Inhealthcare achieves MHRA compliance with support from DigiTEC Innovation

The online world is filled with healthcare applications. Many describe themselves as medical devices. But few meet the legal requirements to do so. With the accelerating shift towards digital health and care services since the onset of coronavirus, the need to demonstrate regulatory compliance has never been more important.

To mark its progress as a company, Inhealthcare worked with Dr Kessar Khaliq, Clinical Director of DigiTEC Innovation, to register its technology platform and associated patient and clinician facing apps as medical devices with the Medicines and Healthcare products Regulatory Agency (MHRA). As Inhealthcare rolls out remote care services on a regional and national level, procurement teams can be assured they are working with a trusted supplier.

Dr Khaliq has a special set of skills: he has worked in the NHS since qualifying as a GP in 1993 and has held a number of senior clinical lead, director and national advisory positions. Throughout his career, he has maintained a strong interest in technology enabled care, working on the redesign and evaluation of new pathways.

Last year, Dr Khaliq founded DigiTEC Innovation to work with the best of the new breed of health technology companies and drive the adoption of proven technologies within the NHS to benefit patient care. He helps innovators like Inhealthcare successfully navigate the medical device regulations and increase confidence in this growing market.

Dr Khaliq shares his top six tips for achieving regulatory compliance:

1. Get buy-in from the CEO. This is important work and senior management needs to be involved from the start, providing visible support and leadership.
2. Have all key stakeholders in the same room. From the project manager to the software architect: everyone has a part to play. Ownership should be encouraged.
3. Agree a road map. Make sure all stakeholders understand how the project is going to proceed and their individual responsibilities.
4. Constantly review your progress. Ask yourself and your team, how are things progressing? Is anything missing?
5. Prioritise continuously. Some elements will take longer than others. For instance, the clinical evaluation report always needs extra time and attention.
6. Teamwork! Understanding complex legislative requirements can be challenging and needs everyone to work together as a team.

For Inhealthcare, this was a valuable and rewarding experience which underlined how far it has come as a company. Inhealthcare is proud to hold an expanding number of accreditations. These demonstrate its absolute commitment to patient safety, information governance and platform security. You can read more about the company's credentials here.

The onset of coronavirus has increased attention on healthcare applications and the potential of technology to improve the way health and care is delivered in the UK. Health tech companies owe it to patients and providers to show they take their responsibilities seriously.

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What is the MHRA?

The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK.

The MHRA has published guidance on how to determine whether software should be classified as a medical device.

In the UK, software and apps that meet the definition of a medical device are required to be CE marked in line with EU directives to ensure they are regulated and acceptably safe to use.
The European Commission has adopted a proposal to postpone for one year the application of the new Medical Devices Regulation (MDR), which was due to come into force in May 2020. In a nutshell, MDR will places stricter requirements on manufacturers of medical devices.

The Government has said in a no deal scenario the UK's current participation in the European regulatory network for medical devices would end, and the MHRA would take on the responsibilities for the UK market currently undertaken through the EU system.

Introducing Dr Kessar Khaliq:

DigiTEC Innovation

Dr Kessar Khaliq is founder and Clinical Director of **DigiTEC Innovation**. The company provides consulting services on business innovation, digital architecture, product com-mercialisation, MDR regulation, compliance and informatics.

He has worked in the **NHS** since qualifying as a **GP** in 1993 and has held a number of senior clinical lead, director and national advisory positions.

Throughout his career, Dr Khaliq has maintained a strong interest in technology-enabled care, working on the redesign and evaluation of new pathways.

He has complemented his extensive clinical experience with training as a Clinical Safety Officer and in MDR for CE marking standards.

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