

Revision of the Medical Devices Regulations

Crina Cacou

Medicines and Healthcare products Regulatory Agency (MHRA)

Summary

The session will provide an overview of a series of improvements that are being made to modernise the current regulatory system for medical devices and would explore their impact to day-to-day clinical practice.

Aims and objectives

The following topics will be included:

- Overview of the MHRA and its role in the regulation of medical devices
- Outline of the regulatory system for medical devices and key messages from the new regulation for medical devices (MDR), which entered into force on 25th May 2017 (<https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr>)
- Impact of the MDR on health institutions and healthcare.
- The role of adverse incident reporting in improving the protection of public health and patient safety, with case studies.

Participants may be interested in MHRA's introductory interactive guide to the [new EU regulations for medical devices \(MDR\)](#)

Email: crina.cacou@mhra.gov.uk

There will not be a Q&A session after this presentation – if you have questions for Crina, please visit her and MHRA colleague Phillip Davenport on Stand 45 in the exhibition.