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We were very impressed by Kendle's ability to understand the issues and interact with us and our colleagues who aren't experts in regulatory matters.

*Regulatory Affairs Manager
Italian medical device company*

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Preview Kendle's capabilities

- Market research
- Business development strategy, including gap analysis, for Class I, II and III medical devices, *in vitro* diagnostics and Active Implantable Medical Devices
- Strategic development planning and project management
- Regulatory advice from product concept to commercialization
- Identification and liaison with applicable Notified Bodies on behalf of companies
- Operational assistance in preparing medical device files for submission, including suitability review of data for inclusion in technical file and application submission
- Preparation of clinical expert/evaluation reports according to international guidelines
- Regulatory system audits
- Review of promotional and educational material
- Development of quality systems
- Training to address internal systems and understanding of global regulatory requirements
- Post-marketing activities, including vigilance programs

Getting the most out of devices

The category of medical devices is extremely broad, ranging from diagnostic products to active medical devices and devices incorporating a medicinal component. This broad definition means that each new device brought to market presents its own challenges and must be treated as unique. Furthermore, despite international efforts such as the Global Harmonization Task Force on Medical Devices, the legislative framework governing the regulation of medical devices varies in different regions. That's why, when developing a new medical device, it's vital to have not only the flexibility to address new issues swiftly as they arise, but also an understanding of local requirements to bring the product to market globally.

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I had a positive experience with Kendle. Their internal organization was great – I had contact with one person who liaised internally and fed back to me.

*Clinical Study Manager
Global pharmaceutical company*

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The Kendle difference

Kendle's Medical Devices group provides a comprehensive service to ensure that our customers' devices are professionally developed and brought to market in a timely manner. We'll work with you to understand the specific needs of your product and will bring the requisite knowledge of device development and regulatory issues to maximize appropriate market entry.

We offer local and global expertise to ensure worldwide development requirements are met. Our experience and rapport with regulatory agency divisions allow us to explore the shortest and most efficient route to bring your product to market. Our regulatory experts around the world work together to provide strategic advice on the global development of your medical device, as well as global clinical and regulatory services.

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*Thank you, Kendle, for your fine work on this report.
I will gladly recommend your services.*

*Clinical Study Manager
Global pharmaceutical company*

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Device or drug? Explaining the subtleties

An Italian medical device company in the early stages of development of a product that was neither a pure medical device nor a drug decided it needed to involve a partner with regulatory experience and expertise in such combination products. Kendle was recommended to the company, and very quickly provided suggestions on how to explain the concept to the regulatory authorities, confirming the appropriate classification of the product with the European Medicines Agency (EMA). We also liaised with the EMA over which specific regulations had to be fulfilled during the product's development.

Our medical writers and statisticians prepared a protocol for the product that was accepted by the EMA.

Kendle also assisted the company with the preparation of briefing documents and a face-to-face meeting with the UK Competent Authority (the Medicines and Healthcare products Regulatory Agency) to help successfully resolve outstanding issues associated with another device-related aspect for the same project again involving a combination product.

For more information

about Kendle's capabilities in regulatory affairs for devices, please contact us at info@kendle.com or at one of the telephone numbers listed below:

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