



Formulation Development

Introduction

The customer is a privately owned company started in the 1990's. The company does most of its Research and Development at a nearby university.

The agreement with the university provides many benefits to the company including low operating expenses, use of state-of-the-art laboratories and greenhouses, and access to the diverse expertise of a leading university.

The company's mission is to discover, develop and manufacture novel botanical therapeutics using proprietary platform technologies.

Challenge

- + *Bilcare was asked to develop a capsule formulation for a developmental API.*
- + *The API is a novel, orally bioavailable, multi-mechanism botanical drug for auto-immune diseases.*
- + *The drug was delivered to Bilcare in a 5 gallon plastic pail. It was a black tar-like substance with tack characteristics.*
- + *Bilcare needed to overcome the tackiness and develop a formula with suitable flow properties to fill capsules with the targeted dose in a uniform and precise manner.*
- + *Timelines were tight.*
- + *The budget was small since it was an exploratory study.*
- + *Bilcare was responsible for blending and encapsulation of the product.*
- + *In addition to development and manufacturing of active capsules (68,000 capsules), the company asked Bilcare to source and over-encapsulate a comparator (45,300 capsules), manufacture matching placebo (22,700 capsules), blister, card, label and assemble kits for 125 patients for 6 months and distribute supplies.*

The customer would use the product in a randomized, double-blind, controlled, parallel design, two arm, multi-center study.

Outcome

Bilcare developed, manufactured and released the product in weeks.

The clinical study using active, placebo and over-encapsulated drug was initiated on time.

Phase II trials for rheumatoid arthritis have been completed using the drug. Phase III is scheduled.

Benefit

The customer launched the clinical study on time.

The company established a relationship with a CMO who is attentive to their needs.

The company has returned to Bilcare for the development/manufacture of several other botanical products.

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