SommaTech Applies Drug Development and Regulatory Expertise to API Manufacturing in Asia

The Client: Celator Pharmaceuticals, Inc.

Celator® is a privately held biopharmaceutical company working to develop new and more effective therapies to treat cancer. CombiPlex[SM/TM], the company's drug ratio technology platform, represents a revolutionary new approach to the development of combination therapies designed to target cancer cells. Based on the strength of the CombiPlex technology platform, Celator is positioned to develop a range of products targeting many different forms of cancer.

The Situation:

Celator contracted SommaTech to evaluate the overall quality, cGMP conformance and business reliability with respect to a secure supply chain, robust quality system, validated processes and a clear understanding of batch capacity/final lot size and overall supplier support/responsiveness. Both manufacturing suppliers are located in Asia and will supply Celator with four active pharmaceutical ingredients (API), all of which have a drug master file (DMF) with FDA.

Valuable Insight:

SommaTech assessed the client's manufacturing requirements, developed a plan and performed a facility inspection and documentation audit to determine the cGMP preparedness of the two Asian suppliers. An international project team, led by SommaTech, was established and included R&D, quality and compliance personnel as well as representatives from the two Asian suppliers for an integrated, collective team effort.

The SommaTech team of experts possessed extensive practical experience in identifying development, manufacturing and compliance issues. In addition, the team included a complimentary scope of technical skills focused on analytical and testing aspects, language proficiency and, most important, experience in bringing fourteen products through regulatory submission and pre-approval inspection. These professionals provided Celator with a strong presence as well as value beyond that of a standard cGMP audit.

SommaTech provided proven, valuable insight into the overall quality of both suppliers' day to day operations. Our extensive expertise enabled us to base our observations and propose recommendations to consistently maintain quality and compliance directly to Celator's contract manufacturing need to maintain two cGMP qualified API manufacturing suppliers.

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.