Developers guidance

Meeting design requirements for medical devices: meeting UK MDR 2002

This is required guidance

It is legally required and it is an essential activity.

This Guide covers:

- Great Britain (England, Scotland, Wales)

From:

- Medicines and Healthcare products Regulatory Agency (MHRA)

To meet UK regulations, you need to show you've designed medical devices to the appropriate safety standards.

Designing medical devices to appropriate standards

The Medical Devices Regulations (UK MDR 2002) state that you must design and develop medical devices to meet the safety requirements.

Creating and maintaining design and development documents makes compliance and operational tasks more robust.

The documents form part of the device's technical file, which is used to prove you're complying with regulations. The technical file will also include your clinical evidence and risk-management documents.

Design documents are crucial in further development work, failure investigations and company growth. They make sure that device knowledge and quality-control processes are maintained as you progress through the device's lifecycle.

Creating design documents mostly happens in the development stage. However, user needs are typically generated in the conceptualisation stage. So, the documents must be kept up to date throughout the device's lifecycle.

Included in the design documents

To prove you're meeting the design requirements of the UK MDR 2002, you need to create version-controlled documents containing the design and development information for your medical device.

Exactly what documents are produced varies between medical devices. It depends on factors such as the complexity of the device and the development process. Typical documentation may include:

- describing what the device looks like at a technical level (for example, architectural diagrams and schematics)
- information on suppliers of components not made in-house
- defining the user needs for development of functionality
- design inputs and outputs from the development process; that is, the target functionality and result achieved after development

- verification and validation information relating to original user needs
- risk management and clinical-evidence documentation
- a record of design changes and testing to demonstrate maintained or improved functionality

The Quality Management System (QMS) you design to meet ISO 13485:2016 standards will help you generate these regulatory documents. They are created in line with best-practice standards.

This information is not intended to replace formal statutory guidance regarding legal requirements. For an authoritative view of what regulations require beyond this digest, please see the relevant gov.uk web pages pertaining to the MHRA.

