The revision of the Medical Devices Regulations: what it means for the posture and mobility world

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Summary
This session will be run as an interactive workshop focusing on the new Medical Devices Regulation (MDR) including the health institution exemption (HIE) in Article 5.5.

Aims & objectives
Topics for consideration and discussion will include:

- What are the main MDR requirements for manufacturers and health institutions;
- What would you need to do if you intend to place on the market, or continue placing on the market, a risk Class I medical device as from May 2020;
- What more actions would you need to take if your device is a higher risk medical device;
- What are the General Safety and Performance Requirements;
- What is the role of Standards in the regulatory process;
- What could be 'appropriate quality management systems' [MDR, Article 5.5 (b)];
- Under what scenarios could you justify applying the HIE;
- Who could be responsible for regulatory compliance: for CE marking or for in-house manufacture;
- Would you have to register as an in-house manufacturer with MHRA;
- What are the requirements for in-house manufacturing of a custom-made medical device;
- What if the device is being manufactured for a research purpose;
- What is the MHRA's role at pre CE-mark and post CE-mark phases of medical devices;
- How adverse incident reporting ensures patient safety.

Participants should go away with a better understanding of the implications and some of the details of the implementation of the 2017 Medical Devices Regulation. Particularly, they should understand when and how to apply the health institution exemption so that they are exempt from a full conformity assessment in line with Article 5.5 of this Regulation. It would be helpful if participants had read this in advance (please see page 21 of http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&qid=1498855375001&from=EN).

Participants should also be aware that by the date of the conference, the MHRA draft guidance on the HIE, currently out for consultation until March 31st, may have been issued, and may clarify some of the issues above (please see https://www.gov.uk/government/consultations/health-institution-exemption-for-ivdrmdr).

Additional information and resources can be found via the PMG website:
https://www.pmguk.co.uk/news/medical-devices-regulation-mdr

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