



Partnering to Advance Human Health



# CASE STUDY

## DEVELOPMENT OF A NOVEL BLINDING METHODOLOGY FOR A MARKET LEADING DPI

*Innovation is one of Almac's core values. Our unique inhaler blinding services provide a perfect illustration of this. While Almac has already developed and validated blinding techniques for most leading inhalers, continued launches of new inhalers mean we consistently face new challenges in this specialized area of clinical trial supplies.*

### CHALLENGE FACED

A mid-sized pharmaceutical company was planning to enter a phase III trial with a promising new treatment for asthma and COPD. To eliminate bias, the client's clinical team had designed a double-blind clinical trial. While manufacturing active and placebo forms of their own product was possible, developing a method to blind their product against the visually different active comparator was more of a challenge. The company approached Almac to help solve this problem. Almac had never handled this product before, and within a limited time frame we had to develop and validate a cost

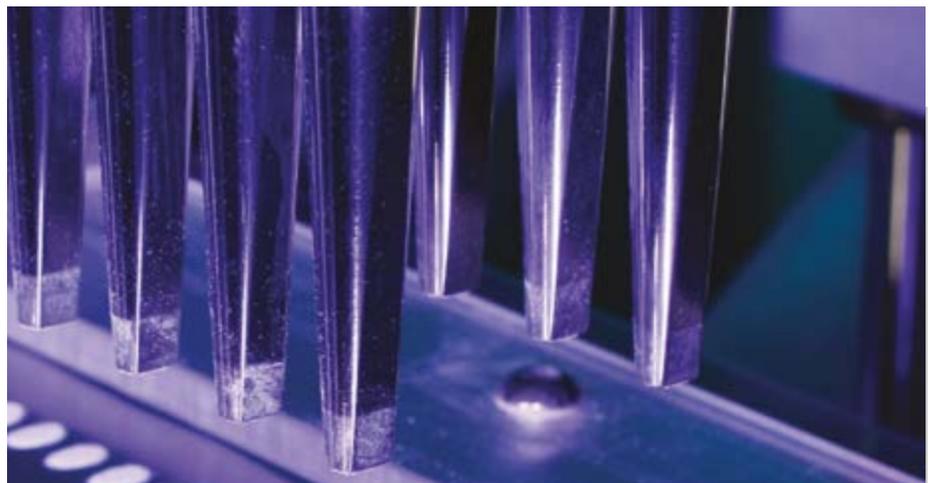
effective, reliable, and reproducible blinding method capable of handling the volumes required to support the client's planned clinical trial demand.

### ALMAC APPROACH

Based on the major visual differences between the two products, we suggested that the client use a double-blind, double-dummy design for the trial (patients received 2 inhalers each: either active innovator product + placebo comparator product OR placebo innovator product + active comparator). To enable this approach, Almac had to develop a method to convert commercial active comparator units to placebo.

ALMAC HAS DELIVERED HUNDREDS OF BATCHES OF INHALER DEVICES FOR USE IN DOUBLE-BLIND CLINICAL TRIALS FOR OVER **25 YEARS**.

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## RESEARCHING THE MANUFACTURING PROCESS

Almac researched the manufacturing process used for the comparator product. We were able to identify the equipment used commercially to fill the inhaler units. However, the cost of acquiring similar equipment to produce smaller clinical trial volumes was prohibitive, besides which, rights to the filling process were owned by the manufacturer.

The challenge was therefore to develop a new method that, for a reasonable cost, would allow us to disassemble commercial comparator inhalers without damaging them, remove the blister strip containing the API, manufacture matching placebo blister strips, develop a method for inserting these into the inhaler body, and then to re-assemble the inhaler without impacting its functionality. In parallel, Almac had to develop analytical methods to support the absence of active testing, identify and source a placebo powder with similar characteristics to the API blend, and to perform a stability program for the placebo units.

## SOLUTION

As an integrated group, the Almac project team was able to recruit experts from several disciplines to support development of the placebo inhalers. Our engineers developed a blister line and powder-filing technique that enabled us to replicate the active blisters. Almac engineers also developed specialized equipment to disassemble and reassemble commercial inhalers - including winding placebo blister back into the inhaler units at the correct tension to support correct functioning of the unit once reassembled. Our particle sizing team helped us to identify a suitable grade of lactose-for-inhalation to replace the API. Almac analysts developed methods to test for absence-of-active and stability. Finally, our QA and Validation teams helped us to prove our technique worked, and developed in-process and finished product tests that enabled us to guarantee finished product functionality.

## RESULT

Our highly experienced and knowledgeable team was able to produce sufficient placebo and blinded active inhalers to support the client's clinical trial. Feedback from the client was that performance of the placebo units in the field was superb.

Almac produced several thousand placebo units for the client in support of their initial trial requirements, and fulfilled several repeat orders over the course of the client's development program. Other clients have availed of this process, and more than half a million placebo units of this type have now been produced for clinical trials around the world ranging in various sizes and complexities.

## GET IN TOUCH

### UK

Almac Group  
(Global Headquarters)  
9 Charlestown Road  
Seagoe Industrial Estate  
Craigavon  
BT63 5PW  
United Kingdom

info@almacgroup.com  
+44 28 3836 2436

### US

Almac Group  
(US Headquarters)  
25 Fretz Road  
Souderton, PA 18964  
United States of America

info@almacgroup.com  
+1 215 660 8500

### SINGAPORE

Almac Pharmaceutical  
Services Pte. Ltd.  
9 Changi South Street 3  
#01-01  
Singapore 486361

info@almacgroup.com  
+65 6309 0720

## Inhalers we blind:

Metered Dose Inhalers (MDIs)

Dry-Powder Inhalers (DPIs)

Capsule-Based DPIs

Reservoir-Based DPIs

Blister-Based DPIs