

One partner, all the brains you need



Nutraceuticals

Functional Food and Dietary Supplements

Clearing the scientific and regulatory path

The commercial potential of nutraceuticals, functional food and dietary supplements has grown to very substantial proportions. However, the increasing complexity of the regulatory requirements to warrant safety and to support product claims for these products, may represent a pathway full of hurdles.

Kinesis Pharma helps clients to navigate through the scientific and regulatory requirements these products encounter during the development process before they are granted market authorization, by offering a wide range of (non-)clinical and regulatory related services.



What Kinesis offers

Kinesis supports product manufacturing and control and evaluates the non-clinical and clinical safety of different products. Kinesis also identifies and substantiates possible health claims, and designs, subcontracts and monitors safety and efficacy studies for clients. In addition, Kinesis offers advice on regulatory procedures and development strategies, and prepares concomitant reports, summary documents and dossiers. Kinesis is therefore able to respond to a wide variety of food- and nutraceutical-related needs, either for start-up-companies or established companies.

- **Consultancy**

Kinesis has a high level of experience and expertise in the field of nutrition. Kinesis advises clients on health claim opportunities and strategic development options for functional food or nutraceuticals. Kinesis can also support to identify the non-clinical and clinical safety profile of the product to meet the regulatory requirements. In addition, Kinesis prepares literature overviews and recommendations in a wide range of health areas.

- **Product Chemistry, Manufacturing and Control (CMC)**

Kinesis develops strategies for product chemistry and manufacturing, gives valuable technical input and supports

clients with the various aspects of the production process of the product. Furthermore, Kinesis can help clients by reviewing and analyzing manufacturing processes and product specifications for compliance with regulatory requirements and standards for nutraceuticals and functional food.

- **Non-clinical and clinical services**

In order to demonstrate the safety and/or efficacy of functional food or nutraceuticals and to substantiate claims in accordance

with regulatory guidelines (EFSA/FDA), Kinesis helps to design, develop and outsource all the necessary non-clinical and clinical safety and efficacy studies. Kinesis has an extensive network of contract research organizations (CRO's) and works closely with the CRO and the client to design, coordinate and monitor these studies. If needed, Kinesis can qualify and audit CROs on behalf of the client to ensure protocol consistency and compliance with Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) guidelines.



One partner, all the brains you need



● Regulatory affairs

Kinesis' regulatory experts have up-to-date knowledge of the regulatory requirements in the field of nutrition, particularly novel food and nutraceuticals. Kinesis can support clients with the development of a regulatory strategic plan. Furthermore, Kinesis prepares regulatory dossiers (novel food dossiers, dossiers for health claim substantiation) and can represent clients at the EFSA or the FDA.

Summary of services

Kinesis' food- and nutraceutical-related activities and services include:

- Consultancy
- Product specification analysis and manufacturing (CMC)
- Design, outsourcing and monitoring of non-clinical and clinical safety and efficacy studies

- CRO selection and qualification
- Project management
- Safety and risk assessments
- Preparation and submission of regulatory dossiers (novel food, (health) claim)
- EFSA / FDA representation
- Medical writing (reports, literature overviews, position papers, summary documents, registration dossiers, patents)

Why Kinesis Pharma?

- Experienced food and nutraceutical experts
- Surrounded by an in-house multi-disciplinary team
- Understanding the food- and nutraceutical industry
- Experience with (global) regulatory authorities and strategic development services

- Broad scientific- and CRO network
- Committed to client's projects and timelines
- Flexible approach
- Independent of outsourcing activities to third parties

Contact details

Tel: +31 76 54 80 666

E-mail: info@kinesis-pharma.com



[linkedin.com/company/kinesis-pharma-bv](https://www.linkedin.com/company/kinesis-pharma-bv)



twitter.com/KinesisPharma



**'Let food be
your medicine
and medicine be
your food'**

(With thanks to Hippocrates)

About Kinesis Pharma

Kinesis Pharma is an independent drug development organization with headquarters in Breda, the Netherlands. Kinesis Pharma aims to facilitate an efficient and high quality development and registration process for medicinal products and nutraceuticals through consultancy and contract research services. Kinesis Pharma's service offering includes CMC, non-clinical, clinical, regulatory, quality and project management activities for pharmaceutical, nutraceutical and biotech companies.

Kinesis Pharma: One partner, all the brains you need.

