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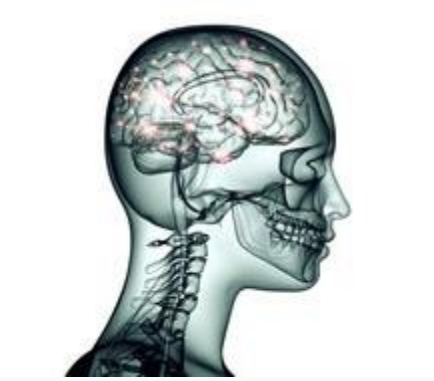

Regulatory review

Your monthly medical device update

October 2017

The general Safety and Performance Requirements (SPR) in the New Medical Device Regulation (MDR)

A full gap analysis of the SPRs against the Essential Requirements (ERs) of the Medical and Active Implantable Devices Directives identifies several new requirements and many areas of increased emphasis and specificity. It is important that you understand how the ERs relate to the new SPRs as you start to plan your MDR transition.

Understanding the changes

Use our comprehensive white paper, which compares the ERs and SPRs and indicates additional guidance documents and standards.

Download now

Join BSI experts for our new webinar on 29 November at 4pm GMT to understand the main impacts from the new SPRs and consider what actions you need to take now to be prepared for the change in

requirements.

Register now

A successful business is... Robust

Robust businesses are resilient to change, can adapt to advances in their industry and take advantage of new opportunities. Learn about BSI Medical Devices from BSI Certification Lead, **Sharmila Gardner**, in our latest video.

Watch the video

Understanding human factors: what are the requirements?

Human factors, or usability, describes the ability of a human to interact with a system, product or procedure easily and relatively error-free. Manufacturers are expected to provide a safe product that the user understands, minimizing errors.

Looking for more information?

Our new, complimentary webinar explores usability requirements in more detail, references the associated guidance and standards, and explores the upcoming changes to requirements. Join BSI AIMD Product Expert **Richard Stein** on 12 October at 4pm BST to find out more.

Read more

The UK **Medicines and Healthcare Product Regulatory**

Agency (MHRA) has released a new guidance document aimed at clarifying usability requirements. The guidance, developed with input from BSI's Global Head of Active Devices, **David Adams**, highlights the link between human factors and patient safety.

Access the guide

NEW BSI webinars:

Technical Documentation requirements under the MDR, including requirements for your legacy files

The new Medical Device Regulation (MDR) has arrived, and it contains enhanced requirements for Technical Documentation. This webinar will help you to consider what actions you need to start now to be prepared for the change in requirements and allow you to start planning how to meet them for your legacy files. Join Clinical Oversight & Training Lead, **Dr Amie Smirthwaite** on 30 October at 4pm GMT to find out more.

Register now

Critical update on Medical Device Single Audit Program (MDSAP): Countdown for Canada.

Health Canada has confirmed the requirement for medical device manufacturers to transition from CMDCAS to the Medical Device Single Audit Program, MDSAP, to place devices into Canada. This webinar will cover a summary of the Program, including what manufacturers can expect, and will focus on the timelines and actions

you need to take now to ensure continuity of supply for your products. Join BSI Global MDSAP Manager **Patricia Murphy** on 16 November at 4pm GMT to find out more.

Register now

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