Soaring Regulatory Demands In The Medical Device Sector: How Are Compliance Strategies Evolving?

As medical devices become more critical to patient outcomes, regulators around the world are steadily increasing controls around the manufacturing, distribution and monitoring of devices. Drawing on new research, Peter Muller and Mike Baird of Schlafender Hase assess how well Class 2 and 3 medical device manufacturers in Europe and the US are adapting.

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. Globally, the medical devices market is projected to grow from $542.21 billion in 2024 to $886.80 billion by 2032,[1] while medical device sector representatives now account for 50–70% of the attendees at meetings of RAPS, the Regulatory Affairs Professionals Society (just three years ago, delegates were mostly from pharma).

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, spanning 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.

A new international benchmark report[2] has set out to determine how well manufacturers and their regional or national partners are adapting to the rising regulatory demands. The 2024 study, conducted with 202 regulatory professionals at Class 2 and 3 medical device companies in the EU (Germany) and North America (the US), highlights the number of challenges currently vying for attention and investment and assesses device companies' current state of regulatory readiness.

Medical Devices: The Rise of Regulatory Requirements

The research first tested medical device companies' involvement with a number of increasingly prominent regulatory initiatives.

E-labelling/eIFU

E-labelling is high on the medical device regulation agenda on both sides of the Atlantic. Electronic information provision and management promotes standardisation 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.

Providing critical safety and identification information digitally (*e.g.* under expectations associated with electronic instructions for use, or eIFU) makes it easier to issue prompt updates to information, too. It also simplifies international content and translation management and, in the case of user advice or safety information, facilitates spontaneous online or mobile lookup by clinicians or patients. Crucially, e-labelling allows device manufacturers to provide more detail than can fit on a physical label.

Currently, just under two-thirds (62%) of medical device companies are involved in e-labelling initiatives, and up to a third of these (30%) are 'very' involved. EU companies are more likely to be actively involved in e-labelling than those in the US (71% vs 53%, respectively). This makes sense as the EU is ahead of the US with the practice; companies here are also less likely to outsource labelling as a service.

FHIR/Standardised Data Exchange

Fast Healthcare Interoperability Resources is a proposed new global standard, designed to streamline data exchange 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 digitisation in the production and management of regulated medical device information and content.

In the 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 (FHIR is not as high profile in the US), though the FDA is encouraging manufacturers to adopt interoperability standards.

UDI/Device Identification

Unique device identification (UDI) employs a unique numeric or alphanumeric code to identify individual devices across the healthcare supply chain. Although approached slightly differently, a UDI system is advocated by both EMA and the FDA as 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%) express involvement in UDI activity.

Anti-Counterfeiting

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

In the 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.

Strategies & Challenges when Navigating Regulatory Demands

Medical device companies are dealing with the impact of increasing regulations in a number of ways, including the implementation of key standards (*e.g.* ISO); process digitisation and automation; greater use of outsourcing or third-party collaboration; and hiring of more regulatory people – all cited by more than a third of companies.

The difficulty of finding and appointing qualified professionals to alleviate soaring regulatory workloads is a particular problem on both sides of the Atlantic. Over a third (34%) of respondents cited this as the greatest challenge facing their company currently, while almost a quarter (23%) said that staff retention was their biggest issue.

Upcoming Priorities

Asked about the main projects their department would be working on over the next 2–3 years, respondents said projects would primarily involve existing devices (cited by 32%, rising to 35% among US respondents); emerging healthcare trends (28%, rising to 34% of German/EU respondents); and new materials & technologies (27%).

Device companies plan to use a range of technology solutions to support these projects, most notably electronic document management (EDM); content management; proofreading/content comparison; labelling management; and product lifecycle management solutions, each cited by around a third of respondents.

Compared to the pharmaceutical market, the use of regulatory information management (RIM) systems is currently less prominent in medical device companies, featuring for just 29% of respondents, followed by structured authoring/creation tools (27%). The penetration of formal systems in the medical device sector is likely to grow as ambitions rise and regulations expand.

Improving Efficiency in Regulatory & Safety Document Preparation

To keep pace with the rising volume and complexity of regulatory submissions, more than a third (36%) of medical device companies already use software for the proofreading and content review process for regulatory documents, labelling materials, and promotional content, while 29% still resort to manual proofreading in house, rising to 37% in the US. In the EU, more respondents (41%) use software to help them review content quality.

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

Packaging & Labelling Challenges

As tracking and supply chain transparency requirements rise, the challenges of producing compliant and correct device packaging and labelling for each respective market intensify. In the research, the subject 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 sterilisation, 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).

Technology could offer a powerful solution here, although enhancements to processes will also be important to get the most from any investment.

Lessons Learned & Next Steps

The study (the full report is available here) ended by asking for device companies' top five takeaways from the last year that will inform their next regulatory actions. The responses cemented the need for greater investment in company culture (cited by 35%, rising to 43% of German/EU respondents); bolstered resources/recruitment (34%); more emphasis on wellbeing (33%); more investment in technology (33% – rising to 42% of US respondents); and increased focus on education and training (32%).

The prioritisation of company culture and employee wellbeing is further evidence of the growing pressure that regulatory functions are under, and the criticality of making teams – and the way they work – part of the solution.

REFERENCES

1. Medical Devices Market, Fortune Business Insights, June 17, 2024: https://www.fortunebusinessinsights.com/industry-reports/medical-devices-market-100085
2. The independent Censuswide survey, commissioned by Schlafender Hase, 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). Link to full report: https://www.schlafenderhase.com/ebooks/medical-device-report-how-are-compliance-strategies-evolving

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