THE BOOMING MEDICAL DEVICE SECTOR & ITS SOARING REGULATORY DEMANDS: HOW ARE COMPLIANCE STRATEGIES EVOLVING?

New independent research, commissioned by Schlafender Hase, July 2024

Medical device sector growth: ever smarter solutions to global health

Technology innovation, combined with pressures on health services to treat patients more effectively, efficiently and conveniently, has led to sharp growth in advanced medical devices and their prominence within care pathways. This increasingly diverse product category today spans everything from infusion pumps, ECG machines and CT scanners to heart valves, pacemakers and deep-brain stimulators. Globally, the medical devices market is projected to grow from $542.21 billion in 2024 to $886.80 billion by 2032[1]. It is no coincidence that medical device sector representatives now account for 50-70% of the attendees at meetings of RAPS, the Regulatory Affairs Professionals Society when, just three years ago, delegates were entirely from pharma.

In parallel with the sector's accelerating advancement, awareness has risen sharply of the importance of device traceability right across the product lifecycle, for purposes of quality and safety assurance. As devices become more critical to patient outcomes, and as safety-related scrutiny is intensified, regulators around the world are steadily increasing their expectations and controls around the manufacturing, distribution and monitoring of devices. The aim is to bring developers and suppliers of these products more closely into line with the requirements around pharmaceutical goods. This has implications right across the medical device industry internationally, including a potential need for new systems and processes, attention to the way these are linked and tracked, and the distribution of appropriate skills across the workforce.

New insights into the industry's regulatory readiness

In the light of the sector's significant evolution, and the accompanying introduction of tighter regulations, Schlafender Hase commissioned a timely benchmark report to determine how well manufacturers and their regional or national partners are adapting to the rising regulatory demands.

Although the large global Life Sciences brands tend to be in step with the latest regulatory developments and what's needed to maintain ongoing compliance, smaller start-ups that have entered the medical device sector from outside the Life Sciences industry won't necessarily share that advantage, and so will face a steeper learning curve to achieve adherence.

The Censuswide survey was conducted in late May/early June 2024, among 202 regulatory professionals at Class 2 and 3 medical device companies (those deemed of intermediate to high risk in the event of a malfunction or quality/safety issue). The samples were split 50/50 between respondents in the EU (Germany) and North America (the US).

The study highlights the number of challenges currently vying for attention and investment, and where progress is most vs. least advanced currently. The key findings, and their implications, are discussed here.

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1   Medical Devices Market, Fortune Business Insights, June 17, 2024:
     https://www.fortunebusinessinsights.com/industry-reports/medical-devices-market-100085

Medical devices: the rise of regulatory requirements

To determine companies' growing awareness of and exposure to increased regulation, we tested respondents' involvement with a number of increasingly prominent regulatory initiatives. These included:

- Requirements around the electronic provision and management of labeling and instructions (e-labeling, or electronic instructions for use (eIFU));

- Conformance with FHIR (Fast Healthcare Interoperability Resources), the proposed new global standard for passing healthcare data between systems;

- Unique device identification (UDI); and

- Anti-counterfeiting measures.

E-labeling/eIFU

E-labeling is high on the medical device regulation agenda on both sides of the Atlantic. The concept of electronic information provision and management promotes standardization and consistency (e.g. of format and terminology), making it easier to manage and process the contents in any market. It also plays a key role in product traceability, a critical safety lever (see also UDI).

As well as fostering quality control, providing critical safety and identification information digitally (e.g. under expectations associated with electronic instructions for use, or eIFU) supports prompt updates to information. It also facilitates easier management of international content and translation management and, in the case of user advice or safety information, spontaneous online or mobile lookup by clinicians or patients. Crucially, e-labeling allows device manufacturers to provide more information than they can fit on a physical label.

Encouraging, but not surprising, was the finding that just under two-thirds (62%) of organizations are involved in e-labeling initiatives, and up to a third of these (30%) are 'very' involved. Conversely, just a third (34%) of all respondents said this was not something that currently occupied them. Comparing EU/German respondents with those in the US confirmed that the former are more likely to be actively involved in e-labeling (71% vs 53%, respectively). This could be explained by where the respective regions are in their timelines for e-labeling requirements (the EU is ahead of the US), and also by the extent to which companies look after their own labeling (versus outsourcing this as a service, which is more prevalent in the US).

62%

30%

34%
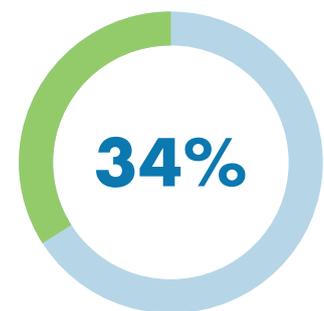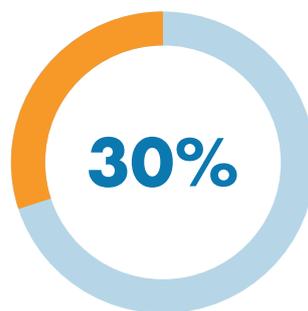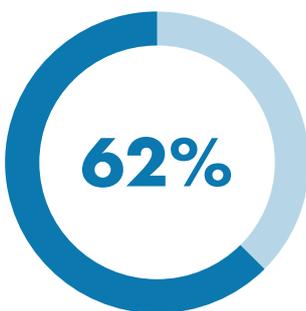
- Organizations involved in e-labeling initiatives

- Organizations 'very' involved in e-labeling initiatives

- (Of all respondents) Not something that currently occupied them

vs

71%   **53%**

More likely to be actively involved in e-labeling
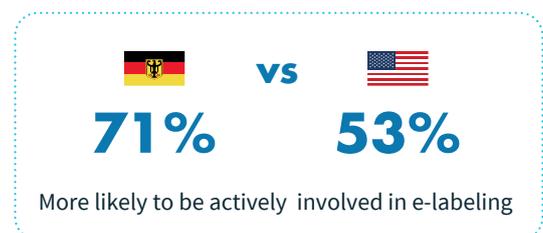
FHIR/standardized data exchange

Fast Healthcare Interoperability Resources is a proposed new global standard for passing healthcare data between systems. It is designed to streamline data exchange between different systems and organizations, and facilitate real-time information access for healthcare providers.

Once fully supported, FHIR will make many regulatory professionals' lives easier by shifting the emphasis of content creation and management to 'publishing' rather than 'printing'. It is this kind of development that will help drive process digitization in the production and management of regulated medical device information and content.

In our survey, three in five respondents (60%) claimed to be involved with the standard, rising to 67% for EU (German) respondents (in the US, only just over half were occupied with FHIR; here FHIR is not as high profile, though **the FDA is encouraging manufacturers to adopt interoperability standards**).

Of the 60%, almost just over a fifth (28%) are 'very' involved. A third of all respondents (36%) are not involved with FHIR currently.

UDI/device identification

The unique device identification (UDI) is a unique numeric or alphanumeric code related to a medical device, used to mark and identify devices within the healthcare supply chain. Approached slightly differently by the respective regions, a UDI system is advocated by both EMA and the FDA and is intended to provide an efficient and effective means of tracking and identifying medical devices globally. Benefits include expedited and more targeted product recalls, a reduction in product counterfeiting, and a better, safer experience for patients.

In the survey, two-thirds (66%) of respondents (rising to 74% of EU survey participants, but accounting for a much lower proportion in the US at 57%) say they are involved in some form of UDI activity. One in four of the 66% are 'very' involved; while a quarter of the total research base have no current UDI involvement.

Anti-counterfeiting

Taking proactive measures to counter the threat to product quality and patient safety posed by counterfeits products is a further expectation of Life Sciences companies, and robust product identification and traceability are a cornerstone of this practice, along with robust supply chain monitoring.

In our survey, over half (55%) of respondents indicate at least some involvement with anti-counterfeiting. Of these, just under a quarter (24%) are very involved and just under a third (32%) are somewhat involved, while just over a third (39%) say this is not within their remit. EU (German) respondents in Germany are more likely to be involved in the practice than their US counterparts (63% vs 48%).

55% **24%** **32%** **39%**

■ At least some involvement in anti-counterfeiting
■ Are 'very' involved in anti-counterfeiting
■ Somewhat involved in anti-counterfeiting
■ Not within their remit

🇩🇪 **vs** 🇺🇸
63% **48%**
More likely to be involved in the practice
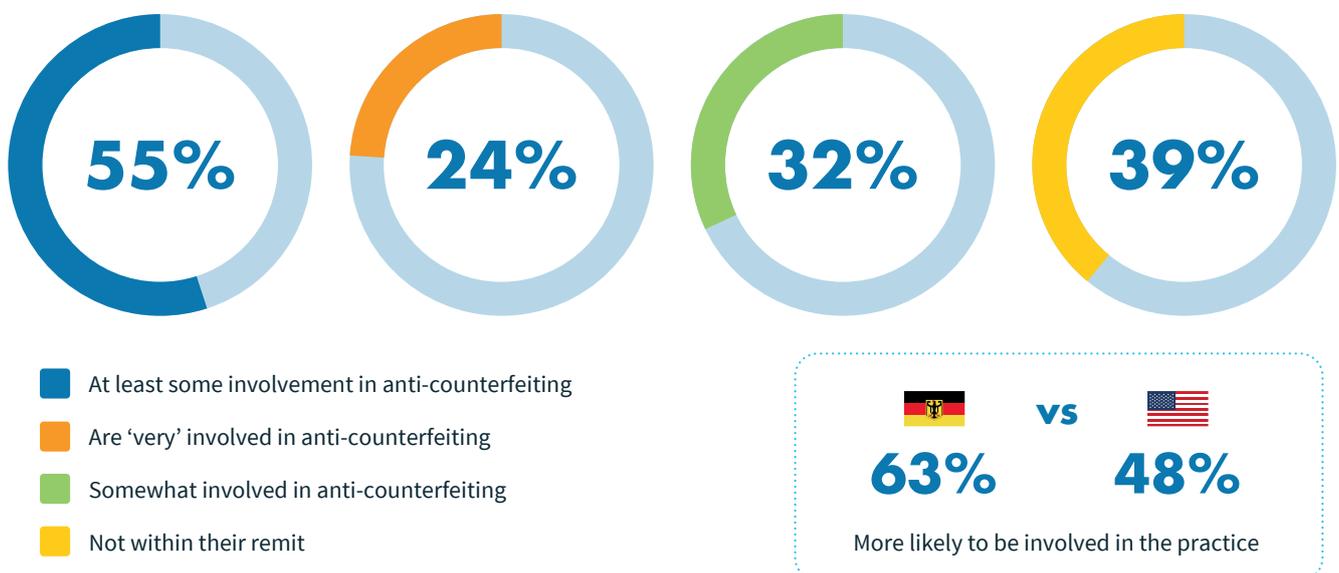
The impact of regulatory initiatives

As the range and extent of regulatory expectations grow, so the demands on responsible teams within medical device companies are intensifying, as would be expected. There are also process and timescale considerations, which need to be navigated with care to balance any additional quality and safety measures with the drive to bring products to market promptly and cost-efficiently.
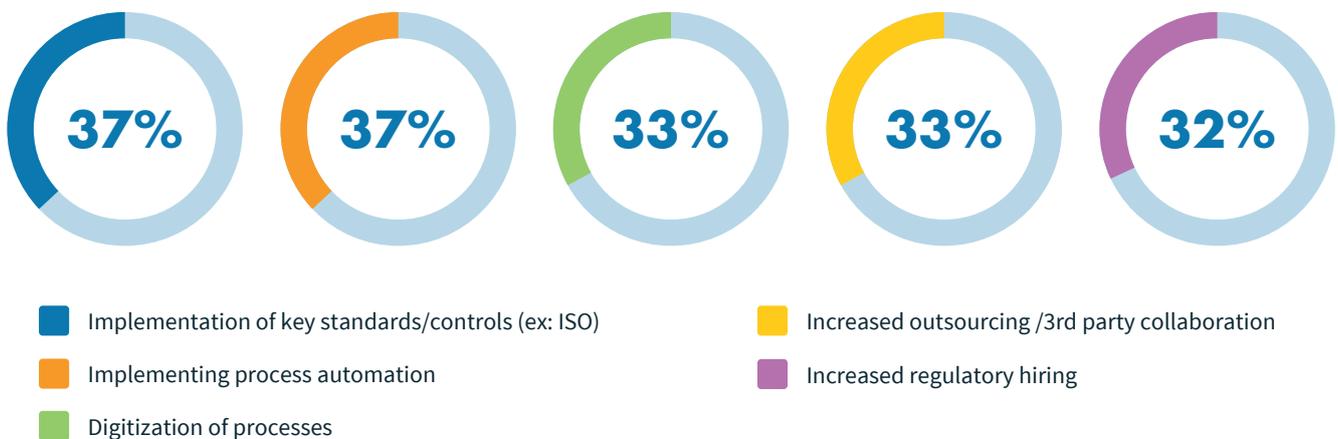
Where respondents had signaled first-hand involvement with the specified regulations, the implications most notably included concerns about increased workloads, longer go-to-market timelines/market access delays, higher compliance costs and, in many cases, increased product retirement.

Strategies for navigating evolving regulatory demands

Since regulations exist for a reason, and are non-negotiable, medical devices companies must develop strategies to streamline compliance activities.

In the survey, respondents say they are dealing with the impact of increasing regulations in the following top five ways:

1. Implementing key standards/controls (such as ISO standards) – cited by 37%, but rising to 41% of EU (German) respondents
2. Implementing process automation (37% overall; again, more common in Germany/the EU, where more than four in 10 companies were taking this approach)
3. Process digitization (33%)
4. Increased use of outsourcing /3rd party collaboration (33%)
5. Hiring more regulatory people (32%).

■ Implementation of key standards/controls (ex: ISO)	■ Increased outsourcing /3rd party collaboration
■ Implementing process automation	■ Increased regulatory hiring
■ Digitization of processes	

Even where standards are not yet mandatory for content creation and management in the medical device sector, **Ghent Workgroup**, a collective of publishing software vendors including Adobe and Microsoft, advocates use of ISO standards among its workflow best practices for print and publishing. These include ISO 19593-1, applicable in packaging. Awareness of the Ghent Workgroup and its work around standards appears to be low or variable, however, based on the responses to some of the early questions in this research. If awareness were higher and more companies worked with standardized PDF documents, for instance, compliance, process digitization and automation would be more readily achievable.

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Talent & other operational challenges

Ahead of other expected challenges affecting medical devices companies on both sides of the Atlantic, is the difficulty of finding and appointing qualified professionals to alleviate soaring regulatory workloads. Over a third (34%) of respondents cited this as the greatest challenge facing their company currently; this figure rose to 38% in the EU.

Almost a quarter (23%) said that staff retention was their biggest issue, meanwhile. That **people and skills issues** are identified as the biggest challenge suggest a growing need for external support and trusted advice, and/or smarter use of technology to alleviate process bottlenecks and free up professionals' time.

The biggest discrepancy between regions was related to concern about innovation/new product development, where significantly more German respondents were more likely to be concerned than those from the US (39% vs 26%). Across both territories, three in 10 (30%) were most challenged by maintaining existing products.
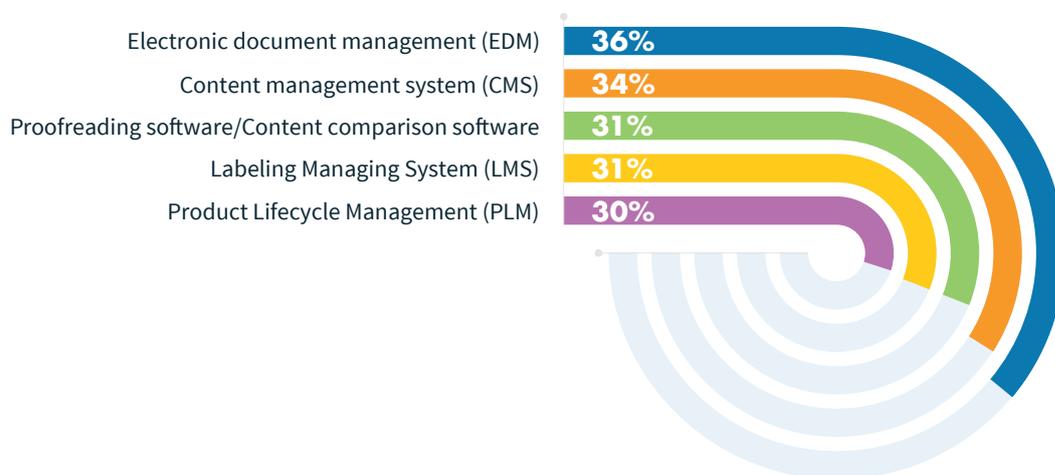
Upcoming priorities

Against the backdrop of current challenges, respondents indicated the main projects their department would be working on over the coming 2-3 years. The top three undertakings involved or were linked to:

1. Improving existing devices (cited by 32% of all respondents, rising to 35% of US respondents)

2. Emerging healthcare trends (28%, rising to 34% of German/EU respondents)

3. New materials & technologies (27%)

Other planned areas of focus included global reach/accessibility (cited by 24% of all respondents); exploring some aspect of AI/machine learning (23%); sustainable practices (23%); and progressing or enhancing data-driven decision-making (22%).

To support these priorities, medical device companies are using or planning to use a range of technology solutions. Most notably these include electronic document management (EDM) systems (cited by 36%); content management systems (cited by 35%); proofreading/content comparison solutions, (mentioned by 31%, rising to 36% of German respondents); labeling management systems (31%), and product lifecycle management solutions (30%). Compared to the pharmaceutical market, regulatory information management systems are less prominent currently, featuring for just 29% of respondents, followed by structured authoring/creation tools (27%), as a support for key projects.

Although the types of solutions at play, or scoped for implementation, largely mirror those used by pharma organizations, the penetration of formal systems is generally lower in the medical device sector currently. This is likely to change as ambitions in the sector rise, and as regulations broaden and deepen.

Electronic document management (EDM)	36%
Content management system (CMS)	34%
Proofreading software/Content comparison software	31%
Labeling Managing System (LMS)	31%
Product Lifecycle Management (PLM)	30%

Improving efficiency in Regulatory & Safety document preparation

As medical device products advance, and as regulators strive to keep pace with those developments and tighten quality controls to keep patients safe, it follows that regulatory, quality and safety teams will need to work harder to successfully and efficiently navigate associated submissions processes.

In most cases, this suggests the strategic use of IT to create and manage content, and to meticulously check this against correct, approved source materials. As the volume and complexity of required content grows, dependence on human quality control alone is risky. Internal teams are already time-pressed, while hiring and retaining talent is a persistent and growing challenge right across Life Sciences specialties. It is only by engaging external talent, and/ or making more strategic use of appropriate technology solutions, that medical device companies can hope to stay ahead of requirements.

In the survey, more than a third (36%) of companies are already using some form of software solution as their primary way of managing the proofreading and content review process for regulatory documents, labeling materials, and promotional content, while 29% say they rely mainly on manual proofreading in house. This percentage rises to 37% in the US. In Germany/the EU, more respondents (41%) use software to help them review content quality.

A third (34%) of all respondents currently outsource their content proofreading, potentially as part of a broader arrangement with an external partner.

Levels of comfort with advanced technology such as AI

All industries are coming to terms with accelerating advances in technology, and the relative maturity and value of associated solutions in their own sector, with reference to their particular purposes.

In our survey, respondents seemed surprisingly at ease with AI. Over two thirds (67%) claimed to be 'comfortable' with the technology in the form of natural language processing and machine learning-based solutions, including 37% who were 'very comfortable'. Fewer than a third (29%) said they did not feel comfortable with AI technology.

This level of comfort was even slightly higher than for cloud-based software adoption (as an alternative to desktop solutions). Although an equivalent proportion of survey respondents (67%) expressed comfort with the idea of cloud-based solutions, only 30% were 'very comfortable' with the idea of adopting cloud-based capabilities, while more than 3 in 10 (32%) of the total research base were not comfortable with the prospect. Overall, evidence of acceptance of the importance of modern software is high.

The findings in relation to AI are especially interesting in what they say about the medical device sector's expectations of technology, and where new efficiency gains might originate.

The US FDA guidance on AI use suggests that the technology should be used only where its performance is demonstrated to be equal to or above that delivered by humans. Yet, in Life Sciences, existing **proofreading/content comparison** capabilities - which do not depend on AI - are already accurate to the point of 99.999% reliability. That is in identifying and flagging anomalies between even the most lengthy and complex sets of content. Even checking for the correct symbols, or potential errors in translation, is reliably automated now. This is easing the burden of global packaging and labeling preparation and management, as well as the creation and checking of regulatory submissions, even without the contribution of AI.

> In Life Sciences, existing proofreading/content comparison capabilities are accurate to the point of 99.999% reliability.

Packaging & labeling challenges

As tracking and supply chain transparency become more prominent requirements for medical device approval around the world, the challenges of producing compliant and correct packaging and labeling for each respective market intensify. This is reflected very clearly in the research; compared to other questions in the survey, this question yielded particularly strong responses.

Just under two thirds (65%) of respondents said they find translations challenging to manage; 61% find barcodes challenging to manage; 60% struggle with graphics including symbols (shorthand guidance on device sterilization, for instance); and 59% have difficulty with tables. This is on top of any issues getting the text right (cited as a challenge by 54% of respondents).

65%	61%	60%	59%	54%

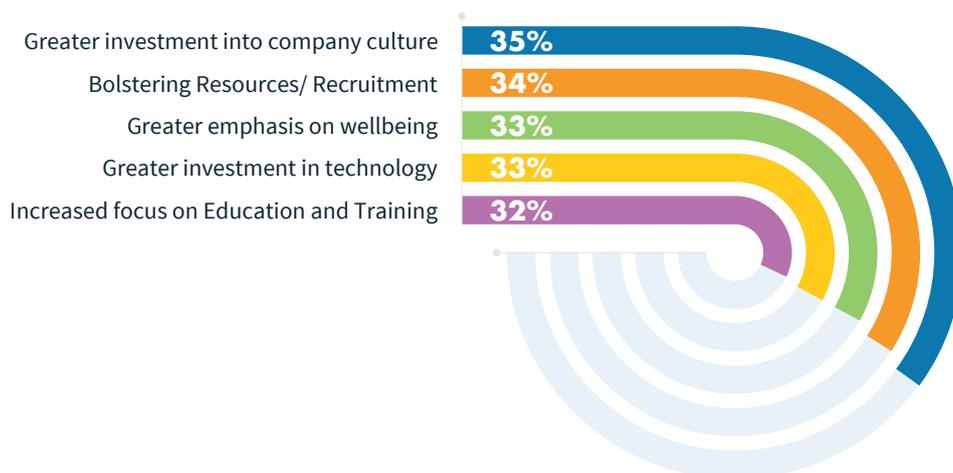■ Translations ■ Barcodes ■ Graphics, including symbols ■ Tables ■ Text
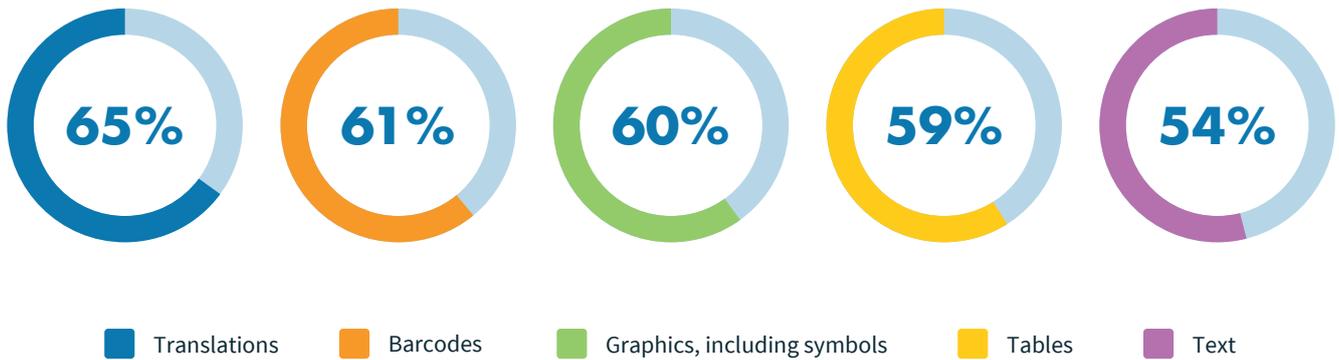
This is an area where technology could offer a powerful solution, although simply fielding clever software will not automatically deliver transformation. Team acceptance of the technology, along with enhancements to processes, will also be important to get the most from any investment.

Lessons learned

So how will medical device companies move forward with all of these competing priorities, and what have they learned from recent activity that might help with their next ambitions?

We ended the research by asking respondents the top five takeaways from the last year that will now inform their next actions. In order of prevalence, the most common lessons cemented the need for:

Greater investment into company culture	35%
Bolstering Resources/ Recruitment	34%
Greater emphasis on wellbeing	33%
Greater investment in technology	33%
Increased focus on Education and Training	32%

The prioritization of company culture, along with deliberate emphasis on employees' wellbeing, is further evidence of the growing pressure that regulatory and adjacent functions are under - and the criticality of making teams, and the way they work, part of the solution. It also underlines the efforts that are needed to alleviate stress, to make daily workloads more manageable, and to attract new talent into vacant or new positions, at a time when talent scarcity is acute on an international scale.

Beyond the top five lessons, 3 in 10 (30%) respondents said they had learned, and planned to act on, the importance of increased communication between all role levels, while 28% would now look to set regular targets. These factors are also important in ensuring that any technology-based process improvements have the desired impact.

Conclusions & next steps

Generally, medical device providers demonstrate strong awareness of the tightening regulations across developed markets, as products become more sophisticated and safety considerations intensify. However, differences between responses in Germany (representing Europe) and the US (representing North America) reflect the former region's head start with stricter controls and their enforcement.

In the EU today, companies typically have more regulatory professionals proportionally, as a percentage of the workforce. The greater emphasis on cultural considerations in Europe also suggests a greater appreciation of the need to review processes first, rather than looking to a particular technology solution to drive the hoped-for transformation. That's even though medical device companies in both regions plan to increase their technology use to improve regulated content creation and management.

Interest in process digitization and automation is on the rise across the board, which is further evidenced by the medical device sector's growing representation at RAPS events. This is in direct response to increased regulation in the sector, and as companies look for examples of best practice in digitizing key activities and achieving compliance efficiently. Start-up 'medtech' companies often face the sharpest learning curve as they strive to formalize processes without sacrificing agility. As they look to fill immediate gaps in their regulatory knowledge, skills base, and technology capabilities, it is likely that companies will need to continue to draw on external expertise in this way, and by engaging specialist partners.

With so much activity underway and ahead in the sector, it will be fascinating to revisit this research over the coming years.

About the research

About Schlafender Hase

Schlafender Hase offers an easy-to-use proofreading software. Our solution, TVT®, was built specifically for Life Sciences to help reduce the risk of errors which can lead to costly misprints and recalls.

TVT is the trusted proofreading software for global pharmaceutical and medical device companies as well as health authorities. TVT verifies your text, artwork, barcodes and spelling, ensuring that only approved content is printed or published.

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