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

*Vice President, Regulatory Affairs
Shire HGT*

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Preview Kendle's capabilities

- CMC experts located in all major regions of the globe
- Detailed knowledge of region-specific requirements for CMC documentation
- Close relationships with regulatory agency evaluators to help expedite reviews
- Detailed understanding of the requirements for Good Manufacturing Practice (GMP) clearance of overseas manufacturers
- Post-marketing maintenance service

We can hit the ground running

Shire, a rapidly-growing, global specialty biopharmaceutical company, needed additional regulatory resources for its human genetic therapies business unit, Shire HGT. The aim was to undertake two major CMC variations to a European Union marketing authorization in parallel and in a very compressed timeframe. They decided to bring in an external team who could begin productive work on the project quickly, without a long learning curve. Experienced Kendle experts were swiftly integrated into the in-house team, and were able to ensure that both variations were completed professionally and on time.

Understanding all the variations

The Chemistry, Manufacturing and Controls (CMC) process is at the heart of drug development, underlying every step of the progression from concept to market and beyond. Unless the CMC development process is undertaken diligently, problems can materialize at any stage of a product's development: during clinical trials, in the preparation of a marketing application, once an application is submitted or even after the marketing application has been approved. These can lead to significant regulatory agency requests for further information and clarification.

Different regions around the globe have quite different CMC requirements, adding to the complexity of preparing and submitting appropriate CMC documentation. Detailed knowledge of region-specific requirements is vital to ensure that a dossier is accepted by a regulatory agency.

The Kendle difference

At Kendle, our strength lies in our first-class CMC experts located in all major regions of the globe. In the United States, these consultants are chemists and biochemists who have worked at the U.S. Food and Drug Administration, and are familiar with FDA expectations and processes.

Global CMC development

Due to their proximity to the FDA, experts in our Rockville, Md., office can facilitate contact with FDA officials to expedite responses to specific questions or situations.

In Europe and Australia, our consultants include pharmacists, chemists and biochemists with extensive pharmaceutical industry experience. In the EU, they are experienced in converting CMC documentation that has been prepared for U.S. submission to Common Technical Document format, often adding new quality data. Our consultants are able to assist in preparation for meetings with the regulatory authorities. In Australia and New Zealand, our detailed knowledge of the Therapeutic Goods Administration (TGA) and Medsafe-specific CMC requirements, and understanding of how these differ from the U.S. and EU requirements, allows us to provide specific advice and generate targeted documentation.

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We needed to bring in experts who could hit the ground running. We needed to hire them and be able to utilize them immediately and we were able to do that with the associates from Kendle.

*Vice President, Regulatory Affairs
Shire HGT*

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Our global reach allows us to prepare CMC dossiers in exact accordance with region-specific requirements, helping to reduce the number of questions asked during the approval procedure and accelerate a product's passage to market. Indeed, our frequent interactions with agency evaluators help expedite reviews through informal discussion rather than formal agency questions.

We offer a flexible approach, which means documents prepared by customers can be reviewed by Kendle experts to help identify areas where further information is required or clarification and justification is needed. We also routinely offer a post-marketing maintenance service, which includes preparation of variations to approved marketing authorizations.

Our detailed understanding of the requirements for GMP clearance of overseas manufacturers, based on experience and agency interaction, can minimize the occurrence of GMP-related delays to product approval. Delays to final product approval caused by country-specific GMP requirements are unnecessary and can be avoided, in most cases, with appropriate advice and planning.



For more information

about Kendle's capabilities in global CMC development, please contact us at info@kendle.com or at one of the telephone numbers listed below:

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