



## Accelerating your approval

Even before the last pivotal trial has been completed, the race is on to submit your global marketing authorization applications and reach the market. What is the ideal approach to preparing a comprehensive, targeted regulatory submission without limiting license flexibility or providing unnecessary information that prompts time-consuming agency questions? Kendle can provide the answers you really need.

## Preview Kendle's capabilities

- Associates in all geographic regions collaborating to deliver multiple submissions around the world
- Expert advice on global submission processes, requirements and individual regulatory agency differences
- Strong relationships with national and regional regulatory agencies, and close proximity to the U.S. Food and Drug Administration
- Anticipation of agency questions and rapid response
- Knowledge of appropriate submission formats
- Validated publishing system for the production of paper and electronic submissions, including electronic Common Technical Documents (eCTDs)

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*I appreciated coming to Kendle because they're experienced, dedicated and take responsibility for all aspects of what we ask them to do.*

*Manager, Imaging Research & Development  
Global medical imaging company*

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## Our experts succeed where others fail

When a global medical imaging company based in the United States needed European Union regulatory approval for its imaging drug, it was disappointed to discover its incumbent clinical research organization lacked the comprehensive expertise, quality procedures and management processes for the project and was not able to estimate the amount of work involved. The imaging company discovered it had only a few months to complete more than a year's worth of work, which included reviewing, reformatting and interpreting complex safety data.

The imaging company asked Kendle to take on the project. Our expertise in the EU's Centralized Procedure allowed us to complete the required submission sections successfully within the aggressive timeframe. The drug was approved. Since this initial success, we've completed other major projects for this customer, including risk management planning, and we're now the largest partner on its most important project. We're enlisting our global regulatory resources to help the company gain approval for an imaging product in a number of markets.



### The Kendle difference

We offer global reach and unrivalled experience to help meet your goals. Our Regulatory Affairs associates are located around the globe and have detailed knowledge of the different local submission processes, administrative requirements and agency-specific ways of working, combined with the expertise to complete submissions in most major markets. In line with the growing need for simultaneous global submissions, we work to ensure your drug's final licenses around the world differ minimally in therapeutic indication, patient population and manufacturing requirements without compromising flexibility upon approval.



*Whenever we have issues, we get a good, reliable response back very quickly from Kendle. This matters in regulatory affairs, and it's why we go back to Kendle immediately if we have an issue.*

*Vice President  
Aurobindo Pharma Ltd.*



Where necessary, we're able to serve as a local agent in areas such as the United States, Latin America, Canada and Australia. We also can help to establish a local presence in the EU. Our strong relationships with the regulatory agencies around the globe help us maintain up-to-the-minute awareness of any changes that could affect your submission. We work to anticipate agency questions and provide rapid responses during the review process, clarifying issues so your submission progresses as smoothly as possible.

Our associates work with you to design a strategy for pursuing the various routes of registration for small molecules and biological products. We have the technical expertise to write all sections of your dossier, and offer expert awareness of the appropriate submission format for each regulatory agency along with the ability to produce the necessary documentation using our validated publishing system.

This high-volume, state-of-the-art tool allows the production of high-quality paper and electronic dossiers including eCTDs. Furthermore, our location in Rockville, Md., is located close to FDA headquarters, enabling hand delivery of your application and saving you even more valuable time. Additionally we're comfortable using agencies' electronic submission systems, such as the FDA Gateway.

Our in-depth understanding of what is needed to register a product with minimal concerns raised by the regulatory agencies allows us to provide a fast, streamlined submissions service. We will work with you to minimize the time to commercialization allowing you to maximize your returns.



### For more information

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

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