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EU MDR Panel Discussion: Why An Extra Year Is Not Really A Delay For The MDR – How To Survive Changing And Confusing Times

by Amanda Maxwell

26 May 2020, the date that the Medical Device Regulation was originally due to apply in the EU, was a good time to take stock of where the medtech sector finds itself. Three of the most renowned and outspoken experts on the EU medical device regulatory system gave their views in this exclusive interview.

The one-year delay in the application of the EU Medical Devices Regulation (MDR), until 26 May 2021, does not offer as many flexibilities as it seemed to promise, and neither does it span a whole year. Some who play an important role in the sector still seem unaware that a postponement has even been formally agreed.

With so many recent changes and a backdrop of uncertainty, confusion and shifting requirements, Bassil Akra of TÜV-SÜD notified body, Gert Bos of Qserve consultancy and Erik Vollebregt, of Axon Lawyers, all agreed that "a year extra is not a full year extra" during a recent interview (see below) with *Medtech Insight*.

Akra was speaking as vice president of global strategic business development for medical health services at notified body TÜV-SÜD in Germany. He is moving to a new role at the Qunique Group consultancy as one of the owners and CEO of the German office. Bos is executive director and partner at Qserve consultancy. Vollebregt is partner at Axon Lawyers.

The Panel

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Discussion Timings

Topics covered and certain highlights of the panel discussion can be found at the following times within the video:

How ready was the medtech sector going to be for the original MDR deadline of 26 May 2020? 1.06

The balance between manufacturers making use of the grace period and those complying with the new MDR. 5.20

Medtech sector resource issues and why capacity shortfall meant a delay in essential implementation documents. 8.13

How continuous change and the expectations of new guidance documents can shift the regulatory bar unfairly 14.10

Why some companies are challenging the legality of some regulatory changes in MDCG guidance documents 16:51

The vital personal connection with notified bodies to help tease out member state regulatory positions and how this connection is undermined by lockdown 20.14

Plea for reasonable expectations around guidance from member states and to make guidance documents similar to standards to avoid different interpretations 27.00

Why the MDR one-year postponement does not offer the sector an additional year. It is not a delay; that would be a delusion. The pressure is on! 30.32

The impact on notified body timeframes of the delay and what happens when notified bodies have decided to only work on the MDR now more companies wish to use the directives 31.46

Implications for products of notified bodies not being allowed to issue any initial certificates without doing on-site auditing 35.08

Preparation for implementation of the IVDR: resources and challenges and COVID-19 obstacles 38.00

Will the one-year delay be sufficient or what is the answer to put the medtech sector on the right regulatory track? 48.07