Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Comment sheet for MHRA draft document:

Human Factors and Usability Engineering – Guidance for Medical Devices Including Drug-device Combination Products

Deadline for comments: 5 August 2016

Send comments to: dts@mhra.gsi.gov.uk

Section number	Page no.	Comment	Proposed change
1 (Definitions)	5	'See above' for the key definition is too weak given that the definition is spread across several paragraphs.	
1 (Definitions)	5	There should be a definition of Human Factors (as opposed to Human Factors Engineering).	Insert new definition
1 (Definitions)	5	User interface is commonly misinterpreted (especially in industry outside of manufacturers of electrical medical equipment) as something that only electrical medical devices contain	Add some more specific examples here or later in the document to highlight the many and varied real life types of user interface (e.g. connectors, valves, peel tabs, brake releases, activation mechanisms etc.).
1 (Scope)	5	The scope of this document is not wide enough to be consistent with the title. During presentations from speakers and with clarification questions asked at the meeting, and within the scope section, it became apparent that the focus of this is manufacturers of medical devices. If that is the case, then the title cannot be "Human Factors" and should be changed to Usability Engineering. It seems that in the USA the meaning of these terms is clearly understood as meaning different things, whereas at this meeting it was evident that the terms are being used interchangeably. This creates a misconception that the guidance tackles the issue of Human Factors, which it does not. It should be made explicit that Usability Engineering is one facet of Human factors, but does not address the Human Factors associated with the	Either (i) change the title to Usability Engineering, or (ii) insert complete new sections on the wider aspects of Human Factors that are excluded by the last sentence in this section. If (i), then it should be clarified who will provide the wider guidance on Human Factors.

		introduction and use of medical devices in clinical environments. Bearing in mind that Managing Medical Devices (Apr 2015) is a MHRA publication, which addresses the introduction into service and the use of medical devices, it could reasonably be expected that any publication by MHRA on the subject of Human Factors should also tackle this wider context.	
1 (Scope)	5	The scope must surely be ALL medical devices sold or supplied in the EU regulated by one of the 3 directives in Section 2. What is called a Scope here is more like a Purpose or Objective. The final sentence of the Scope (about clinical decision making) is actually about the scope. Does it include Custom Made medical Devices? How does it apply to medical devices that have been on the market for many years in their current form and have never been put through formal usability testing?	Clarify the applicability to non-electronic devices, and to devices that have already been CE marked prior to usability testing.
1 (Scope)	5	Should we also mention that it is aimed at researchers developing devices for use in clinical evaluations, as it does touch on this later in the document in section 8.	
1 (Scope)	5	Slips into referring simply to ‘devices’ rather than ‘medical devices’.	If ‘devices’ is going to be used as an abbreviation then it is stated up front (e.g. henceforth written as devices).
1 (Scope)	5	The last sentence of the first paragraph (relating to commissioners) does not fit.	Separate the aims into different paragraphs.
2 (Regulatory Framework)	6	Reference is made to MDD93/42EC. Will this be revised to ref the MDR?	
2 (Regulatory Framework)	6	It may be beneficial to also cite the Machinery Directive 2006/42/EC (which applies to many medical devices) as it contains specific requirements regarding user errors and error prevention (e.g. Annex I, section 1.5.4. of Directive 2006/42/EC).	
3 (standards)	9	Consider EN 13485 and EN 14971 the parents of the three key standards referenced. EN 13485 calls for Design Validation (the medical device performs as intended when used for its intended use by its intended user in its intended environment). EN 14971 requires hazard identification in normal and fault conditions, which includes user errors and foreseeable misuse. Usability engineering is not about a special process; it is about designing and installing a safe and effective product for the intended use	

		and intended user.	
Table 1	13	Pleased to see the importance of the end user highlighted. Devices to be used by patients/carers may have different design requirements to those used by healthcare professionals	
Table 1	14	'possible user errors'	'possible use errors'
4 Summary of the usability engineering process – Fig 2	11	The process mapped (Fig 2) identifies "device launch" and then post-market surveillance. This is again very much from a manufacturer's point of view, but does not tackle HF measures that should be taken prior to introduction to service	
5.3	15	'in order to reduce risk through design' An important point. Device weaknesses should be tackled by design where possible before looking at warnings and user training.	
General across sections 4 - 8	9 - 21	These sections seem to mainly summarise the content of the standards. Is that really the intention? Consider placing extra emphasis on ergonomics, and incorporation of case studies. e.g.1: a bariatric manual wheelchair for users up to 200kg where the manufacturer expected someone to manually push a 200kg user with no mechanical aid, whilst using push handles that were nearly 1m apart. e.g.2: Operating theatre equipment that is intended to be portable but the handle is situated so low on the device that users have to significantly stoop down to push the heavy equipment from one theatre to the next with no consideration of the ergonomics.	Consider additional input from MHRA in terms of the adverse incident data that either shows examples of where medical devices with poor usability have led to adverse incidents and potentially harm, and examples of where products with good usability have been shown in clinical literature to perform better (these case studies can be made anonymous rather than naming products/manufacturers).
6.3	19	Should there be a link or reference here to Clinical Investigations and ethical approvals etc.? Non-CE Marked medical devices may be used on healthy volunteers or actual patients in order to generate the type of data that is required.	
7	20	Should we not also draw down incident data reported on the NRLS as many incident reports do give full device information?	

8 product life cycle and continuous improvement - Figure 3	22	It is not clear what value this diagram adds in its current format	Either remove figure 3 entirely or modify to include regulatory requirements (whether from regulations or guidance) and Healthcare provider requirements (HF analysis, standardisation, training, incident analysis and reporting).
General comments		Useful document for manufacturers; well referenced to standards and relevant publications. Helpful Table. Will the usability engineering documents for devices be available to potential customers? A good document for clinical engineers who design devices for in-house use or advise 3rd parties about medical device design. Could the document be expanded to include advice about pre-purchase clinical evaluations? How can we make better choices using human factors and usability engineering tools?	
General comments		Consider a section providing guidance for commissioners or health care providers, i.e. what they should be looking for in terms of evidence.	
General comments		Consider guidance about how ergonomic principles and Human Factors can be applied to the installation of a suite of equipment in a ward or theatre or clinic etc.? (E.g. using usability and human factors to set-up a physical location that optimizes the usability of the medical devices within the location, aligned with the work flow / work patterns that occur within that space.)	
General comments		A consequence of the limitation in aiming only at manufacturers is that there are no sections to address introduction into service and use errors. It would be very useful to have guidance on how to undertake a Human Factors assessment before devices are put into use, e.g. what considerations should be undertaken in selecting the most appropriate devices, are there learned behaviors that must be un-learned etc. One crucial missing element is that there is no feedback loop via Regulators to require manufacturers to adopt conventions that relate to the	

		use of devices. This issue was also raised at the meeting on 10th June, with the MHRA response that this would stifle innovation and that manufacturers independently design user interfaces. This means that in real life clinical environments, clinical staff are faced with a variety of devices from different manufacturers in which controls and data entry are different. The same key presses on one device will invoke a different function when used in the same way on a different device. In a clinical environment, with the common distractions and pressures, this means that clinical staff commonly make “use errors” by following a data entry or command process for one device that is from a different device that they are familiar with. Only with a standardised convention for data entry could this aspect of Human Factors be addressed. It is believed that the US FDA are looking at how this could be implemented.	