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Friday Weekly Run Through

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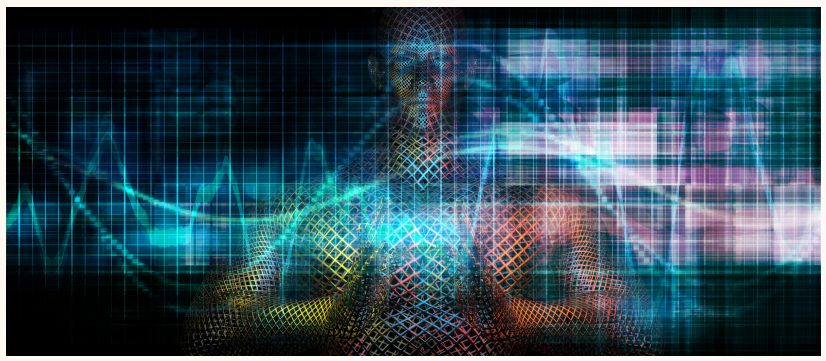
Medicines & Healthcare products Regulatory Agency

MHRA launches public consultation on future of UK medical device regulation

Medicines and Healthcare products Regulatory Agency (MHRA) launched a 10-week consultation to give everyone the opportunity to draw on their own experiences and contribute to the improvement of the regulatory framework and therefore patient safety in the future.

Our Experts are here to help you navigate any uncertain changes. Contact us at mdd@mddltd.com



Software As a Medical Device (SaMD)

IMDRF defines “Software as a Medical Device” (SaMD) as a software used for one or more medical purposes that perform these purposes without being part of a hardware medical device.

Any algorithm, code, or software program used for medical purposes and is not a part of a hardware medical device will be classified as SaMD.

A thin line of difference is stated in MDR classification where - Software for general purposes, even when used in a healthcare setting, or software intended for lifestyle and well-being purposes is not a medical device.

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8 Challenges Affecting Medical Devices

1

Uncertain Supply Chain

2

Cybersecurity

3

Duplication, Imitation and Counterfeited devices

4

Regulatory Challenges

5

Recalls and Lawsuits

6

Interdisciplinary Competition

7

Technological Advancements

8

Rising Costs

European Union
European Regional Development Fund

MEDILINK MIDLANDS

AFORTIORI DEVELOPMENT

GRS® Global Regulatory Services

Medilink Midlands Presents

The Final Furlong –

Your Clinical Trial Data and top tips on Regulatory Submission

6 October

10 am - 11 am

When a trial finishes, the ultimate goal is to have usable data that can be presented to regulators to make your case for your product's approval. Join us to understand the key considerations you'll need to be aware of when getting your data ready for regulatory scrutiny.

This free to attend event is held as part of the SoLSTICE programme – a project part-funded by the European Regional Development Fund

Registration link in Caption

www.medilinkem.com/event

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Greer Deal

Director
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Devices, Diagnostics and Digital Health!

MDD NUGGETS

There are over 500 000 types of medical devices and IVDs on the EU market.

IVDs are used to perform tests on samples, which includes HIV blood tests, pregnancy tests and blood sugar monitoring systems for diabetics.

Contact us for comprehensive Regulatory Support for your IVD innovation

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#MDR #IVDR Experts

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