



DCB0129 Compliance Services

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Background

DCB0129 is a mandatory clinical risk management standard that applies to all health IT vendors, medical device manufacturers and security and infrastructure suppliers operating in the NHS in England. This standard is now an integral part of tenders and can be requested by any of the following stakeholders:

- Clinical Safety Officers (CSOs) or compliance teams at individual healthcare organisations
- Regional bodies covering compliance work/DTAC processes
- National regulators running procurement frameworks (NHS Digital)
- Other vendors, resellers and managed service companies you may be working with

Challenge

Compliance with the standard itself can be complex and laborious and there are a number of specific processes and documents that need to be put in place. All vendors need to do the following:

- Appoint a Clinical Safety Officer (CSO)
- Define an appropriate Clinical Risk Management Process
- Issue a specific set of documents to help show compliance – the Clinical Risk Management Plan, the Clinical Safety Case Report and the Hazard Log
- Ensure appropriate on-going clinical risk work – vendors must ensure on-going clinical safety activities are in place to cover current and new products and releases

Solution

At the AbedGraham Group we have provided DCB0129 consultancy services for the largest technology vendors in the world, to SMEs and start-ups, and at the national and international governmental level. We can cover all aspects of DCB0129 for you in a two-step approach:

Step 1 – Core Documentation Creation

A series of structured workshops with your team will provide the knowledge for us to create the key documents required (Clinical Risk Management Plan, Clinical Safety Case Report and Hazard Log).

Step 2 – Ongoing Compliance

For ongoing compliance, any new release or new product needs to be vetted, any clinical safety incidents need to be captured and written up, and questions and reviews from regional leads or national regulators will need to be responded to. We have deep experience of all of the above with our flexible retainer (with us assuming the CSO role as well).

Timeline

We can be flexible for your requirements around these processes. For a typical company with a single product, we can undertake Step 1 within 3-4 weeks, or even quicker if a procurement or compliance process requires it. We can then assume the CSO role and cover Step 2 thereafter for full DCB0129 cover.