Ideagen Launches Toolkit to Help Companies Comply with New EU Medical Device Regulations

The project will enable a smooth transition from the Medical Device Directive (MDD) to Medical Device Regulation (MDR) requirements

NOTTINGHAM, EAST MIDLANDS, UNITED KINGDOM, January 30, 2020 /EINPresswire.com/ -- Ideagen, the UK-based, global software firm, is to launch a new toolkit designed to help medical device organisations comply with a new industry standard allowing them to continue to trade in Europe.

The EU Medical Device Regulation (MDR) is set to come into effect in May and businesses which do not comply will not be able to place their product on the European medical device market.

The new regulation is expected to impact the way in which medical device manufacturers operate, increasing their compliance costs and significantly altering change management processes.

Now Ideagen – which has hundreds of medical device organisations as part of its 5,000 strong client base – is launching its new toolkit to ease the transition for its clients.

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> *George Hall, Q-Pulse Product Manager at Ideagen*

"A very strong theme of the new MDR requirements is risk management," said William Coupe, Life Science Consultant at Ideagen. "Companies will have to demonstrate that the management systems they operate have integrated touchpoints and that processes are automated. A purpose-built software framework serves these needs and will provide an effective remedy to paper based headaches."

The MDR standard replaces the current EU Medical Device Directive (MDD) to enhance quality and safety of medical devices being produced in or supplied into Europe.
With more scope and scrutiny in the new standard – the documentation from MDD to MDR has

risen from 60 to 174 pages – it's believed more and more companies will turn to software to help with compliance.

The announcement that MDR would be replacing MDD was made in 2017, sparking a three-year transition period for businesses. Until the deadline of May 25, 2020, certificates under MDD will still be valid but all devices placed on the market from May 26, 2020, must conform to the new MDR.
Ideagen's new toolkit includes;
•A transition checklist
•EU MDR white paper
•EU MDR information flyer
•A series of feature content designed to highlight and increase understanding of the transition

George Hall, Q-Pulse Product Manager at Ideagen, added: "At Ideagen we try and make transitions like this as smooth as possible for our customer base and have done so for other industry shifts, such as the move to ISO 9001:2015 or the move from OHSAS 18001 to the ISO 45001 standard.

"That's why we have our industry experts create these Toolkits related to our software and why we believe this particular MDR toolkit will be extremely beneficial for organisations making the transition in the coming months."
Ideagen is one of the largest providers of regulatory and process management software to the Medical Device sector and wider Life Science industry.

Q-Pulse, the firm's quality and process management software, and PleaseReview, its document co-authoring and review application, help medical device and the wider Life Science industry achieve and maintain compliance to industry standards as well as provide overall business process improvements.

Currently, the company counts hundreds of Medical Device organisations amongst its client base, with more than a further 300 across Life Science.
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