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EU MDR Compliance Will Cost More Than 5% Of Revenues For Half Of Medtechs, Survey Says

Manufacturers must address IT needs for process efficiencies and cost effectiveness

by Ashley Yeo

Almost half of companies polled on extra resources needed to comply with the EU Medical Device Regulation are preparing for considerable outlay. Manufacturers are also falling short in digital readiness.

A survey by Munich, Germany health care software company Climedo Health has revealed that medtech companies serving the EU market are mentally preparing for a significant dent to their profit and loss accounts.

Compliance with the Medical Device Regulation will cost over 5% of annual sales, according to 48% of 101 companies polled in July and August about their MDR-readiness. The size range of respondents spanned from under 20 to over 1,000 staff.

Most of those surveyed were based in Germany, Austria and Switzerland, and 77% were medtech manufacturers, with products from all risk classes, including 60% with class I products and around 19-20% with class III devices.

Among the findings, 55% of respondents said addressing the MDR's new demands would take an additional five hours of company time per week; and 67% said it warranted taking on extra full-time employees, over 15% saying more than five additional staff will be required.

Simply "understanding the new demands" requires most of a typical company's extra time needs, but doing extra clinical evaluation and trials, as stipulated in the MDR, is almost as costly

timewise, the *survey* found.

As to monetary cost, clinical evaluations and trials were cited by 75% of companies as a key factor, and 53% said compliance with post-market surveillance (PMS) and post-market clinical follow-up (PMCF) will be significant cost burdens.

Perhaps the most striking finding is that, while 32% of companies polled in a spring survey were forecasting that the headline cost of the MDR would be over 5% of their annual sales, in the latest survey, the proportion had risen to 48% of companies that shared that belief. 33% are putting it between 1% and 5% of sales.

Climedo Health COO Veronika Schweighart commented that, while the MDR is an expensive reality, companies are not doing enough to mitigate the extra costs, bearing in mind their data-system readiness. Half of respondents still use paper-based systems. But clinical studies and PMS costs can be defrayed with digital solutions, she said.

Data system solutions require initial investment outlay that can dissuade users, but over the longer term, the investment is repaid in terms of automation of tasks saving time and costs and avoiding human factor errors. For the medtech industry, Climedo translates this as the ability to remain MDR-compliant and keep products on the EU market.

Elsewhere, the survey found:

- 69% of respondents principally use Excel, 47% paper, and 11% electronic data capture (many use a combination);
- 83% spend over 10% of their time currently on clinical studies and PMCF;
- 45% spend more than one hour per week in stakeholder outreach; and
- 51% have no automated PMCF processes.