

SommaTech Assists Client in Achieving Novel Therapeutic Product Development and Commercialization Goals



The Client: AkaRx, Inc.

AkaRx, Inc. is a New Jersey based biopharmaceutical company dedicated to the development of novel therapeutic treatments to address unmet medical needs and provide significant benefits over currently available therapies. The company was formed as a spin out of Yamanouchi Pharmaceutical Co., Ltd and Fujisawa Healthcare, Inc. merger of 2005.

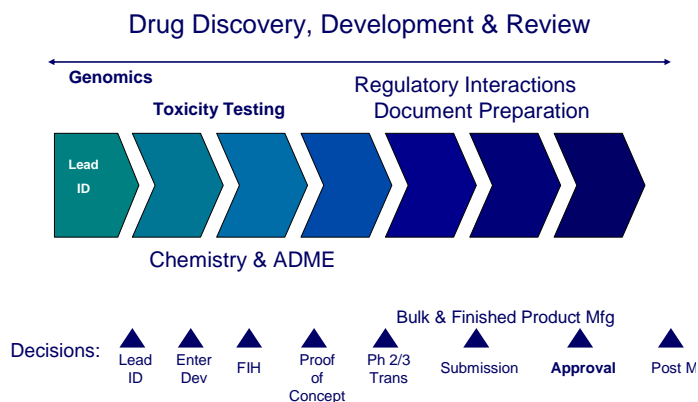
The Situation:

AkaRx contracted SommaTech to assist with the process and pharmaceuticals review for the product development and technical support of three compounds, ranging from Proof of Concept through Phase II clinical development. The overall plan was to progress these compounds to Phase III and subsequently into clinical and full-scale manufacture, submission and ultimately commercialization.

Valuable Insight:

- SommaTech provided proven, valuable insight along with the technical know how, enabling early entry into First-in-Human clinical trials – initiated ahead of schedule and within budget.
- Tapping into our extensive expertise, SommaTech conducted expert review of the physiochemical aspects of the lead compounds as well as conducted and applied fundamental formulation techniques – avoiding the usual technical pitfalls - leading to clinical dosage forms which were developed and manufactured within a very short timeframe.
- The SommaTech team of experts proposed recommendations to consistently maintain quality and compliance for the manufacture of future cGMP clinical batches.
- SommaTech assisted in assuring that early/late process and development aspects were captured, providing the necessary history expected in today's risk-based product development arena.
- We provided a detailed road map, identifying each development step along with key deliverables through submission. A rudimentary example is provided below.

Basic Road Map and Key Points



By utilizing our broad spectrum of drug development services and compliance expertise, SommaTech directly impacts the product development lifecycle, through integrated, results-oriented programs. From product development and production to clinical, regulatory and marketing expertise, SommaTech offers a highly specialized approach to closing functional gaps, designed to support critical supply chain initiatives.

About SommaTech

SommaTech, LLC is a pharmaceutical technology consulting company focused on providing clients with value-added solutions that speed pharma and biopharma products to market as well as helping clients achieve their business goals. SommaTech assists clients with strategic and tactical implementation to bring products to peak sales rapidly and fully realize the potential of the product's life cycle. Located in Somerset, New Jersey, SommaTech has over 21 successful NDAs and more than 50 product and product assessments. For additional information, please visit www.sommatechconsulting.com.