News story: MHRA delivers guidance on human factors

This guidance is intended for manufacturers, developers and notified bodies to highlight the important influence human factors have on patient safety. The advice is also relevant to device components of drug-device combination products that are regulated as medicines.

Although it seeks to clarify regulatory expectations of medical devices marketed in the UK, the guidance does not represent a compliance requirement.

An engaging multi-disciplinary stakeholder day on human factors and the implications for patient safety led to the formation of the Human Factors Task and Finish group. The group was chaired by Dr Peter Nightingale, who is also the chair of MHRA Devices Expert Advisory Group (DEAC) and Tony Sant, group manager in the Devices Division, MHRA.

Membership was drawn from MHRA, academia, industry, NHS Improvement, NICE, notified bodies, professional associations and trade bodies, and the resulting guidance is the collective effort of that group and of feedback from further stakeholder engagement and the public consultation of a first draft published in June 2016.

In simple terms, 'human factors' refers to how a person will interact with the system surrounding them, including the technology they use. Human factors takes into account the environment, user population and potential competing distractions.

John Wilkinson, MHRA Devices director, praised the collaborative effort to produce the guidance.

"Medical devices are becoming ever more complex and diverse, encompassing drug-device combinations and companion diagnostics.

"Patient care is increasingly being transferred from hospitals to patient homes and community settings. As these developments occur the potential for use error increases. We recognise this and have collaborated with partners to produce the first UK guidance on human factors."

This guidance will complement the work being carried out by the NHS to apply human factors approaches in the design of healthcare workplaces and practices.

View the complete guidance.

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