The AbedGraham Group
Clinically Optimized Success

EU MDR Compliance Services

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Background

For vendors that are, or anticipate becoming, a medical device, there are stringent requirements that they must follow to demonstrate that their devices are safe to use. Globally, these requirements can differ in nature so navigating the jurisdiction-specific compliance needs around medical devices is difficult and requires a trusted partner to do so. These include EU MDR 2017 (EU) and the UK MDR under the MHRA. Specifically in the UK the latest stance is:

"Manufacturers of medical devices can use either the UKCA marking or the CE marking on devices they place on the GB market until 30 June 2023. From 1 July 2023, a UKCA marking will be required in order to place a device on the Great Britain market."

Challenge

For medical device manufacturers accessing the EU and UK market they will need to be assessed by a Notified Body (located in the EU) to receive a CE marking prior to the 30 June 2023 deadline and for the UK, the relevant conformity paperwork can be amended and submitted to be assessed by an Approved Body (located in the UK) to receive a UKCA marking as required.

Medical device manufacturers are required to show evidence that their products are safe to use, including evidence that they comply with safety standards such as ISO 13485 and ISO 14971. A critical part of this process is the provision of a 'Clinical Evaluation' to demonstrate the characteristics and performance under normal conditions of use of the device, and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio based on clinical data including:

- **A Clinical Evaluation Plan (CEP)**
- **A Post-Market Clinical Follow-Up (PMCF) Plan)**
- **A Clinical Evaluation Report (CER)**

Solution

At the AbedGraham Group, we have reviewed or created medical device documentation for a range of small and large technology vendors. Our exclusively clinically focused team understands all aspects of healthcare and can help guide compliance for any medical device that is looking to be sold in the UK or EU marketplace. We can provide:

- An initial status review of any existing medical device documentation you may have
- Review or creation of the Clinical Evaluation Plan documentation
- Review or creation of the Post-Market Clinical Follow-Up documentation
- Review or creation of the Clinical Evaluation Report documentation
- Ongoing support and compliance through our flexible retainer – this can include acting as the official sign-off for the documentation produced, handling questions from partners, deploying organisations or regulators and updated the document suite as required in response to changes policy landscapes

Timeline

With no existing documentation it takes 2-3 months pending support from your compliance and product teams. Reviews of existing documents on average take 3-4 weeks to complete.