Change is coming

The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) has released guidance on applying human factors to device design. **Dr Azad Hussain**, research fellow at the Medical Devices Testing and Evaluation Centre project, and **Anthony Sant**, group manager of information and operations at MHRA, speak to Percy Ledger about what these user-focused changes mean for medical device manufacturers.

An increasing number of people are operating devices at home, schools and other non-clinical settings, usually without any formal training. This makes human-factored design essential in keeping users safe. How they interact with the technology, their ages, levels of education and degrees of physical strength are important considerations.

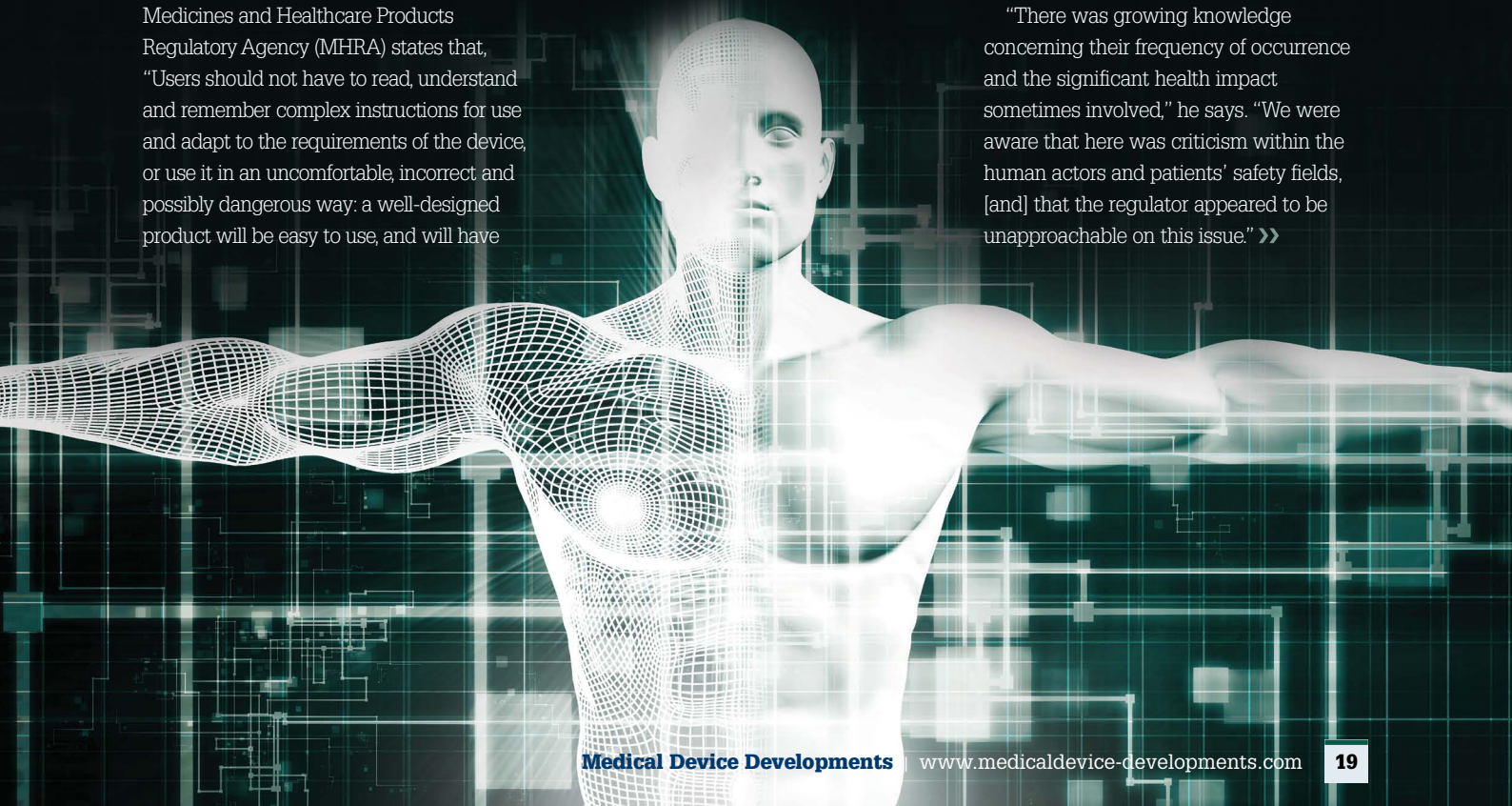
The 'Human Factors and Usability Engineering – Guidance for Medical Devices Including Drug-device Combination Products' document, published in September 2017 by the Medicines and Healthcare Products Regulatory Agency (MHRA) states that, "Users should not have to read, understand and remember complex instructions for use and adapt to the requirements of the device, or use it in an uncomfortable, incorrect and possibly dangerous way: a well-designed product will be easy to use, and will have a user interface that is consistent with user experiences and expectations."

The document aims to help manufacturers meet the usability standards set out in the EU Regulation on Medical Devices (MDR) and In-Vitro Diagnostic Device Regulation (IVDR), which were implemented on 25 May 2017 and have a transition period of three and five years, respectively, by which time all EU member states will need to comply.

MHRA's guidance makes note of devices, including infusion pumps, ventilators, automatic electronic defibrillators, and drug-device combination products and auto-injectors as "potentially having use-related design issues that can result in various problems, such as overdoses, incorrect therapy and dangerous delays or difficulties with delivery of medication".

Several factors were behind the new guidance, according to Anthony Sant, group manager of information and operations at MHRA, including the agency's involvement with improving international and European guidelines for reporting incidents of use error concerning medical devices.

"There was growing knowledge concerning their frequency of occurrence and the significant health impact sometimes involved," he says. "We were aware that here was criticism within the human actors and patients' safety fields, [and] that the regulator appeared to be unapproachable on this issue." ››



MHRA states that electronic defibrillators, auto-injectors and many other devices could be dangerous if used incorrectly.

To resolve this, the agency launched a multidisciplinary group to compile the guidance document. It was led by the chair of the Devices Expert Advisory Committee and populated by members with expertise in medicines and medical devices, as well as industry partners, representatives from the healthcare sector, and key people from notified bodies and Chi-Med.

"Although this guidance aims to clarify the regulatory expectations of medical devices marketed in the UK, it does not represent a compliance requirement," Sant stresses. It applies to the design of future products and the changes in user interfaces for existing products, rather than those already approved for the UK and EU market.

Devices can enter the market during the transition periods, which end in 2020 for the MDR and 2022 for the IVDR, but will need to adhere to current EU Directives or the new regulations; devices that enter the market after this time frame have to comply with the regulations, but device manufacturers must use the extended period of CE marking certificate validity.

Robust safety requirements, in regard to having a desired end result for a device's design based on a specific use, had already been set out in Annex I of the Medical Device Directives (MDD) and in section two of the future MDR. However, Sant says the problem was that there was very little regulatory guidance within Europe on how this might be achieved, hence the MHRA's motivation to provide it.

Fit for use

The MDD already sets out requirements to ensure medical devices are designed in an ergonomic way that makes them fit and usable for their intended purposes, but the new MHRA guidance brings them more in line with MDR, says Dr Azad Hussain, a research fellow at the Medical Devices Testing and Evaluation Centre (MD-TEC) that provides a facility for medical technology companies to test devices and products for usability and safety.

The MDR and IVDR set out rules for manufacturers "to look at continual improvement, in terms of usability and, essentially, not rest on their laurels once [a device] has been made and approved for release into the market," Hussain explains.

Manufacturers should strive to improve the safety of medical devices, especially as designs become more complex, connected and integrated with technology.

The regulations require manufacturers to meet additional obligations, such as assigning at least one person responsibility for regulatory compliance and ensuring quality management systems meet stringent requirements, including vigilance standards and reporting serious incidents. The design terms set out in the MDR and IVDR also give manufacturers a list of requirements they must meet when designing and rolling out devices. These encourage manufacturers to think about functionality from the beginning.

"The inclusion of human factors and usability at the earliest stages of design will help manufacturers to refine the development of a device," Hussain argues. "By involving the end user in the process – from healthcare professionals to the patient – there is more opportunity to design out risk."

However, Hussain warns that medical devices are not just used by trained healthcare professionals in clinical settings, but also by patients or their caregivers at home. "The designers, developers and manufacturers of devices have to take that into consideration when making medical devices, keeping in mind its intended use to reduce the risk associated with incorrect use," he advises. MHRA's guidance consolidates the information to help medical device manufacturers "integrate human factors into the device development life cycle", the researcher adds. This not only provides a coherent framework for manufacturers to use when designing and developing medical devices, but also assists with the relevant technical documentation for CE marking submissions.

A duty of care has always been placed on manufacturers to ensure good design and limit risk, Hussain says, while emphasising that the MHRA's guidelines are key for explaining what is required for good practice, and how manufacturers can meet the MDR and IVDR's requirements.

Unique device identification (UDI)

The UDI system that is to be rolled out under the regulations is a notable consideration for manufacturers. It mandates that they provide a unique identity number for every medical device that enters the healthcare supply chain, which must be added in machine (AutoID) and human-readable forms to packaging and, in some cases, the device itself.

UDIs also necessitate that certain details, such as the manufacturer name, model and associated serial numbers, be obtainable via a 2D or 3D barcode.

"This facilitates the traceability of medical devices through the supply chain, thus enabling faster and more comprehensive implementations of field-safety corrective actions involving medical devices," Sant states. "If UDI can be captured in healthcare records systematically in the future, then this could improve the post-market surveillance of medical devices significantly."

UDIs make devices traceable. Tracking individual products will also yield more detailed information about performance, once a device has been released.

Hussain also outlines the long-term benefits the UDI system will bring, saying, "[It will] help to improve patient safety, allow greater detail to be collected and analysed for post-market surveillance, while facilitating medical device innovation through iterative step changes in the design and manufacture of future devices.

"If the information is also available to other start-ups and manufacturers, in terms of the performance of devices currently on the market, it will [guide] them towards better designs and devices, avoiding any pitfalls that may be highlighted during post-market surveillance," he adds.

Challenges posed by change

If manufacturers follow MHRA's guidance, designing human-factored devices will be relatively straightforward. However, there are hurdles to overcome.

"The main challenges are reviewing the guidance to ensure that their design processes for new or modified devices credibly ensure they are achieving compliance with the relevant essential requirements," Sant highlights. "This guidance is aligned with FDA where possible, but has been written in a European-regulatory context, facilitating its use in the UK and other parts of Europe."

The MDR and IVDR will increase workloads for manufacturers and SMEs, but they should already be in the process of adapting their systems to meet the new requirements. "It will require time, resources and money to do that," Hussain admits. "If the resources are there, in terms of materials and people with relevant knowledge, then it should be a process that can be planned out and completed."

Stakeholders need to determine how to bring systems in line with the regulations. "It is also the will of people, from senior management to the shop floor, who are prepared to change and adapt, that will be the biggest asset for a manufacturer," Hussain says.

MHRA's document also helps manufacturers ensure their medical devices pass the conformity assessment, as demanded by the MDR and IVDR. They can then place a CE mark on the product if it has passed the assessment, which is a vital step in guaranteeing product safety.

"The guidance provided by the MHRA is a very helpful pointer towards the relevant standards and other guides that manufacturers will also find useful in helping to get their device through the CE conformity assessment route," Hussain states. "The information has always been available for manufacturers from multiple sources, but it is now much clearer as to what is expected of manufacturers because there is a structured approach to it."

While the transition period grants medical device manufacturers a grace period before requiring full compliance with the MDR and IVDR, they should already be working at getting their products ready for the deadline. By accessing MHRA's guidance and focusing on human factors as early in the design phase as possible, manufacturers can ensure their devices not only work as intended, but also keep users safe while operating them. ■