will allow a decrease in maintenance costs and efforts for maintaining not only tech files, but also associated clinical and safety documents. Finally, the most forward-thinking organizations should be evaluating their overall product portfolios to ensure that the return on investment (ROI) for new and existing products can be justified vis-à-vis the cost of EU MDR implementation and life-cycle maintenance. In other words, in some cases, the cost of compliance will outweigh the value of a product in the marketplace, thus necessitating potential product rationalization.

The full spectrum:

Looking ahead to post-market surveillance and EUDAMED

The challenge

Despite much more stringent PMS requirements under EU MDR, 58% of survey respondents do not yet have a data collection strategy in place for post-market activities.

What to do now

Organizations should already be in the process of instituting required PMS obligations for CE-marked products defined in their QMS. This will allow adequate time for the gathering of relevant clinical data required for CERs, as well as highlighting and resolving gaps in data and surveillance. Additionally, all data coming out of a PMS should be incorporated into devices' technical documentation.

To demonstrate EU MDR compliance, a manufacturer should implement a strategy for addressing PMS for each device through the development of a PMS Plan. In combination with a Periodic Safety Update Report (PSUR), the plan should comprise a proactive and systematic process for collecting information, suitable indicators and threshold values for use in the continuous reassessment of the benefit-risk analysis, effective and appropriate methods and tools for investigating complaints and analyzing market-related experiences collected in the field, and methods and protocols for communicating effectively with affected parties through EUDAMED submissions.

EUDAMED is changing how the European Commission handles medical device data, thus obliging many organizations to transform their business processes to meet these new requirements. This database integrates information regarding devices on the market, relevant economic operators, certain aspects of conformity assessment, notified bodies, certificates, clinical investigations, vigilance, and market surveillance. Manufacturers need to take the time to understand which datasets must be submitted and in what format, as the guidelines are scattered throughout the regulation. This aspect of compliance may prove to be particularly challenging, as the EUDAMED database is still in development and may not go live until after the May 2020 EU MDR deadline. If this is the case, manufacturers will not get a reprieve from collecting required data, but will instead have six months from the go-live date to submit the backlog of data. Decisions need to be made about who will own EUDAMED submissions, which systems will communicate with the database, and how to ensure that cross-functional teams have adequate processes and templates in place to gather the necessary data.

The long run

CE-marked devices will be associated with more extensive post-market obligations, require more rigorous documentation of clinical data before MDR certification is granted, and be subject to continuing vigilance to ensure they remain safe to use. Establishing proactive, systematic and sustainable processes for collecting information from both a pre- and post-market standpoint are critical for maintaining compliance with MDR.

Conclusion

The good news is that there is still time to accomplish all of the above and more, if companies work smart.

While the biggest challenge may be securing the resources and budgets to ensure that all pieces of the puzzle can be addressed, it will likely be helpful to position your EU MDR effort with leadership as more than just a regulatory obligation. Companies should instead reframe their EU MDR initiatives as an opportunity to simultaneously transform their organizations' processes, products, systems, and structures—a mindset shift that will have far-reaching value, long after compliance is achieved.

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 pharmaceutical 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.

About RAPS

The Regulatory Affairs Professionals Society (RAPS) is the largest global organization of and for those involved with the regulation of healthcare and related products, including medical devices, pharmaceuticals, biologics and nutritional products.

RAPS tracks regulatory developments and evolving professional competencies, and uses the latest information to develop tools and resources to meet the current and emerging needs of regulatory professionals.

We connect the global regulatory community and empower professionals to share knowledge, ideas and expertise with one another. Both online and in person, we provide multiple opportunities for discussion, networking and relationship building among those based in disparate parts of the world or within the same local area.

We also deliver relevant regulatory news and analysis for busy professionals, and informational and educational resources for those who need a deeper understanding on key topics. As the need for qualified regulatory professionals continues to grow around the world, we help promote a competent regulatory workforce. RAPS created and continues to support Regulatory Affairs Certification (RAC), the profession's only accredited post-academic credential.

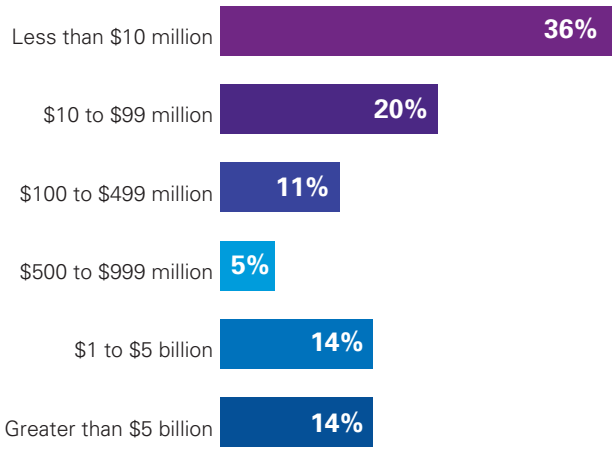
RAPS helps regulatory professionals effectively communicate the vital role they play in ensuring safe and effective healthcare products for patients and healthcare providers—giving them a voice in important conversations within their organizations and beyond, as they are increasingly being called upon to play leading roles.

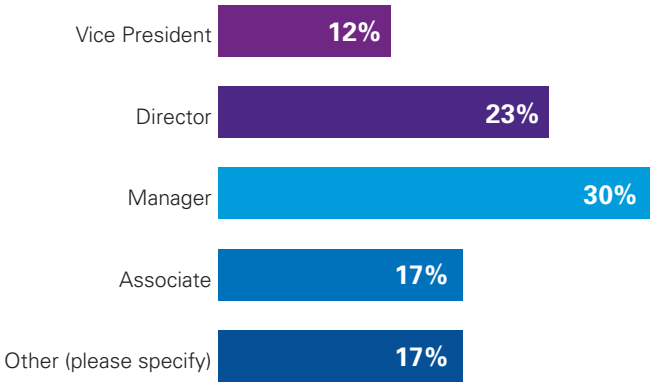
Survey procedure

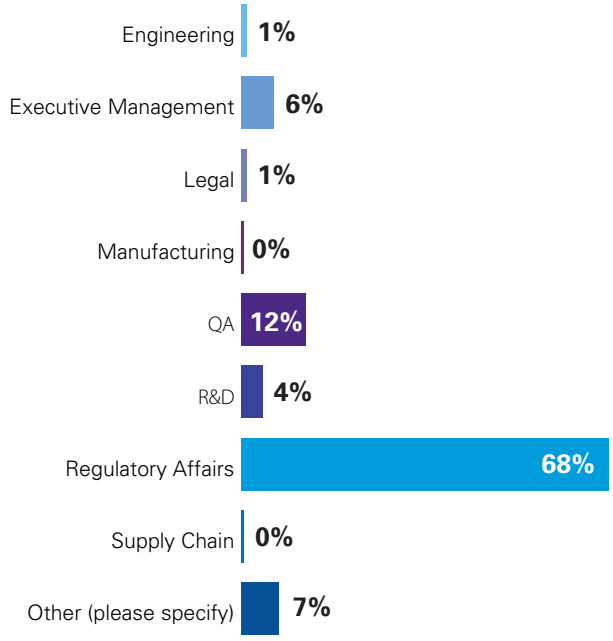
The KPMG & RAPS EU MDR survey was distributed to the RAPS member base and is an analysis of 220 responses from various medical device organizations. The range of respondents represented includes 36% companies with revenue less than US$10 million, 36% companies with revenue between US$10-999 million, and 28% companies with revenues over US$1 billion. The geographies represented by participating companies spanned Africa, Asia, Europe, the Americas, the Middle East, and Oceania, with 91% of participants from the EU and North America. Most respondents were regulatory affairs or quality assurance directors and managers. The survey closed on 15 June 2018.

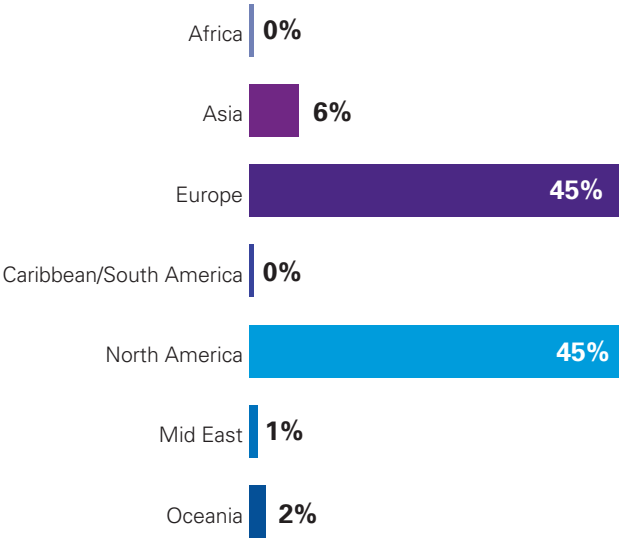
KPMG and RAPS EU MDR Survey Results and Key Findings

Survey Participants







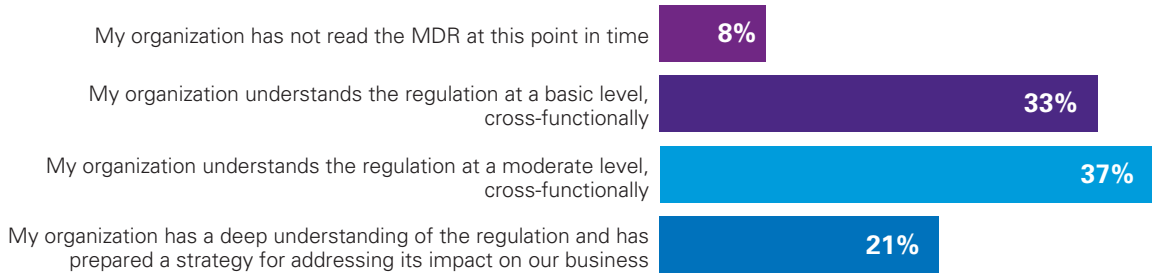


Note: 1. The total number of respondents (N) for each question may vary, depending on their responses

2. The terms 'Respondents' and 'Organizations' have been used interchangeably in some cases, as we have considered each respondent to be a unique representative of his/her organization. In most of the cases, a single individual from each organization has taken part in the survey

KPMG and RAPS EU MDR Survey Results and Key Findings

How well does your organization understand the MDR regulation and timeline for implementation?



Key observations

– Twenty-one percent have a deep understanding of the regulation and its impact on the business.

– However, 41% have neither read the regulation nor do they have more than a basic understanding.

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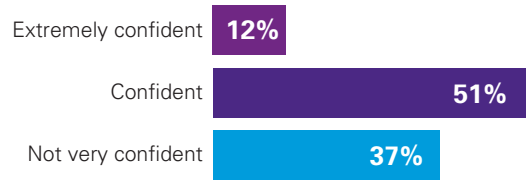
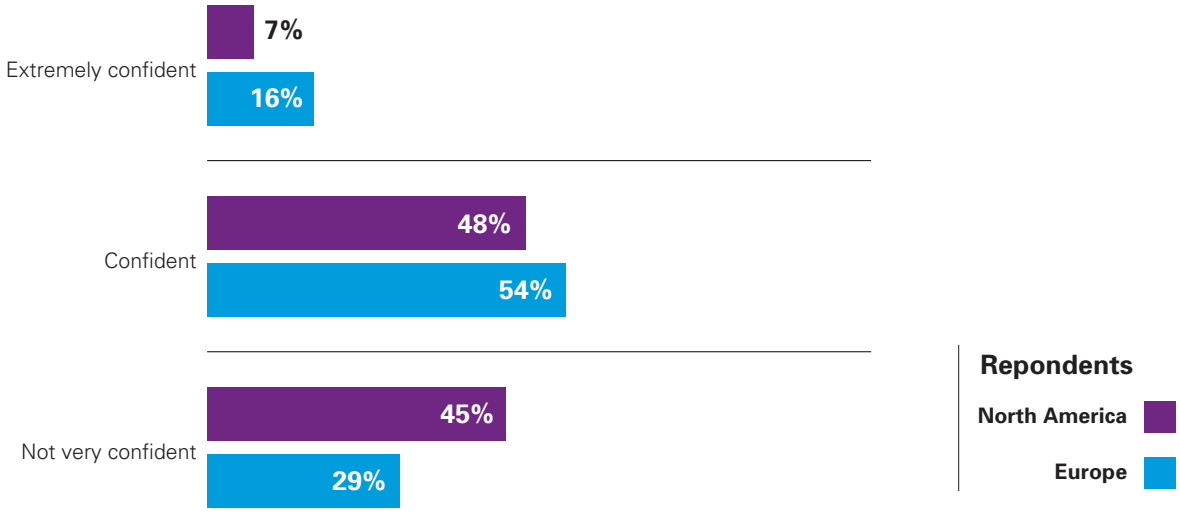
KPMG and RAPS EU MDR Survey Results and Key Findings

How confident are you that you understand and will be able to meet the impending deadlines?

Response analysis of companies in the revenue range of US$1-99 million



Response analysis of respondents in North America and Europe



Key observations

– Companies in the revenue range of US$0-99 million are most likely to feel that they understand and will be able to meet the deadline in 2020.

– There is a gap between North America and Europe in terms of meeting deadlines.

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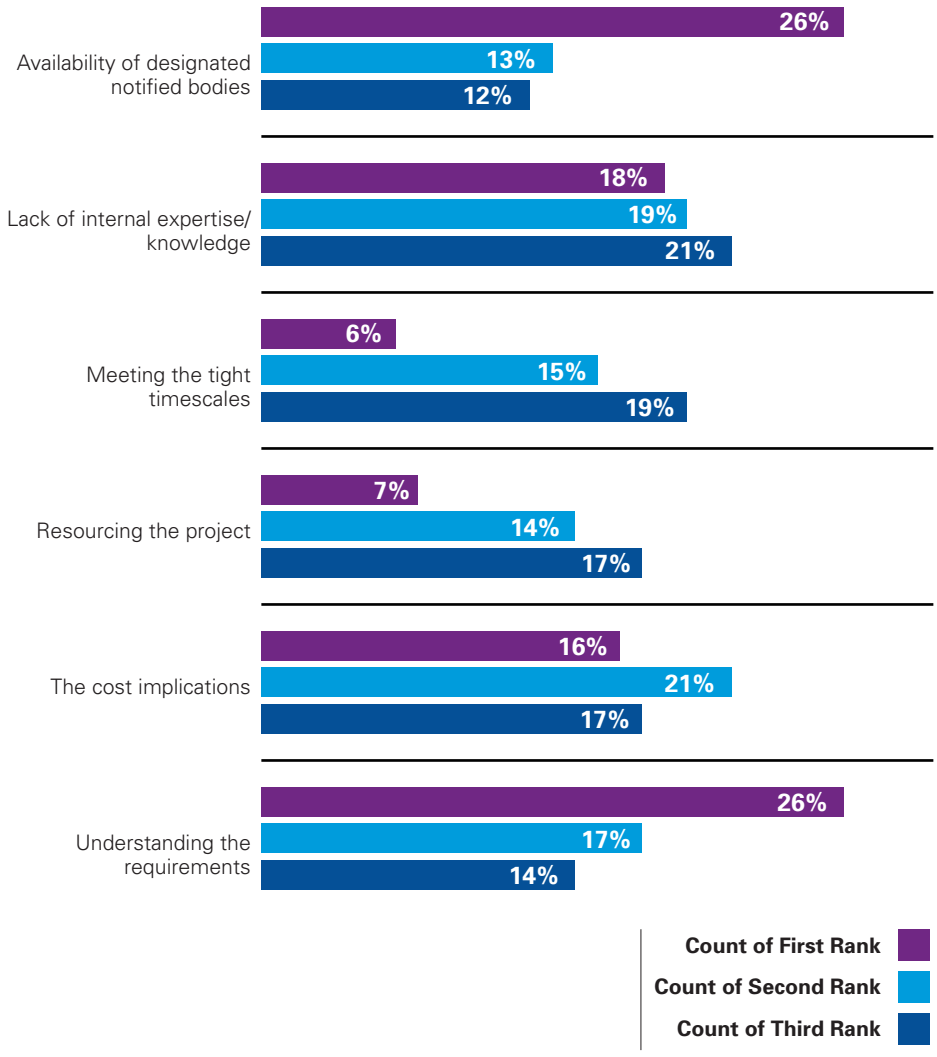
KPMG and RAPS EU MDR Survey Results and Key Findings

What do you believe is the greatest barrier to MDR compliance? (Please rank 1-6, with 1 as the most difficult and 6 as the least difficult.)



Key observations

– Most respondents felt that "Understanding the requirements" and the "Availability of designated notified bodies" are the greatest barriers to establishing MDR compliance.

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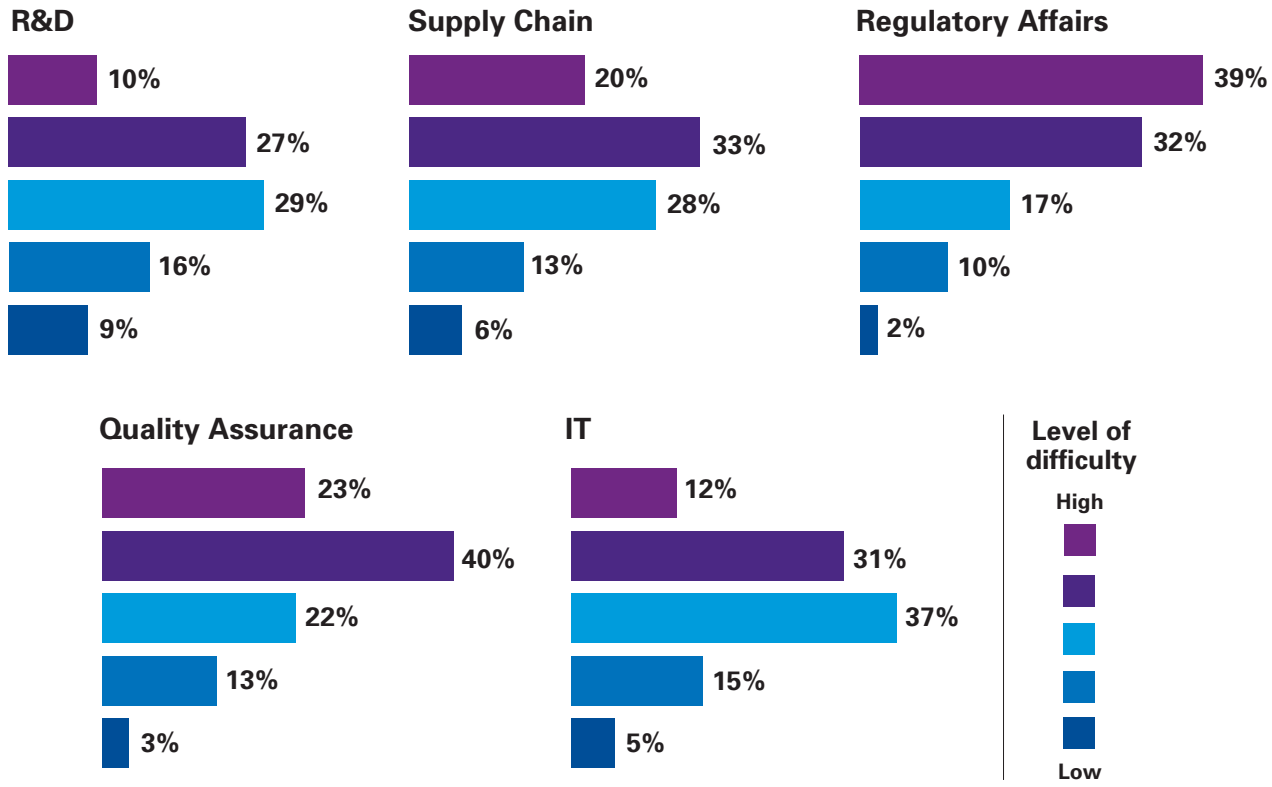
KPMG and RAPS EU MDR Survey Results and Key Findings

How challenging do you anticipate the journey from MDD to MDR compliance will be for each of the following functional areas?



Key observations

– The transition from MDD to MDR is considered to be comparatively more difficult for the Regulatory Affairs function, followed by Quality Assurance.

– Most feel the transition will be the easiest for the R&D and IT departments.

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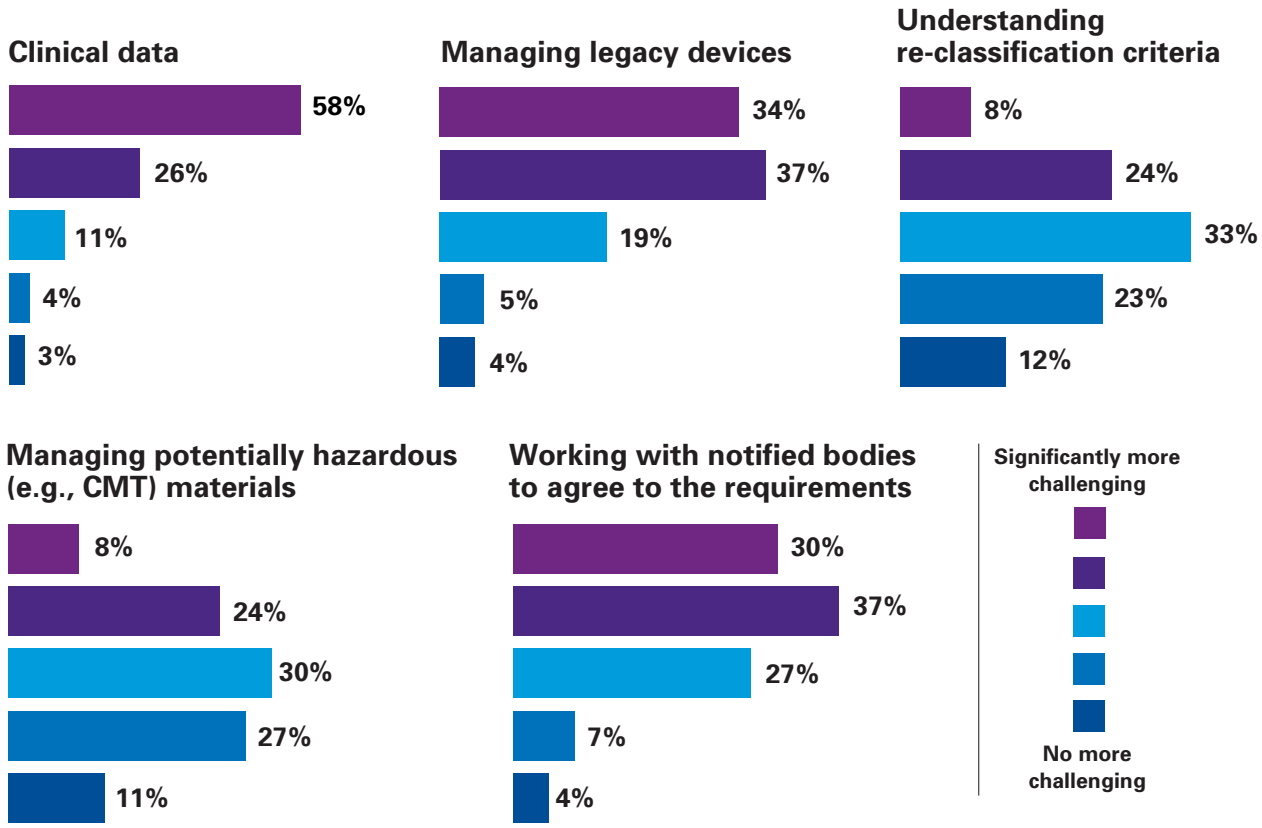
KPMG and RAPS EU MDR Survey Results and Key Findings

Compared to current MDD requirements, how challenging do you anticipate the following areas will be under the new regulations?



Key observations

– Clinical data ranked as comparatively more difficult than current MDD requirements, followed by managing legacy devices (71%).

– Managing potentially hazardous materials is considered the least challenging.

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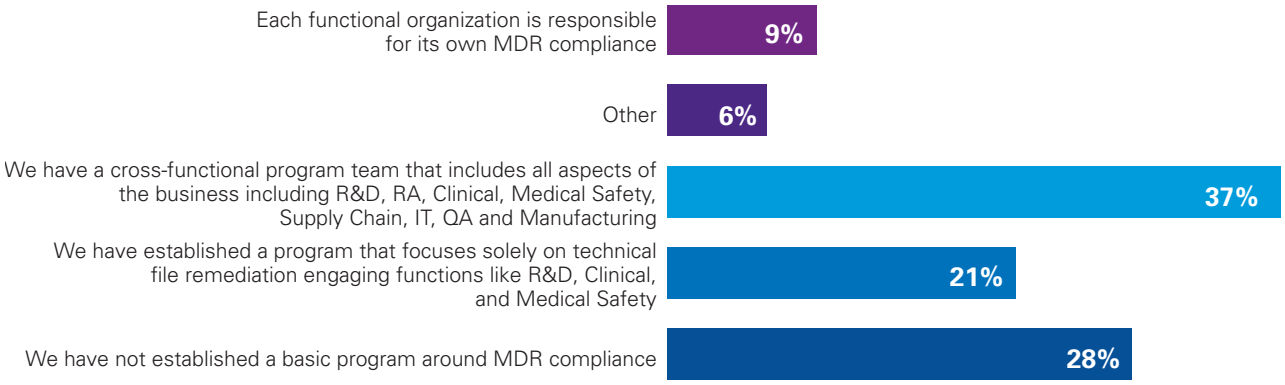
KPMG and RAPS EU MDR Survey Results and Key Findings

Even though R&D, Clinical, and Medical Safety are the most heavily impacted by the new regulation, the MDR addresses multiple functions within an organization including Supply Chain, Quality Assurance, IT, and Manufacturing. Has your organization built a program that includes a cross-functional team?

Percentage of respondents



Key observations

– Fifty-eight percent of respondents have an MDR compliance program that crosses at least some functions, while 28% have not established an MDR compliance program at all.

– Large companies are more likely to have a cross-functional program that includes various functions (41%), while smaller organizations are less likely to have such a program (71%).

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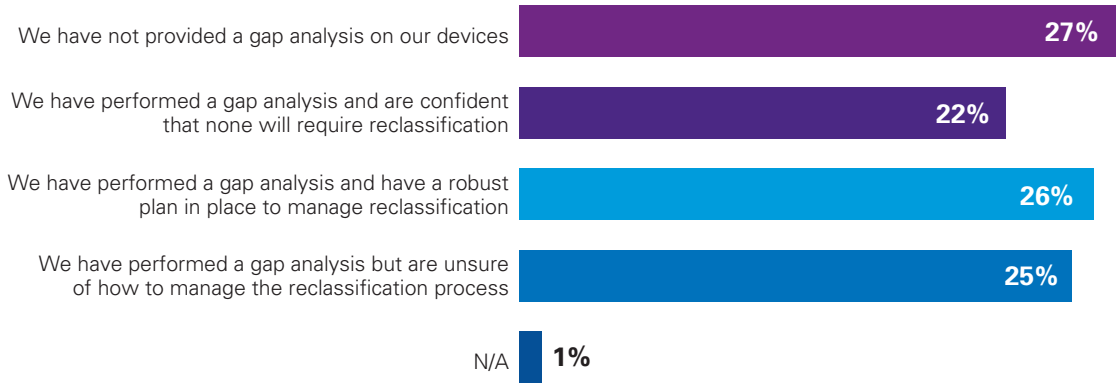
KPMG and RAPS EU MDR Survey Results and Key Findings

Has your organization assessed its product family and, if so, determined its reclassification action plan?

Percentage of respondents



Key observations

– Most respondents say that their organizations have performed a gap analysis on their devices.

– An almost equal number of respondents say that their organizations either have a robust plan to manage reclassification or are unsure how to manage the reclassification process.

– Twenty-two percent say their devices would not require reclassification.

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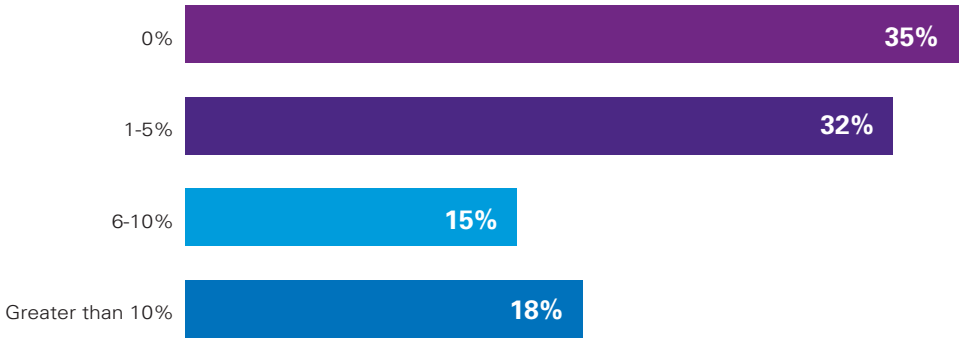
KPMG and RAPS EU MDR Survey Results and Key Findings

What percentage of legacy products do you expect to discontinue due to new MDR requirements?



Key observations

– Most of the respondents say that their organizations would discontinue either no or very few products, and this is true across both RA and QA departments.

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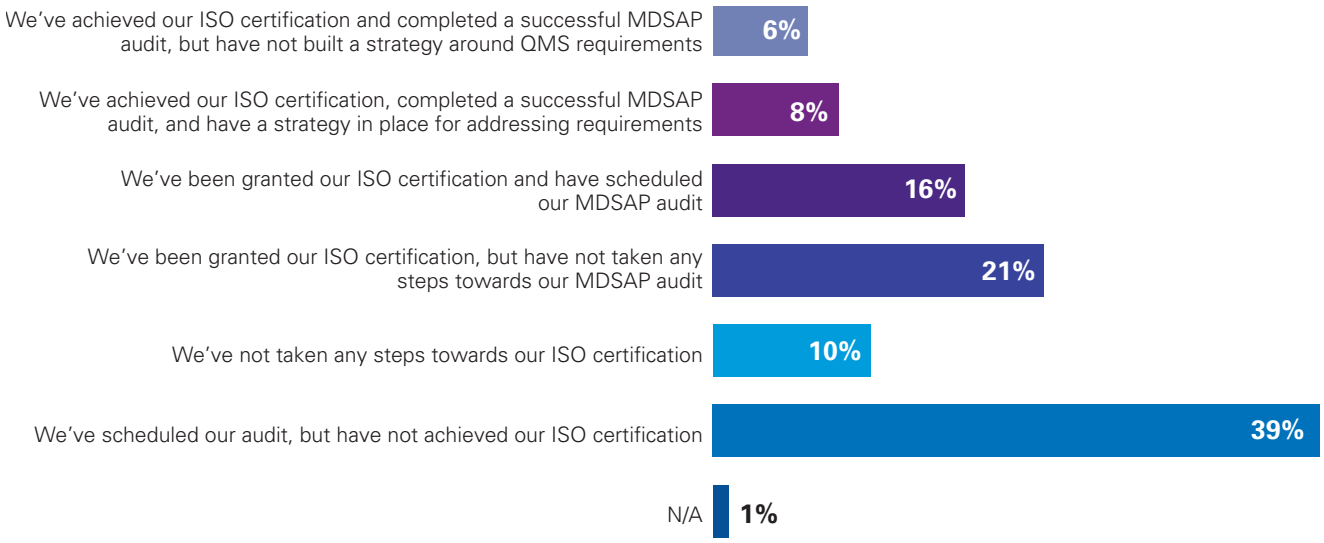
KPMG and RAPS EU MDR Survey Results and Key Findings

Have you achieved your ISO 13485:2016 certification, knowing that this certification makes the impact of the QMS requirements of EU MDR more achievable? Has your organization developed a strategy to implement the EU MDR QMS requirements?



Key observations

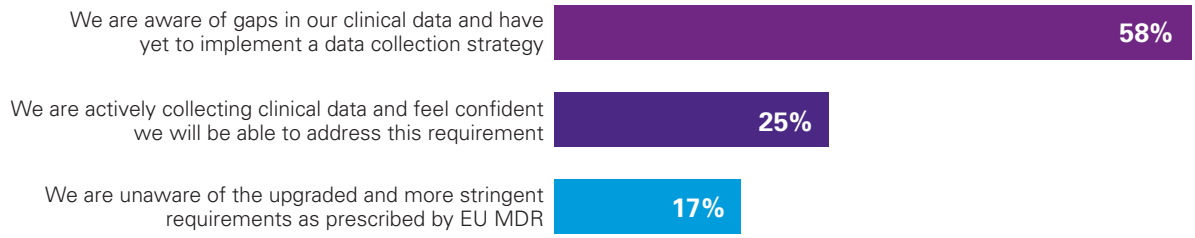
– Overall, a majority (51%) of respondents say that their organizations have been granted the ISO certification.

– Organizations with higher revenue are more likely to have been granted ISO certification, and to have scheduled the MDSAP audit.

– North American companies are more likely to have achieved ISO certification than those in Europe.

KPMG and RAPS EU MDR Survey Results and Key Findings

Has your organization determined its strategy for evaluating clinical evidence and preparing clinical evaluation reports to maintain CE marking?



Key observations

– More than half of all respondents have yet to implement a data collection strategy.

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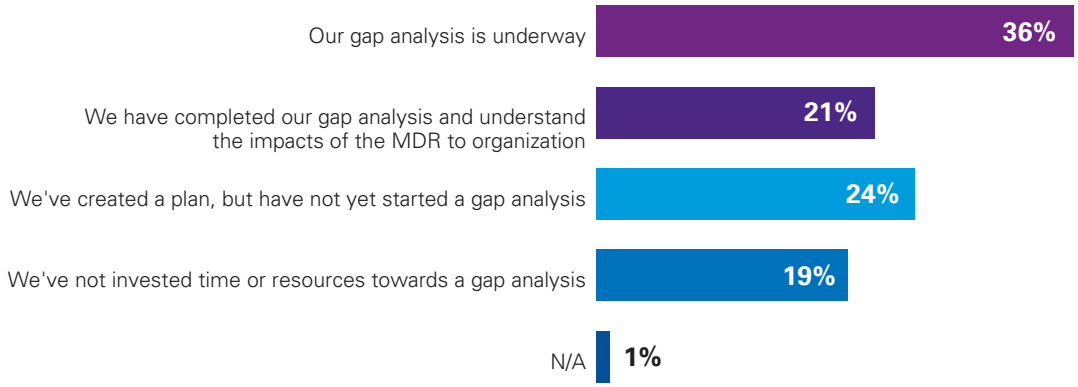
KPMG and RAPS EU MDR Survey Results and Key Findings

Has your organization started a gap analysis of its compliance against the MDR, and if so, where does it stand?

Percentage share of respondents



Key observations

– Nineteen percent of respondents say their organization has not yet invested time or resources towards a gap analysis.

– The majority (53%) of smaller organizations have either not figured out time/resources for the gap analysis or have just created a plan for doing it.

– Among the larger firms, only about 7% have yet to conduct an analysis.

– Sixty-five percent of organizations in Europe have started a gap analysis, vs. 51% in North America and 36% in Asia.

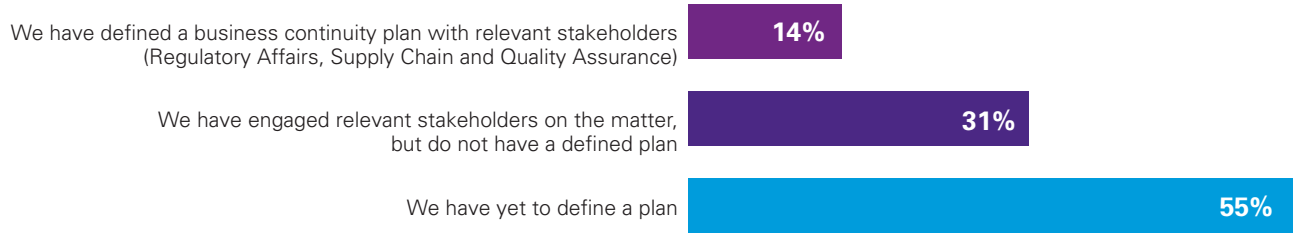
Note: 1. The total number of respondents (N) for each question may vary, depending on their responses

2. The terms 'Respondents' and 'Organizations' have been used interchangeably in some cases, as we have considered each respondent to be a unique representative of his/her organization. In most of the cases, a single individual from each organization has taken part in the survey

KPMG and RAPS EU MDR Survey Results and Key Findings

Have you developed an operational plan for business continuity that addresses how to diminish MDD inventory while ramping up the sale and distribution of MDR certified products?

Percentage of respondents



Key observations

– The majority of respondents have not defined a plan to diminish MDD inventory while ramping up the sale and distribution of MDR-certified products.

– Among the companies who do not have a defined plan, companies having revenues <US$10 million have the highest market share.

Note: 1. The total number of respondents (N) for each question may vary, depending on their responses

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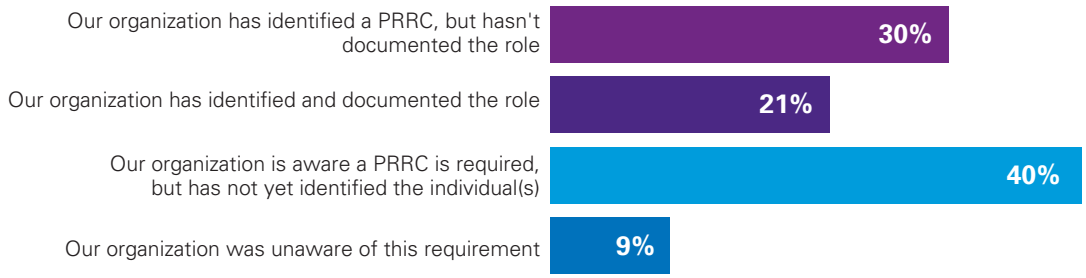
KPMG and RAPS EU MDR Survey Results and Key Findings

Have you considered the individual(s) within your organization who should be identified as the Person(s) Responsible for Regulatory Compliance (PRRC)?

Analysis of overall respondents



Key observations

– While the majority of respondents know that a PRRC is required, 30% have not documented the role.

– This disparity is more pronounced in North America than in Europe.

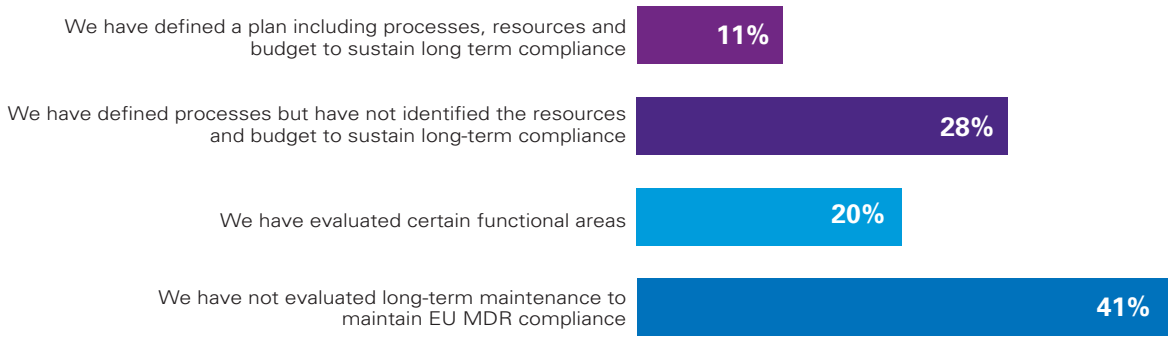
– Larger companies are more likely than smaller companies to have identified the individuals.

Note: 1. The total number of respondents (N) for each question may vary, depending on their responses

2. The terms 'Respondents' and 'Organizations' have been used interchangeably in some cases, as we have considered each respondent to be a unique representative of his/her organization. In most of the cases, a single individual from each organization has taken part in the survey

KPMG and RAPS EU MDR Survey Results and Key Findings

Has your company assessed the changes needed for your organization to be able to remain in compliance over time?



Key observations

– Forty-one percent have not evaluated long-term maintenance to maintain EU-MDR compliance.

– Organizations with higher revenue are more likely to have a long-term maintenance plan.

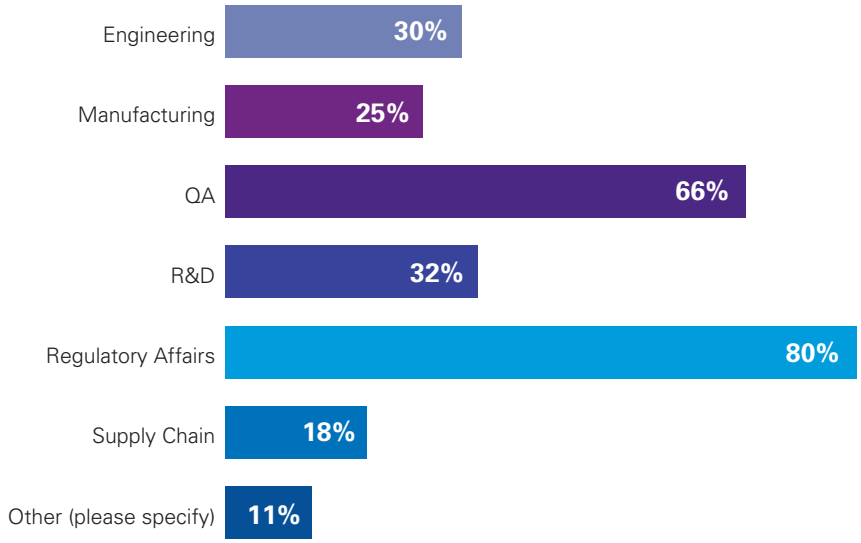
– QA & RA are the functional areas that are most likely to have created a plan.

Note: 1. The total number of respondents (N) for each question may vary, depending on their responses

2. The terms 'Respondents' and 'Organizations' have been used interchangeably in some cases, as we have considered each respondent to be a unique representative of his/her organization. In most of the cases, a single individual from each organization has taken part in the survey

KPMG and RAPS EU MDR Survey Results and Key Findings

Provide the functional areas that have been evaluated:



Key observations

– Eighty percent of respondents have evaluated their regulatory affairs function.

– Sixty-six percent have evaluated their QA function.

– In contrast, fewer than 30% of respondents have evaluated engineering or R&D.

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