Developers guidance

Implementing a quality management system for your technology

This is best practice guidance

Although not legally required, it's an essential activity.

This Guide covers:

- Great Britain (England, Scotland, Wales)

From:

- Medicines and Healthcare products Regulatory Agency (MHRA)

Although not legally required for non-medical devices, implementing a quality management system (QMS) is best practice and essential to placing your technology on the market.

What is a quality management system?

A QMS outlines processes that minimise the risks associated with the production, deployment and surveillance of technologies. A QMS provides structure for key company processes. These internal processes and policies ensure:

- robust documentation management
- risk assessment
- tracking of key decisions and
- clear routes for sign off

Depending on scope, a QMS will help you with activities that may include:

- design and development
- evidence generation
- post market surveillance

Your QMS should evolve in line with company aspirations and throughout the lifecycle of the technology.

Management systems can take significant time and personnel to set up, certify and operate. So, make sure you set up your QMS during technology conceptualisation and wider strategic planning.

To learn more, please review our guidance on setting up a QMS for medical devices. Although this guidance is tailored to medical devices, it gives a complete overview of what you need to do to meet best practice principles.