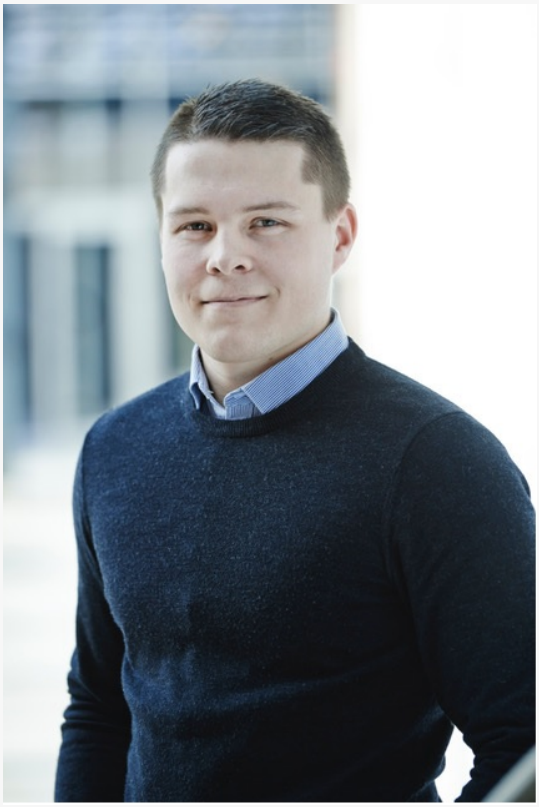
MEDEI Issues MedTech Advisory on Mandatory EU Medical Device Regulation

Roadmap to the EU 28 medical device markets



AALBORG, DENMARK, May 8, 2018 /EINPresswire.com/ -- MedTech data management enabler MEDEI ApS today released an Industry Advisory outlining changes and advice that medical device manufacturers can use to comply with the mandatory requirements set out by the new European Union Medical Device Regulation (EU MDR) for a CE-mark approval in the EU.

Entitled “Navigating the EU MDR – Strategies for Success,” the Advisory can be downloaded at https://info.smart-trial.co/whitepaper/navigating-the-eu-mdr-strategies-for-success.

More medical devices are entering the EU 28 countries than ever before and are transforming healthcare. The EU MDR aims to better regulate the booming MedTech industry and now requires that medical devices sold into the EU adhere to the stringent Regulation by 2020. In vitro diagnostics (IVD) devices will have to comply with the Regulation by 2022.

As the MDR allows “no grandfathering,” manufacturers with products already in use in EU 28 markets will have to re-certify all of their devices and existing compliance documents will have to be aligned with the new MDR/IVDR requirements.

One of the stringent changes in the EU Regulation is the increased focus on clinical evaluation, post market surveillance, and access to data. This places a higher strain on both regulatory and clinical operations.

> Compliance with the EU MDR is uncharted and time-consuming territory for many medical device manufacturers. This Industry Advisory will help them to navigate EU requirements.”
>
> *Pall Johannesson, MEDEI’s CEO*

In the past, common practice within the MedTech industry was to refer to an equivalent (predicate) medical device and its scientific data in order to document clinical effectiveness. In a move to enhance data transparency, the MDR requires all manufacturers to fully document their own device effectiveness, safety and usability.

One of the main focus areas for regulators of EU MDR will be the creation of a Eudamed database and device manufacturers will need the tools necessary to transfer required data into the database.

“Compliance with the EU MDR is uncharted and time-consuming territory for many medical device manufacturers,” said Pall Johannesson, MEDEI’s CEO. "This Industry Advisory will help them to navigate the EU MDR requirements and support them on their road towards compliance and market access in the ever growing EU MedTech market.”

About MEDEI
MEDEI ApS is a Danish medical software innovator delivering industry-leading solutions to facilitate data management and the R&D of medical devices. Its flagship platform SMART-TRIAL helps medical device manufacturers to better illustrate the quality and safety of their products and eliminates chaos in the collection and management of clinical data. Visit https://www.smart-trial.co

Ends

Hugh Paterson
Whoosh PR
+447768175452
email us here
