WAINWRIGHT associates
Regulatory Affairs

Medical device services

Products bearing a CE mark can be freely marketed in all Member States – illustrating the importance of achieving this standard at the earliest opportunity.

Medical device services

We offer wide-ranging consultancy services relating to medical devices, *in vitro* diagnostics, as well as medicinal products. Our team of highly qualified experts includes pharmacists, biologists, microbiologists, chemists and medical practitioners. We can provide advice on product development, preclinical and clinical research, regulatory affairs and quality assurance, as well as post-marketing aspects such as vigilance.

Our experienced consultants can assist with planning R&D programmes for novel products; including design of suitable studies to meet regulatory requirements and achieving timely access to market in countries of interest. Audits of client companies, their suppliers and subcontractors can be undertaken by our specialist auditors to ensure that the appropriate standards of quality are met.

CE marking

In the European Union, harmonised rules relating to regulation of medical devices are defined by three Directives:

- Medical Devices (93/42/EEC)
- Active Implantable Medical Devices (90/385/EEC)
- *In Vitro* Diagnostic Medical Devices (98/79/EC)

Furthermore, a variety of non-legally binding guidance documents (e.g. MEDDEV), assist with ensuring uniform application of relevant provisions of these Directives within the EU.

In principle, products bearing a CE mark can be freely marketed in all Member States without further control. Thus, the importance of achieving timely CE marking cannot be overemphasised.

We have a wealth of experience with medical devices and *in vitro* diagnostics, particularly with regard to CE marking. We can provide advice on the optimum route to market and assistance with classification, essential requirement checklists, risk analysis, compilation of technical documentation or design dossiers, and other preparations for conformity assessment, as appropriate. Where applicable, we can provide a recommendation as to which Notified Body may best suit the situation and, if required, act as the point of liaison.

We handle all types of products: active and non-active devices, including sterile and electromedical products, *in vitro* diagnostics, as well as drug-device combinations and borderline products. Our multidisciplinary team can provide detailed technical evaluation of all documentation against relevant requirements; providing advice on regulatory, scientific

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Determining whether a product falls within drug or device legislation can be a complex process and requires specialist knowledge and expertise.

and quality aspects, including ISO 13485 and other relevant standards.

Device vigilance

EU guidance on a Medical Devices Vigilance System facilitates uniform application of requirements.

We can review your existing vigilance procedures and advise on appropriateness with respect to compliance with relevant guidance. Alternatively, we can assist with setup and operation of an appropriate vigilance system, including implementation of medical device vigilance procedures. This may range from advice as to what procedures are required to preparation of written procedures. Documents can be prepared either in our own house style or according to a client's template, as required.

In addition, if required, we can undertake to carry out day-to-day device vigilance activities on your behalf. This may include:

- documentation and further investigation of any reported incidents.
- assessment and notification to Competent Authorities on your behalf where required.
- generation of Field Safety Corrective Actions where required.
- generation and distribution of Field Safety Notices.
- follow-up with the Competent Authorities as required.

The drug-device borderline

Regulatory requirements for borderline products vary enormously from jurisdiction to jurisdiction and it is not always easy to determine whether a product falls within drug or device legislation, or is perhaps regulated by other means. Thus, specialist knowledge will be invaluable in developing a global marketing strategy.

Our consultants are experienced with both sides of the drug-device borderline and can therefore help to clarify specific regulatory issues that would apply in a particular case, as well as working towards successful achievement of marketed status in territories of interest.

Our international network of local advisors, in over 70 countries, allows us to determine both the regulatory requirements and likely attitudes of regulators around the world toward novel and unusual types of medical device.

In the case of drug-device combinations, we have assisted many clients in the development of their products; planning studies required for multinational launches and establishing satisfactory quality systems. We have considerable experience of the regulation of such products by drug and device regulatory authorities alike.

Contact us:

For a more detailed discussion on how we can help you, contact us on **+44 (0)1628 530554** or email us on **info@wainwrightassociates.co.uk**

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