CASE STUDY

PharmaLex expertise secures CE certification for medical devices ‘at risk’

Situation

An EU-based company manufacture a large portfolio of medical devices for the UK National Health Service. During a recent Notified Body audit, the company’s Technical Files were found to be deficient, and they were issued with a major non-conformity against their Clinical Evaluation Reports (CERs).

With multiple reports requiring update to the new MEDDEV 2.7.1/rev4, there was a real risk of losing their CE certifications and thus, the right to sell their products in the EU. This manufacturer required a consultancy specializing in medical devices, who had clinical writing expertise and strong literature retrieval skills, together with the commitment and can-do attitude to meet a very tight deadline.

PharmaLex used medical device expertise and know-how to overturn major non-conformities and ensure a client’s products retained their CE certification and could remain on the market.

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Challenge

The challenge was to build robust clinical arguments to support the intended uses and claims to demonstrate an acceptable risk/benefit profile despite the limited amount of clinical data the company had generated in-house. There was the possibility that the company would lose the ability to market their devices whilst they conducted further clinical studies.

Solution

With our clinical writing expertise, capability in literature retrieval methods and access to over a hundred search databases, including EMBASE and Medline, we were able to identify all relevant clinical evidence. Our skilled devices team delivered robust CERs with strong justifications for the products' safety and performance attributes based solely on published literature.

- PharmaLex formulated a path forward without the need for additional studies
- PharmaLex designed and implemented appropriate literature searching strategies
- The team included an in-house clinical expert (medic) to review the reports
- Additional guidance was given on gaps identified in the rest of the Technical File so these were addressed

• Benefits •

The medical devices team at PharmaLex delivered:

- ✓ Continued CE certification
- ✓ Protection of the existing sales of millions of £s
- ✓ No requirement for further costly clinical studies
- ✓ Successful closure of the non-conformities.

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