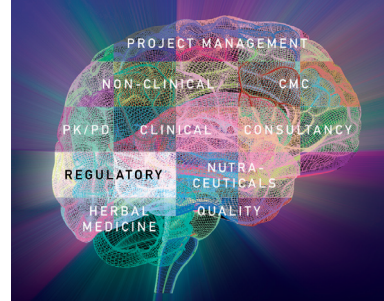


One partner, all the brains you need

# Regulatory Affairs

## Finding the optimal regulatory pathway

Medicinal product development requires input and approval from regulatory authorities from early clinical phases up to market authorization and thereafter. During the different phases of development, critical issues may arise that need input from regulatory authorities. Practical issues need to be considered, such as when is the best time in the development process to consult regulatory authorities, how to formulate questions to get the answer you need and how to get approval from the regulatory agencies for the proposed development program. Kinesis Pharma can help with all the regulatory aspects of the development process. A dedicated team of regulatory affairs consultants can guide sponsors through the regulatory process and can provide the required submission documents at any stage of development.



### What Kinesis offers

- **Strategic regulatory consultancy**  
Strategic regulatory consultancy starts early in the development process and the selected route of submission determines the studies and data required. Kinesis provides regulatory input to project development plans. The goal is to provide sponsors with the optimal regulatory pathway, strategy and marketing opportunities for their product. Based on Kinesis' long history in pharmacokinetics, there is a broad expertise to provide

strategic regulatory and pharmacokinetic advice on bioequivalence programs, suitable for generic or abridged applications.

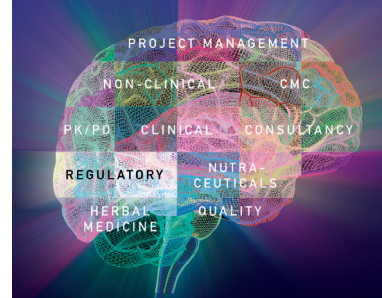
- **(Early) Product development phase**  
Kinesis provides assistance in regulatory processes during the (early) drug development phase, such as coordination of national or EMA/SAWP Scientific Advice, (pre)IND submissions and meetings, orphan drug applications, protocol assistance, and pediatric investigations plan (PIP). Kinesis' regulatory consultants can be the regulatory expert in the sponsors' development team and guide sponsors through all the regulatory challenges of drug development.

- **Communication with regulatory authorities**  
For companies within, but especially outside the European Union (EU), Kinesis can assist with the interpretation of EU regulations, can act as the sponsors' representative in communications and meetings with EMA and local EU authorities, and can convert existing submission dossiers to meet EU requirements. For communication with regulatory authorities outside the EU, Kinesis cooperates with local contract research organizations (CROs).

- **Preparation of submission documents / medical writing**  
Each stage of development and each submission requires writing or adjusting a set of documents specifically focusing on the needs of that moment. Kinesis is accustomed to drafting high quality documents to support a submission. If applicable, documentation will be written electronic Common Technical Document (eCTD)-ready. For this purpose literature searches and literature overviews can also be performed for well-established, abridged, hybrid or generic applications. The regulatory affairs department can draw upon the full range of expertise available within the Chemical, Manufacturing and



One partner, all the brains you need



Control (CMC), non-clinical and clinical departments of Kinesis for drafting the scientific documentation. In addition, Kinesis can compile and submit a full eCTD dossier in collaboration with third parties.

● **Answering questions from authorities**

Kinesis can assist in formulating the answers to difficult question from the authorities. In these assignments, Kinesis focuses on negotiating with the authorities to gain approval of the sponsors' objectives.

Kinesis' track record in regulatory affairs covers over 20 different therapeutic areas. Sponsors can rely on Kinesis' expertise and high quality standards for any type of



application, whether the compound is chemically synthesized, a biological or biotechnological product or a traditional herbal medicinal product (THMP). For all steps in the regulatory process, a check for the most recent formats and guidance provided by ICH, EMA, FDA or national authorities is performed. Kinesis is committed to the sponsors' timelines for submission.

**Key achievements**

- Strategic regulatory input to various product development programs and due diligence processes, assessed as valuable by sponsors
- Successful coordination of national and EMA scientific advice meetings and hearings
- Successful coordination of FDA (pre) IND meetings and submissions
- Responsible for preparation and submission of orphan drug status requests
- Writing of numerous overviews and summaries
- Full dossier submission in eCTD format

**Why Kinesis Pharma?**

- Experienced team of regulatory (senior) consultants (including experience working at the Dutch CBG-MEB )
- Surrounded by an in-house multidisciplinary team
- Experienced in regulatory needs for new compounds and well-known drugs in various therapeutic areas and formulations

- Committed to sponsor's projects and timelines
- Flexible approach
- Independent of outsourcing activities to third parties

**Contact details**

Patricia Baede M.Sc.  
Director Regulatory Affairs  
Tel: +31 76 54 80 622  
Mob: +31 6 12 35 92 02  
E-mail: Patricia.Baede@Kinesis-Pharma.com

**'Dedicated to making your submission a success'**



**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.

