Developers guidance

Creating and maintaining quality management systems for medical devices

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 the requirements of the law you need to create and maintain quality management systems (QMS) for medical devices. ISO 13485 QMS defines the requirements you must meet.

Creating and maintaining a quality management system for medical devices

To meet the requirements of the UK Medical Device Regulations 2002 (UK MDR 2002), developers of medical devices must create and maintain a quality management system (QMS).

A QMS is a series of processes and documents in the form of policies, standard operating procedures and records. These specify the objectives, ways of working and results of your activities. Follow the standards of the ISO 13485 QMS to make sure you are doing it properly.

The aim of a QMS is to:

- mitigate risks
- improve consistency
- improve efficiency
- create safe high-quality medical devices

Building, certifying and maintaining a QMS can cost a lot of time and money. This depends on your existing expertise, the complexities of the QMS and the capacity of approved bodies. Factor this into your development plans early to reduce significant delays later.

Following ISO 13485 QMS standards

Step 1: Read ISO 13485:2016 medical devices – quality management systems

ISO 13485:2016 quality management systems standard specifies the requirements of a QMS system for the development of medical devices.

Step 2: Get ISO 13485 certification

Schedule auditing by an approved body which, if successful, will grant certification against the standard.

Step 3: Maintain the QMS system

Use your QMS throughout the whole device lifecycle and audit it frequently. It will be periodically audited by your approved body.

Note that the scope of your QMS may vary depending on the specific activities done during the lifecycle of the device. You must ensure that all activities you require are included in your scope and audited against. But remember, the scope of your QMS needs to be defined prior to getting assessed and certified. You cannot change the scope of the QMS without getting reassessed by your approved body.

For example, some companies outsource their design activities to another organisation. In which case, each organisation should have a separate QMS. Their remit and scope will cover different processes and have defined processes for the 2 organisations interacting.

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.

