One partner, all the brains you need

Herbal Products

Express lane to success

Herbal products can enter the European market in various ways, as fully developed medicinal product, as traditional herbal medicinal product or as food supplement. Each route has its advantages and disadvantages in terms of permitted health or medicinal claims, distribution channels, time lines and cost of development. For each route, compliance with a different set of EU regulations is applicable.

Kinesis Pharma supports companies in and outside Europe by offering guidance in the possibilities for development and registration pathways. Regardless of the selected route Kinesis offers a superior range of services for each of the possibilities, tailored towards successful registration of herbal (medicinal) products in the EU.

Kinesis
Consultants in drug development

What Kinesis offers

- **Strategic advice on development of the herbal product**

Herbal products can enter the European market in various ways. Entering the market as food supplement implies the product and health claims has to comply with the EU food laws. The so-called simplified registration for traditional herbal medicinal product, specific for Europe, or the well-established use registrations still require significant regulatory expertise. Full development with medicinal claims is open to herbal products in a similar way as for small molecules or biological products. Modified herbal products or compounds extracted from plants often classify in this latter category. A careful evaluation of the product, intended use and claims, and pro and con's of each route is the best first step in the development process. Kinesis has been involved in determining the best strategy for several herbal products and has all expertise in house for evaluation and development of each of these routes.

Consultancy and preparation of regulatory required documents

- **Quality strategy and dossiers**

Quality aspects of herbal (medicinal) products are key to registration and independent of its registration route. Strategic decisions during development and manufacturing have to be taken that impact the manufacturing method and quality control of herbal substances, intermediates and finished products. Product-related information on manufacturing procedures, control of critical steps, validation of manufacturing and analytical methods, and product stability needs to be provided. A high-quality dossier is a prerequisite for successful registration and within Kinesis an experienced team of consultants guides you through the strategic decisions and regulatory requirements.

- **Overviews/safety expert reports**

Overviews of the available safety and efficacy data for herbal medicinal products are essential parts of the documentation necessary for registration. For traditionally used herbals, a significant amount of non-clinical and clinical information is often publically available. This information should be presented in an integrated format. The experienced team of consultants within Kinesis tailors the documents according to the regulatory requirements, with emphasis on the unique attributes of herbal products.

- **Regulatory dossiers and communication with authorities**

Kinesis offers to manage and submit documentation in the required format (eCTD). Communication with the authorities and management of applications and post-approval activities are important parts of Kinesis' core business.

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An experienced team of consultants, who previously worked for European regulatory authorities, offers a complete package of services to ensure rapid and effective submission of the registration dossier. Meeting with the authorities provides a very useful opportunity to present the product and discuss different development and/or registration scenario's. Kinesis organizes and prepares these meetings, supporting you in finding the most optimal regulatory strategy.

Asian cultural bridge in Kinesis Pharma

In Asia, herbal medicines have been used therapeutically for thousands of years. Kinesis understands that herbal medicines have a long tradition based in culture and history and that this differs from the European situation. Despite a number of Asian traditional herbal medicines have gained access to the European market, entry of herbal products to European market still remains a hurdle for many companies based outside Europe. Kinesis can facilitate with typically EU-based regulatory requirements, like import licenses, and temporarily acting as Marketing Authorisation Holder on behalf of the company.

Kinesis consultants know who to contact within the Agencies and Kinesis can perform GMP audits to prepare for EU inspections. The global network, international experiences, competent and multi-disciplinary groups make Kinesis the most suitable partner in the field of herbal products registration in Europe.

Why Kinesis Pharma?

- Experienced team of Asian and European herbal medicinal product consultants
- Previous work experience at the regulatory agencies
- Surrounded by an in-house multi-disciplinary team including full development and nutraceutical specialists.
- Broad experience in the whole process of development and registration of herbal medicinal products
- Committed to sponsor's projects and timelines
- Flexible approach
- Independent of outsourcing activities to third parties

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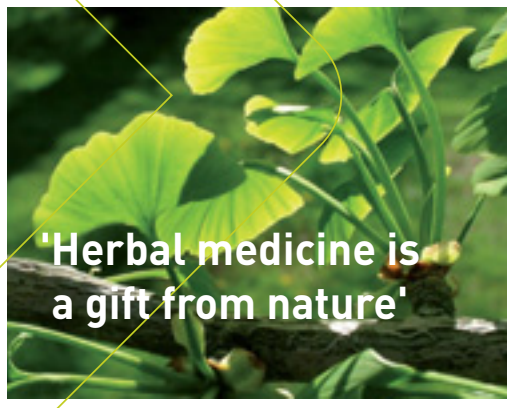

ABOUT KINESIS PHARMA

Kinesis Pharma is an independent drug development organization located 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.

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