Medical Device Regulations in the UK
Specialized expert services on UKCA certification

The new UK Medical Device Regulations are expected to come into force in July 2025. In June 2023, the transitional arrangements for CE and UKCA marked devices came into force in Great Britain. Despite the extension to the implementation of the future UK Medical Device Regulations, manufacturers have been encouraged to transition to the UKCA as soon as possible. To support the transition, it is vital that industry have a clear understanding of the requirements within the UK.

Our services

AKRA TEAM's experience will support navigating industry through the transition and understanding the regulatory requirements.

Ad-hoc Consulting

Do you have specific questions related to the requirement on UK Medical Device Regulations? Book your slot now for a virtual ad-hoc consultancy hour with our key expert.

> Go to www.akrateam.com/service/specific-topics/uk-regulations to book a meeting

Customized Training

AKRA TEAM can provide manufacturers with the necessary training package for the organization's specific competency needs on UK medical device regulations.

> Email us to learn more: info@akrateam.com

Training agenda

A typical example for a customized UKCA training

1. Introduction to the UK legislative framework
2. Scope of the UK MDR 2002 Regulations
3. Requirements relating to a specific topic(s) dependent on client's needs e.g., conformity assessment routes under the UK MDR
4. New UK Post-market Surveillance requirements
5. Future UK Medical Device Regulations and transitional arrangements

Our expert

Jillan Hussein
Senior Consultant

Jillan has over 7 years of experience working at the Medicines and Healthcare Products Regulatory Agency (MHRA). Prior to joining AKRA TEAM, Jillan was a Senior Regulatory Policy Manager within the Devices Regulatory Policy team, where she was responsible for developing policies as part of the future UK Medical Device Regulations. Prior to her role within the Regulatory Policy Team, Jillan was a Senior Medical Device Specialist within the Safety and Surveillance Unit, where she was a lead technical assessor and worked closely with manufacturers and healthcare professionals across a variety of product areas.

Your experts for Regulatory, Quality and Clinical Affairs

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