Will regulatory medical device reforms impact your quality management system?

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Reading time 7 mins

Key Points

- UK’s proposed regulatory medical device reforms (to improve patient safety and promote innovation) will be implemented in mid-2024
- A quality management system is mandatory for medical device compliance
- Manufacturers of low-risk medical devices can self-declare conformity before affixing the UK Conformity Assessed (UKCA) on their product and placing it on the market
- Proposed reforms will not mandate manufacturers to have an internationally certified QMS in place
- However, manufacturers – especially those who self-declare conformity, are likely to be subject to random QMS audits, unannounced visits, and random product testing by regulatory bodies

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Reforms of any kind present both opportunities and risks – regulatory medical device reforms are no different. UK's proposed reforms, which are anticipated to be implemented by mid-2024, are likely to present more opportunities than risks as the goals are to [1]:

1. Improve patient safety
2. Encourage innovation
3. Overhaul outdated frameworks
4. Address health inequalities and mitigate biases
5. Set internationally recognised standards with the aim of making the new UK Conformity Assessed (UKCA) mark seen as a global exemplar
6. Encourage investment

In the UK, organisations must have a quality management system (QMS) for medical device compliance. However, this doesn't need to be an internationally accepted one such as the IS013485 (the medical industry's most widely used standard for quality management). In addition, manufacturers of Class I medical devices (low-risk products, e.g. stethoscopes, spectacles) and general in vitro diagnostics (IVDs) can self-declare the conformity of their devices before affixing the UKCA mark and placing their product on the Great Britain (GB) market.

Will proposed regulatory medical device reforms impact a manufacturer's ability to self-declare? What kind of QMS does self-declaration need? If setting international standards is one of the goals, will adhering to international QMS standards such as ISO13485 become mandatory?

Key QMS requirements for medical device conformity

A quality management system (QMS) helps companies document and prove the effectiveness and safety of all the processes involved in the entire lifecycle of their device or product. QMS is the backbone of any medical device manufacturing company as this helps mitigate risks, improve operations, and provide the documentation needed for conformity assessments. While companies aren't mandated to be ISO13485 certified, this standard nevertheless provides a benchmark to understand the essential QMS requirements [2]. This includes:

- Documented strategy for medical compliance (e.g. clearly defined organisational leadership structure, the legal requirements that apply to the device, the device classification and risk category)

- The process to enable the identification of all General Safety and Performance Requirements (GSPR)
- Process for managing resources – including suppliers and sub-contractors
- Risk management procedures such as a Failure Modes Evaluation Assessment (FMEA). Download a free template here if you don't already have one.
- Procedure for performing Clinical Evaluation
- Product realisation process
- Process for ensuring UDI (unique device identifier) standards are upheld for tracking and traceability purposes
- Setting up and running a Post-Market Surveillance (PMS) system, a Post-Market Clinical Follow-up (PMCF) system, and a vigilance reporting system (to handle incidents if/when they occur) for each product where applicable
- Procedure for handling communication with Approved Bodies and authorities where applicable

Self-declared conformity certification for Class I medical devices

As mentioned earlier, manufacturers and developers can self-declare conformity on low-risk medical devices and IVD. This requires you to [3]:

- Declare conformity against the UK MDR 2002 legislation
- Keep documentation to prove that your product conforms with regulatory requirements. For example, records showing how the product was designed and manufactured and how it conforms to requirements
- UK Declaration of Conformity, which will generally include:
  – your (the manufacturer's) name and full business address and that of your authorised representative (if applicable)
  – the product's serial number, model or type identification
  – a document stating you take full responsibility for the product's compliance
  – the details of the approved body which carried out the conformity assessment procedure (if applicable)
  – the relevant legislation with which the product complies
  – the name and signature of the person authorised to sign on behalf of the

manufacturer or their authorised representative

– the date the declaration was issued

– supplementary information (if applicable)

If you intend to place your product or device on the EU market, self-declaration is still possible. However, you would have to also adhere to EU MDR or EU IVDR and sign a separate declaration of conformity specifically for that market. In addition, you will have to affix the Conformité Européenne (CE) mark on your product/device along with the UKCA mark.

Will regulatory device reforms change conformity requirements?

Regardless of whether you're self-declaring conformity, you still need to have a QMS in place – even if not necessarily a certified one. Bearing in mind that one of the goals of regulatory device reforms is to improve patient safety and make the UKCA mark a global exemplar for international standards, manufacturers can expect to have their products placed under greater scrutiny [4], which could mean:

- Random QMS audits by regulatory bodies
- Unannounced visits by notified bodies to ensure that safety checks are being conducted
- Random product testing
- Independent testing conducted by regulatory bodies rather than relying on self-certified reporting by manufacturers
- Proactive random testing of low-risk medical devices to make sure they're fit for purpose

That being said, the MHRA (Medicines and Healthcare products Regulatory Agency) intends to find the balance between regulatory reforms that improve patient safety while promoting innovation and attracting international investment. As much as the ability to self-declare conformity and non-specific QMS goes, we have much in our favour. The onus is, therefore, on those of us developing and manufacturing medical devices not to cut corners and ensure that the products we design meet the highest available standards.

What are your thoughts on regulatory medical device reforms? Do you have a QMS in place, and do you think it will hold up under scrutiny? Share your thoughts in the comments below – we enjoy hearing them!

Comments

1. Medical Device Reform – creating a landscape for the future. (n.d.). DAC Beachcroft. https://www.dacbeachcroft.com/en/gb/articles/2022/june/medical-device-reform-creating-a-landscape-for-the-future/
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3. UKCA marking: conformity assessment and documentation. (2022, November 14). GOV.UK. https://www.gov.uk/guidance/ukca-marking-conformity-assessment-and-documentation
4. Opportunities and risks around future UK regulatory reform of medical devices. (2021, April). Birmingham Health Partners Centre for Regulatory Science & Innovation. https://www.birminghamhealthpartners.co.uk/wp-content/uploads/2021/08/Opportunities-and-risks-around-future-UK-regulatory-reform-of-medical-devices.pdf

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