# Usability engineering requirements in the UK (MHRA)

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### **SUMMARY**

This paper provides an overview of usability engineering requirements in the UK, now that it is not a part of the EU. Notably, Human Factors vendors do not need to be local to any region to perform usability engineering activities, but human factors processes need to adhere to local requirements.

#### **KEYWORDS**

Usability engineering, Regulatory framework, Medical Devices

#### Introduction

On January 1<sup>st</sup>, 2021, the United Kingdom (UK) formally left the European Union (EU). That is to say, the grace period between instigating Article 50 and leaving the EU ended. Many regulatory requirements in the UK were updated to reflect this, including regulatory requirements for medical devices. Usability engineering for medical devices is the application of usability engineering to risk management of medical devices during development. This is an established requirement internationally (IEC, 2020), with the UK's 'Medicines and Healthcare products Regulation Agency' (MHRA) having their own supplemental guidance on how they would like usability engineering to be implemented in the UK (MHRA, 2021).

As of January 2021, the MHRA usability guidance was updated to reflect the changes to the regulatory landscape. This paper hopes to inform relevant Human Factors Specialists of how leaving the EU will impact usability engineering efforts for medical devices (including software), combination products and in-vitro diagnostic devices that want to enter the UK market, noting that capability to perform usability engineering efforts for other markets is still possible for UK vendors.

### Key update

The MHRA usability guidance document provides an overview of the updates made to the document between version 1 and version 2. This updated version 'reflects the changes to the regulation of medical devices in the UK as a result of exiting the EU' (MHRA, 2021a).

### **Background to Regulatory requirements**

Whilst a part of the EU, the UK was subject to the EU's over-arching regulatory requirements. Readers may be familiar with the 'CE' mark, the symbol that indicates a product is approved for use within the EU. The CE mark means the product has gone through the correct processes during development and the manufacturer plans to apply the proper processes to the lifecycle of the product on the market. This essentially means you can rely on the product to meet a minimum standard of safety and quality.

To meet this minimum standard of safety and quality for medical devices, the manufacturer has to assess, understand and manage the various risks associated with use of their device. For the EU,

these requirements are detailed in the 'Medical Devices Regulation' (The European Parliament, 2017a). The MDR requires manufacturers to comply with processes outlined in standards that are harmonised within the EU. Harmonised in this context, means standards that the EU acknowledges as being the best practice to perform particular processes within medical device development, and includes standards contained within the 'Official Journal of the European Union' (The European Parliament, 2017b).

Uniquely, the standard that is most prevalent for usability engineering is not harmonised, but it is considered the 'state of the art' in applying use-related risk management efforts. Therefore, the most recent version of the IEC standard '62366' is used to apply usability engineering to risk management of medical devices at a 'state of the art' level.

## **Established UK Regulatory requirements**

Great Britain (England, Scotland and Wales [GB]) is no longer subject to requirements for the EU, so the UK has set up their own regulatory framework to establish products on the market in the UK. The UK mark is called the UK Conformity Assessed (UKCA) mark. If you intend to bring a product to the market in GB, then you must adhere to requirements to obtain a UKCA mark.

If you intend to bring a product to the market in Northern Ireland, then the product will still require a CE marking under the EU MDR. The product will likely also require a 'UKNI' mark in order to be placed on the Northern Ireland market. This means that old processes can be maintained for products developed in Northern Ireland (for a CE mark), but new processes may need to be applied as well (for a UKNI mark).

For products that aim to go to the GB market, medical device manufacturers will need to review the 'UK Medical Devices Regulations 2002' (UK Medical Devices Regulations, 2002), referred to as the 'UK MDR 2002'. The MHRA guidance on usability provides an overview of the information that implies usability engineering is required to comply with regulatory requirements;

'The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or safety of patients...... This shall include:

- Reducing as far as possible, the **risk of use error** due to the ergonomic features of the device and the environment in which the device is intended to be used' (MHRA, 2021b)

This is relevant to medical devices, combination products, in-vitro diagnostic devices and also software as a medical device. Manufacturers are obligated to manage risk of use error. This therefore is enough to indicate that you need to apply usability engineering efforts for acceptance on to the UK market. It should be noted that the rigour required of your usability engineering process will also rely on the Class of your device.

## Conducting usability engineering in line with UK expectations

Fortunately, the MHRA usability guidance proceeds as the first iteration; the guidance details the usability engineering process in line with IEC 62366, which means that in terms of activities performed, the process and compliance can be demonstrated in the same way as it has been for the EU CE marking.

The MHRA guidance also refers to the United States of America (USA) Food and Drug Administration's (FDA) Human Factors guidance (CDRH, 2016) and the practices outlined there. This suggests that the UK recognises the FDA guidance and application of usability engineering as well as IEC 62366.

For manufacturers that aim to bring their device to other markets alongside the GB market, this means that there is an opportunity to streamline the process. One process may apply to multiple regions of the world. Final tests (known as 'validation' or 'summative' studies in usability engineering) may need to be performed in each market, but the documentation and risk analysis process used will be appropriate for multiple markets and can be performed by any Human Factors Champion or Specialist. The UK MHRA guidance furthers the possibility to streamline efforts (or eliminate need for duplication) by stating that 'a summary report can be prepared'. This report – the 'Human Factors Summary Report', describes the same content as the 'Human Factors Engineering Report' required for submission to the FDA under a typical submission. IEC 62366 does not call for a final report to demonstrate compliance, rather it outlines compliance is demonstrated through a 'usability engineering effort. By stating that a summary report 'can be prepared', rather than 'should be prepared', the MHRA guidance is enabling flexibility between the requirements in IEC 62366 and the requirements within the FDA guidance.

# Conclusion

If aiming for multiple markets, the device manufacturer can feel confident the guidance provided by the MHRA can be comparable to the processes for the EU and the USA as well. Importantly, there are some differences between the EU and the USA, so any practitioner should be sure which additional markets they are aiming for and plan their process accordingly.

The MHRA guidance is available online for free; it is worth reading for a good overview of the procedure for and the purpose of performing usability engineering, plus a wealth of wider reading and other relevant standards.

In terms of usability activities, Human Factors Specialists can conduct the usability engineering process in line with current practices and feel confident they are complying with the UK regulatory requirements. Ensure the correct standards, guidance, notified bodies and regulatory documents are being referenced in the usability documentation, and make sure to run your final study in the appropriate country or region!

## References

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