



## Clear direction in a complex regulatory world

Whether you're a major biopharmaceutical company conducting global megatrials or a "virtual" operation outsourcing entire studies, continuous regulatory input is vital. In a world of constantly changing regulatory demands, however, the enormous variation and complexity of clinical trial requirements make it difficult to provide the resources or experience necessary at all stages. That's where Kendle can help.

## Preview Kendle's capabilities

- Vast global clinical trials experience
- Global Regulatory Leads offering strategic submissions planning
- Services for all stages, from drafting protocols to coordinating submissions
- Preparation of Clinical Trial Authorizations applications at global and local levels
- Country specialists with extensive local regulatory knowledge and cultural awareness

## Good relationships all around

Sun Pharmaceutical Industries Ltd., the leading pharmaceutical company in chronic therapy areas in India, has been a satisfied customer of Kendle for more than six years. Much of Kendle's work with Sun Pharma has been based in the United States and the company has been particularly impressed with our strategic advice and working relationship with the U.S. Food and Drug Administration. Recently we began working with Sun Pharma in the United Kingdom, and are currently progressing three products in this market.

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*We valued Kendle's ability to get up to speed quickly. Having had such a positive experience with them, we've continued to use their network of regulatory consultants as a resource to augment our organization.*

*Vice President, Regulatory Affairs  
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### The Kendle difference

When you choose Kendle you benefit from our Regulatory Affairs team's vast experience supporting clinical studies worldwide. Our regional knowledge enables us to provide high-quality regulatory packages tailored to your indication and market, minimizing regulatory agency questions and accelerating the approval process.

For a virtual company, Kendle can perform all required study tasks, from the writing of the protocol by our Medical Writing Group to delivery of the complete Trial Master File. On global studies we act as worldwide submissions coordinator, serving as an integral part of your study team from day one to offer our experience, expertise and advice on submission strategy and queries.

Our worldwide network of regulatory specialists works closely with the technical experts in our regional offices to prepare the specific regional authorizations required. Their local expertise enables them to stay abreast of the latest regulations and the evolving requirements of each individual country, and also to know the local language and culture – often critical to a successful clinical trial application.

We also channel local regulatory knowledge from these country specialists into a regularly-updated central repository, enabling our Global Regulatory Lead to proactively plan the most effective submissions strategy for your study's success.

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*Kendle regulatory consultants are a friendly and responsive group of people to work with. You feel like they have a real stake in your project, that they're part of the project team and derive excitement and personal satisfaction from your success. We look forward to working with them in the future.*

*Vice President, Regulatory Affairs  
Acrux*

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### For more information

about Kendle's capabilities in clinical trial regulatory affairs, please contact us at [info@kendle.com](mailto:info@kendle.com) or at one of the telephone numbers listed below:

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