



# Bilcare

## Global Clinical Supplies

## 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.

To learn more about Bilcare Global Clinical Supplies, please visit our website or contact:

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