



Method Development

Introduction

The customer is a biopharmaceutical company focused on the discovery, development and commercialization of therapies for the treatment of inflammatory diseases and bacterial infections.

In this case study, the customer asked Bilcare to manufacture, package, test and label a Phase II product.

Challenge

The customer supplied an assay method against which the product was to be released. The assay method was developed by another contract facility.

When Bilcare applied the method to a freshly manufactured batch of clinical product, the results indicated that the product was sub-potent. The customer urged Bilcare to fortify the batch of clinical product in order to compensate for the low bias. Bilcare would not fortify the batch of clinical product until it could determine the reason for the low bias.

Outcome

After an extensive analytical investigation, Bilcare showed that the customer-provided method demonstrated a low bias. It was that low bias which made the product appear to be formulated sub-potently. Bilcare developed a new assay method that did not have any bias. It tested the product using the new assay method. The new assay method was validated.

Benefit

Bilcare's careful analysis provided value added service and support to the customer. Utilizing Bilcare's highly qualified Analytical and Formulation expertise, the customer avoided problems it might have experienced using an inappropriately fortified batch of clinical product. Bilcare recommended an effective solution that met the customer's requirements without compromising the clinical trial process.

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