One partner, all the brains you need

Chemistry, Manufacturing and Control

Realizing the performance of your candidate medicinal products

The dynamic process whereby the global pharmaceutical industry is regulated results in a regulatory landscape where the drug development goal posts continuously move. This rings true for CMC development and drives the demand for independent, up-to-date and practical advice which can be integrated into drug development programs. Kinesis Pharma's CMC department provides advice on CMC development strategy which strikes a balance between the technical and regulatory demands of each drug development program and the goals of the sponsor, resulting in solutions which are fit for purpose.

Kinesis
Consultants in drug development

What Kinesis offers

- **CMC Consultancy**

The Kinesis CMC consultants focus on addressing the strategic and technical aspects of chemical and pharmaceutical development. This process typically starts with the design of an integrated CMC development plan. The CMC development plan details the CMC Regulatory Affairs (RA), cross-functional and scientific strategy relevant to the stage of development from chemical- or cell line development, analytical method development and validation, formulation development, setting of specifications, stability studies, up to manufacturing and distribution of clinical trial material (CTM). The plan also addresses the strategy for manufacturing of the investigational medicinal product (IMP) for toxicology material and clinical trial supplies (CTS).

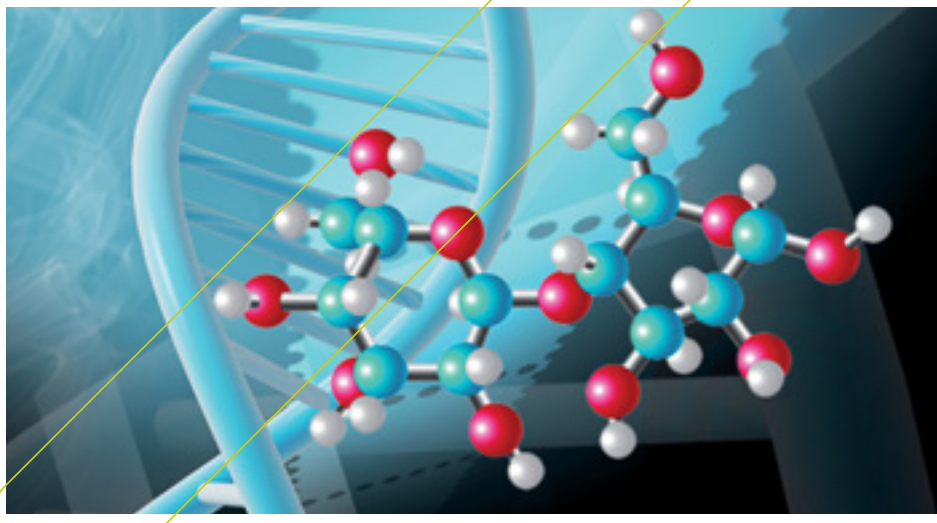
- **Outsourcing and coordination of CMC activities**

Once the details of the CMC development plan are agreed, the next important step is the selection of a contract manufacturing organization (CMO) and contract research organizations (CROs). CMC consultants are skilled at managing and supporting (contracted) CMC activities to deliver the goals of the CMC development strategy throughout the drug development program. CMC consultants provide independent advice e.g. due diligence, gap analysis, define (or review) the CMC development strategy and trouble-shoot technical challenges.

As effective CMC project managers, CMC consultants aim to fully integrate the deliverables of the CMC development plan with the objectives of the drug development program. This is achieved by keeping CMC development off the critical path (where possible) and by delivering non-clinical- and clinical trial materials on time and within budget.In addition, CMC consultants participate in multidisciplinary compound development teams and/or assist sponsors by managing in-house CMC development activities with onsite support. In instances where the sponsor requires the expertise of the CMC consultant on a temporary basis to fulfill an in-house function, interim management services are provided e.g. CMC Manager, Head of CTM Manufacturing, Head of Analytical Development, Head of Formulation Development, Head of Chemical Development, Qualified Person (QP).

- **CMC Regulatory affairs**

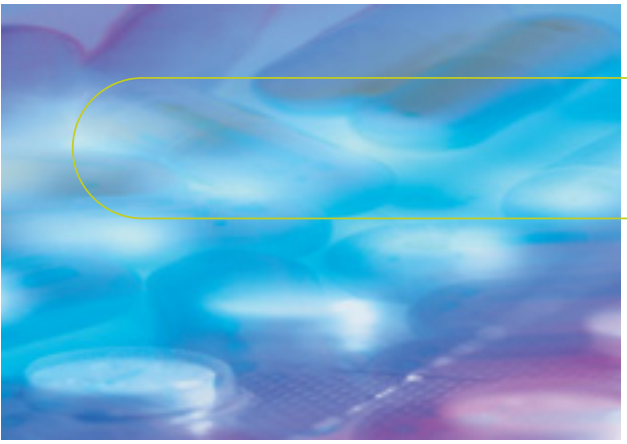
Understanding the nuances of specific regulatory guidance and experience of the differing focus and interpretation of guidelines by national authorities often



contributes significantly to the success of regulatory submissions. Kinesis' CMC RA consultants employ their "insider" knowledge to determine the relevant CMC regulatory strategy and assure the quality, consistency and technical validity of CMC regulatory documentation. The focus is therefore on constructing a documentation hierarchy which supports the relevant quality sections of regulatory submissions e.g. IMPD, IND, DMF, NDA, BLA, MAA, ANDA and CTD Module 3 (Quality).

- **Investigational Medicinal Product management**

The importation and distribution to clinical sites of an IMP manufactured outside the European Union presents a significant logistical challenge. It is a legal requirement that an IMP manufactured outside the European Union be released into the E.U. by a European Qualified Person (QP) before it's distributed to the relevant clinical sites. Kinesis provides services to facilitate and manage IMPs for clinical trials in the EU e.g. arranging for QP release and managing the sponsor's relationship with the QP, label and packaging (treatment kits) and shipment to clinical sites.



Key achievements

- Accelerated drug substance and drug product characterization e.g., by employing forced degradation methods early in the development process
- Successful delivery of newly developed and validated analytical methods e.g., a suite of validated analytical methods for routine analysis and release testing of an ATMP
- Numerous CMC development plans and advice corroborated by competent authorities e.g. virus/TSE risk assessments
- Designed and executed successful strategies for formulation development challenges e.g., poorly soluble compounds and pediatric formulations
- Timely delivery of non-clinical and clinical trial materials for studies in Europe

Why Kinesis Pharma?

- Broad and in-depth CMC development expertise in small molecules and biologics including peptides, therapeutic proteins, antibodies and advanced therapy medicinal products (ATMPs) e.g. gene therapies and cell therapies
- Experience gained in industry and with regulatory authorities
- Detailed experience of good practice (GxP) quality systems
- Knowledgeable of cutting-edge methodology and technology
- Effective technical project management
- Soft skills: proactive and direct communication
- Independent and objective advice
- Committed to sponsor's projects and timelines
- Flexible approach
- Independent of outsourcing activities to third parties

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'Solving CMC challenges shifts the risk profile favorably'

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.

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