



Project Management

Introduction

The customer, based in California, provides neurology and psychiatry patients with important and innovative therapeutic products.

The customer is committed to working closely with patients, patient advocacy groups and healthcare professionals.

This project was for a CIII product which was bottle filled by a third party vendor and clinically packaged in double-blind patient kits at another third party packager.

Challenge

In late July, the third party packager realized it did not have the active drug on its DEA 223 form. With the placebo portion already packaged at its facility, Bilcare was commissioned to package the active portion of the customer's double blind study.

This opportunity had challenges with scope:

- + *First, the timelines were very tight—no time could be lost in any function of Bilcare operations including Receiving, QA, Production, Analytical, and Distribution.*
- + *Second: because the placebo was already packaged at another vendor, Bilcare had to find a way to match the product identically without breaching confidentiality.*

Daily, if not hourly, communication between all three parties was crucial to ensure the project was on schedule and the double blind segment of the study was not compromised.

Besides having to work with a tight timeline and multiple interfaces, Bilcare had to overcome these challenges:

- + *Incorrect drug lot*
- + *Incorrect size tamper seals*
- + *Inconsistencies with component lot numbers*
- + *Kit packaging ideology*

The customer's presence at Bilcare during the production run helped to minimize and quickly correct challenges.

Outcome

Bilcare delivered a quality product on time.

The customer was very impressed with Bilcare's consistent communication, excellent and responsive Project Management, and on time delivery. As a result, the customer has used Bilcare for all analytical testing formerly performed by its labs and third party contractors.

The customer also contracted with Bilcare to manage all bulk product labeling projects.

Benefit

Bilcare provided a service to one of our competitors by using our highly qualified Project Management team, our Packaging and Labeling group and a very cooperative customer. Without the availability of the skilled Bilcare team, the competitor would not have been able to complete the project before the customer's deadline.

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