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Medtech SPECIAL REPORT

Investment in compliance brings peace of mind

The medical device sector is about to undergo a huge change with the introduction of new EU regulation, but business processing software providers stand ready to help manufacturers navigate this new world, writes Jason Walsh

Amy Hughes, sales manager, Envisage Cloud: 'Software will replace previous paper records'

The European Commission's Medical Device Coordination Group (MDCG) has published a preparedness plan as the EU's Medical Device Regulation (MDR) appears on the horizon.

The MDCG's plan sets the challenge out in stark terms.

"It is difficult to quantify the size of this challenge as no specific data has been presented by the industry," it said.

The regulatory move comes as the global coronavirus pandemic hits Europe hard, making the already difficult manufacturing process more challenging.

And, given the scale of changes, companies previously compliant with the outgoing EU Medical Devices Directive (MDD) will not necessarily be compliant under the new regulation.

From May 26, 2020, the MDR will come into law across the EU, despite manufacturers including Germany's BVMed calling for a delay.

Amy Hughes, sales manager at Envisage Cloud, said that in order to keep compliant, manufacturers would need to learn lessons from other sectors controlled by regulation rather than directive.

The good news is that it will give much-needed certainty to both manufacturers and purchasing bodies.

"The Health Products Regulatory Agency believes it will allow for more effective, consistent and robust regulatory framework for medical devices across Europe," Hughes said.

The reason for the change is an assessment that there are weaknesses in the current regulatory framework, she said.

In addition, the technological developments in the medical technology sector have left gaps increasingly visible.

In the end, this should improve healthcare across the bloc, but it will not be without challenges.

"MDR compliance will allow the public to gain access to safe and effective medical devices with appropriate levels of health protection," said Hughes.

Distributors in particular face entirely new obligations under the legislation.

One key challenge is ensuring that they can provide full traceability of medical devices and parts, to verify their origin and authenticity and create a systematic process for storing and tracking relevant device information.

"MDR will see all notable bodies need to record each device with a unique device identification (UDI) number; it aims to improve traceability of medical devices," said Hughes.

Naturally, IT systems will be deployed to support this traceability.

"The goal is greater visibility of the entire supply chain, from manufacturer to end-user. Under the MDR, manufacturers are now obliged to ensure their distributors have up-to-date systems that can track UDI information and enable device traceability," she said.

"By using advancements in software to assist with this, manufacturers and distributors will replace previous paper records. This will allow for greater accuracy and transparency while keeping compliant and in line with such legislation."

Working in a regulated world, Hughes said there is now an expectation that IT should be used to deliver the outcomes that the MDR demands.

"These regulatory requirements are, in fact, forcing businesses to do things better using technology – some changes to legislation are driving businesses to make the changes they need," she said.

Indeed, legislative changes such as making tax digital have already been a driver for businesses to make changes to how they submit Vat returns.

> **Business can see the value in the peace of mind that they are compliant and up to date**

"Ensuring that your enterprise resource planning solution (ERP) is compliant gives you the peace of mind that your business will always be compliant with the latest rules and regulations, including making tax digital, general data protection regulation (GDPR) and Brexit."

Hughes said all of the software vendors Envisage supports work with the company to ensure its accounting products are leading the way in compliance.

The best-known EU regulation, meanwhile, is without a doubt the GDPR – a regulation which no EU business has escaped. However, GDPR has introduced significant and onerous new requirements for record keeping.

"It's not enough to merely comply with the GDPR," said Hughes.

"Any business must be able to prove it's doing so by keeping records and data up to date to comply. Now more than ever it's imperative that businesses ensure they are compliant in terms of the data they produce."

The lesson is percolating down throughout businesses: no matter what industry your organisation is in, corporate compliance is an essential part of operations.

Of course, this has an impact on key software and systems that support the business processes. Old systems designed prior to regulation may struggle. However, new technologies that support GDPR compliance can also bring other benefits to the business, Hughes said.

Cloud deployment, meanwhile, takes the fear out of the upgrade and update process.

"Ensuring your ERP systems remain compliant is vital – continuous updates and product development are the key here; all software will continuously be updated with any legislative changes," she said.

In short, many software vendors will bake legislative changes into their software, giving users peace of mind knowing they're compliant.

"Gone are the days where you search for data manually," said Hughes.

"Therefore, introducing systems to manage such legislative changes can have a positive impact by reducing time spent on previous manual processes."

With the MDR itself there is an opportunity, too. Technology has been a driving force for most businesses within the economy over the past decade, said Hughes. As a result, the MDR need not be feared: the investment in compliance will drive confidence.

"Business can see the value in the peace of mind that they are compliant and up to date with legislative changes," Hughes said.

"This will lead to further improvements in consistency, transparency and performance."

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