CLINICAL EVALUATION REPORTS

Testimonials:

"Work carried out by ProTherax, in connection with clinical evaluations of medical device products was of a very satisfactory standard, in full compliance with the Medical Device Directive requirements...the work was consistently provided in a timely fashion."

Quality Manager – Device Manufacturer

"As usual, the CERs prepared by ProTherax are high quality and comprehensive…they are easy to review"

Medical Adviser – Device Manufacturer

ENSURE YOUR MEDICAL DEVICES COMPLY WITH THE CLINICAL REQUIREMENTS OF THE MEDICAL DEVICES DIRECTIVE:

The EU Medical Devices Directive as amended by 2007/47/EC requires (irrespective of classification) that a Manufacturer verifies the clinical safety and performance of a medical device intended to be placed on the market, at the time of Conformity Assessment. After CE marking, and as part of routine Post-Market Surveillance, the Manufacturer must also periodically re-review the safety and performance of the device and update the benefit-risk assessment in light of emerging evidence.

This "Essential Requirement" of the Directive is often verified by reference to clinical investigations undertaken by the Manufacturer during normal conditions of use with the device. These studies are designed to confirm known and foreseeable risks (including adverse events) and to ensure risks are minimized and acceptable when weighed against the benefits (including any promotional claims) made for the device. In addition to in-house clinical investigations, clinical data should also be supplemented by reference to the current scientific literature, particularly where clinically equivalent devices are available on the market and in all cases of post-market surveillance reviews.

The Clinical Evaluation Report (CER) required by Directive 2007/47/EC therefore comprises a thorough and objective review of all clinical data (positive and negative) with the intention of demonstrating valid safety and performance of the product in its intended indications and that the device is "state of the art".

TO ACHIEVE COMPLIANCE WITH THE DIRECTIVE, ALL OUR CER PROJECTS ARE COSTED AND DESIGNED TO INCLUDE:

- Compliance with the data content and format set out in EU guidance documents, including MEDDEV 2.7.1, Revision 3 of 2009;
- A pre-specified and detailed literature evaluation plan;
- Literature searching (including provision of an audit trail) within a variety of public databases;
- Copies of the (EndNote) database used to manage all scientific references;
- Curriculum vitae of the author;
- Opportunities to review and comment on draft reports before finalisation;
- Reports in either electronic or hardcopy, to fit in with the requirements of your quality system;
- Independent medical review and sign off (on request).

PROTHERAX LTD

ProTherax Ltd is a regulatory and medical writing consultancy business, based in the North of England, with expertise in preparing EU medical device Clinical Evaluation Reports. In our three years of operation, we have prepared multiple CERs for a range of clients, including small, medium and multi-national companies; the devices have included traditional, well-established and innovative products and have covered all classifications of the Medical Device's Directive.

THE COSTS OF CONTRACTING OUT YOUR CERS ARE LESS THAN YOU MAY THINK

At ProTherax Ltd, we are very aware of the cost constraints under which many medical device Manufacturers currently operate. You will be therefore pleased to hear that during 2014 we continue to hold to our 2012 prices! The costs of delivering a compliant CER for your medical device is likely to be less than you may think, with many reports starting from as little as £3,500.

Ensure that your next Notified Body audit goes smoothly. Contact us today for a quotation!

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