



A natural affinity for biotechnology

Bringing a biological or biotechnology product to market is a considerable challenge. Not only must you ensure the overall development program is appropriate for the biotechnological nature of the product, suitable comparability strategies are required for post-approval changes to the product and its manufacture. It's also critical you understand the regulatory terminology and requirements in different countries and regions.

Preview Kendle's capabilities

- Advise on global quality (CMC), nonclinical and clinical requirements
- Negotiate issues and expectations with regulatory agencies worldwide – for example, the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Australia's Therapeutic Goods Agency (TGA)
- Liaise with technical authors, medical writers and contract manufacturers to prepare submissions documents
- Advise on initial applications, follow-up measures and specific obligations, annual reassessments, renewals and post-approval variations
- Define cutting-edge issues such as the classification of advanced therapy products
- Identify appropriate comparability strategies for biosimilars
- Provide insight into the regulatory implications of commercial agreements involving biological products

The Kendle difference

As a leading global CRO, Kendle meets and overcomes the challenges brought by biological and biotechnology products every day. Our expert regulatory consultants are well-positioned to keep abreast of technical and legislative changes on biological and biosimilar products worldwide, and can help you in all phases of development and registration. Our services range from high-level strategic advice to hands-on preparation of dossiers that meet the needs of regulators while avoiding excessively-burdensome restrictions on future product or process changes.

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Kendle handled our Marketing Authorization renewal in a professional, efficient and timely manner. We were extremely happy with the Kendle associate – her knowledge and professionalism and her ability to distill information into an ever-more precise format to communicate with the EMA.

*President
Canyon Pharmaceuticals Inc.*

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Submissions for biological and biotechnology products

We ensure our customers understand the requirements and mechanisms of global approval processes; for example, the Centralized Procedure for European Union Marketing Authorization, FDA expectations in the United States and TGA expectations in Australia. We advise on the regulatory implications of commercial agreements involving biological products, and understand the use in comparability studies of innovator products from the market where registration is sought, for example, Australia and Canada.

Throughout the various stages of a product's development we'll help you define the data you need to meet clinical study requirements through agency contacts and formal scientific advice and meetings. For successful product registration, we'll ensure the data is complete and craft the dossier to the appropriate comprehensiveness while minimizing the number of costly changes or variations following approval. In addition, if you need to make changes in a product's manufacturing process, we can prepare comparability protocols or design bridging studies and define study programs that will meet regulatory requirements.

We also have experience working with biosimilars or follow-on biologic proteins. We can help companies with generic products recognize the specific challenges that may arise when developing such products; for example, the critical role of the manufacturing process in defining the product, or the use of state-of-the-art analytical methods.

Supplying the right information gets results

When Canyon Pharmaceuticals Inc. encountered stock-out problems in Germany and France for their recombinant hirudin product, Revasc, Kendle liaised with the EMEA to secure its approval to extend the shelf-life of the previously-manufactured supply, which still met all the necessary specifications. The swift resolution of this issue ensured the product supply wasn't disrupted, so patients didn't suffer. Canyon also called upon Kendle to handle Revasc's Marketing Authorization (MA) renewal. It took eight months to complete and was recently approved by the EMEA.

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We valued highly Kendle's input and consulting services on our Marketing Authorization Application submission to the EMEA. Not only did you give us excellent direction, but helped us sort through the less-than-complete information and directions we received from other entities – a very valuable service indeed. We look forward to the opportunity to use your services in the future.

*Senior Manager, CMC Development
Leading U.S. biotechnology company*

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For more information

about Kendle's expertise in biological and biotechnology submissions, please contact us at info@kendle.com or at one of the telephone numbers below:

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