MEDTECH INSIGHT
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Video: How To Efficiently Patch A Medtech Regulatory System 'Set Up To Fail'

"Hindsight is a wonderful thing, but foresight is better."

by Amanda Maxwell

Centralization and rationalization of the EU's medtech rules are critical, particularly for conformity assessment and clinical evidence. Hear the views of Tom Melvin and Erik Vollebregt first-hand in a **new** in-depth interview on regulatory problems and opportunities.

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In this video interview with Medtech Insight, clinician and academic Tom Melvin, and legal medtech expert Erik Vollebregt expose the underlying regulatory factors that are undermining medical device safety efforts and damaging continued availability of medical devices in the EU.

Their strong opinions accord over what is now needed to fix the EU's problematic medtech regulatory system.

Neither expert shy away from giving strong opinions about elements that urgently need correcting within the system.

But they also offer solutions that should be relatively easy to accommodate within the current EU rules, including introducing more reproducibility of efforts within the system to make it more efficient.

Deep Dive Into The Challenges

Topics covered during the interview include: role of competent authorities, notified bodies and expert panels; centralized regulatory control in the EU; clinical evidence; clinical standardization; “over-proceduralizing” of regulations; the regulation of high-risk devices versus other devices; creating EU-wide regulatory rationalization and efficiency; and the EU’s role in international harmonization.

Melvin, as associate professor of Medical Device Regulatory Affairs at Trinity College Dublin, gives particularly pertinent insights related to historic regulatory examples, including what has happened with medicines and how the US medtech system has evolved. And as a former clinician, he delivers valuable insights into the challenges that clinicians experience with medical devices on a day-to-day basis.

Vollebregt, a life sciences specialist lawyer and medtech regulatory expert at Axon Lawyers in the Netherlands, is at the forefront of promoting medtech regulatory change, having in summer 2024 helped draft the initiative for amendments to the MDR developed by MEP Peter Liese. (Also see "*How The European Parliament Seeks To Amend The MDR: A Step-By-Step Guide*" - Medtech Insight, 4 Jun, 2024.)

The quotes below offer highlights of the conversation and an indication of the topics covered and approach taken. But to do justice to the depth of this discussion featuring two of the EU’s most impactful regulatory voices on the fundamental challenges and needs of the EU regulatory system, readers can access the whole video interview via the link above.

Moreover, to help navigate your way around the interview, timestamps are provided alongside the quotes.

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