

## CASE STUDY

# Award-winning logistics expertise supports **global drug development program**



### CUSTOMER

NewbiePharm\*

### LOCATION

United States & China

### CHALLENGE

To reliably package, transport and deliver temperature-sensitive active pharmaceutical ingredients (APIs)

### SOLUTION

A customized, reliable cold chain packaging procedure and hands-on, expert support

**The specialized treatments required by 21st century medicine can only be achieved through highly sophisticated pre-clinical pharmacological research. Today, such research is truly global, involving program-critical ingredients and suppliers from all corners of the world.**



In 2017, Biocair began transporting API shipments from China to the US for NewbiePharm\*, then a small, independent US-based research company focusing on innovative drug treatments.

With Biocair's logistical support, their drug development program progressed from initial research, through clinical trial to Food and Drug Administration (FDA) submission and approval.

## **The evolution of a small research company**

Working with NewbiePharm presented Biocair with a complex set of challenges.

First, there was a series of corporate changes at NewbiePharm that had the potential to interrupt its research program. The company was then sold to a large pharmaceutical company called MajorDrug\*, where NewbiePharm initially continued to operate as a separate subsidiary. Less than a year later, the corporate structure changed again with the NewbiePharm brand being folded into MajorDrug, along with its research.

At each point of change, Biocair stepped up with additional logistics support to compensate for the disruption of continuity in program management. Biocair provided consistent, reliable logistics expertise – before, during and after its customer's transition from NewbiePharm to MajorDrug.

## **Logistical challenges of shipping APIs from China to the US**

The primary drug substance, or API, required for the NewbiePharm/MajorDrug program is produced in China and imported in bulk into the US for either further drug production or storage. Biocair is involved in many of these shipments.

Ensuring the regularity of shipments is critical. Patients need precise dosages at specific times to maintain the integrity of the clinical trial. Clinical trial integrity has been key to the new drug treatment attaining approval by the FDA. From initial research, through clinical trials, to commercialization, the continued supply of validated packaging and personalized transportation solutions remain vital.

The challenges to maintaining shipment integrity and regularity include:

- ◆ **Temperature control** – Maintaining the required temperature of the API throughout its cold chain transit from China to the US.
- ◆ **Shipment size** – Each bottle of the API measures 10 liters, and with bulk shipments varying in size, careful calculation is required in order to ensure provision of the correct amount of dry ice to keep the product within the desired temperature range.
- ◆ **Chinese export customs clearance** – Unique documentation needs and unannounced inspections at the time of shipment often lead to plans changing at the last minute.
- ◆ **United States import customs clearance** – Additional documentation is required for import into the US and, even if all documentation is in order, US customs may randomly hold and inspect packages.

## How Biocair maintains pharmaceutical product integrity

### A simple, customized packaging procedure

Biocair's solution to the challenge of temperature sensitivity and unusual shipment size was to create a simple, tailored packaging procedure.

As Biocair's Account Manager explains,



*We don't want to overly complicate the pack out because it's completed by teams across China and the United States, so it needs to be easy to learn if transferred over to another facility or if demand increases. Keeping the procedure simple reduces training time and allows it to be accurately and consistently repeated."*

The procedure includes careful consideration of the separation of primary packaging, the placement of temperature monitors, the calculation of the correct quantity of dry ice and the placement of the dry ice.



Biocair provides the packaging, which is validated using international standards (ISTA 7D temperature profiles or a robust equivalent) and mock shipment testing conducted by Biocair's internal packaging team. These tests further support risk mitigation through stress testing the packaging against the worst-case scenario.

Biocair's Account Manager points out the pitfalls of customers trying to develop their own packaging procedure, including lack of awareness of regulations:



*Customers may decide to use 250 kilos of dry ice with their shipment, without realizing the airline regulation limits the maximum to 200 kilos. Customers may not always know what to consider when developing a packaging procedure. For example, they may be unaware that it's not feasible to use a single aircraft on the route they're looking for."*

## Expert advice on clearing customs

And then there is the potential for mistakes to be made when customers complete documentation in-house without the support of regulatory experts. For example, any errors in the invoice or the air waybill may result in the shipment becoming snagged at customs.

## Navigating customs clearance in China

The in-country Biocair team managing MajorDrug's shipments out of China are experts on the unique export challenges China presents.

The Biocair team is not able to apply for export permits on behalf of the client. The client's team in China, from whom the shipment originates, is responsible for applying for the export permit. This can cause delays if the client's teams in China and the United States are out of sync on the advance application for the permits.

All stakeholders should also be aware of the possibility that Chinese authorities may require inspection of the shipment immediately before it is exported from the country. If this happens, plans (such as routes, departure times and flight numbers) often need to be changed at the last minute.

To remain adaptable and ensure all parties involved are aligned, Biocair holds weekly meetings with the client and internal stakeholders.



With so many logistical challenges, plus the added complexities of MajorDrug's corporate and personnel changes, regular, clear communication has been a hallmark of the customer relationship.

## The classification and declaration of dangerous goods

Biocair's experts make sure that our customers, such as MajorDrug, know which products need an export control license, as there can be significant penalties and fines for shipping without one.

Biocair's operations team members are extensively trained in the preparation of all the relevant shipping documentation, including the classification of dangerous goods. In addition, senior operations team members will always review the classification of the product prior to collection. By working with Biocair's in-house customs brokerage firm, Biocair Customs Brokerage (BCB), a third set of eyes validates document accuracy.

## Navigating customs on entry to the United States

On entry to the US, to avoid the MajorDrug shipments getting delayed during the customs clearance process, the Biocair operations team, US Imports team and BCB all closely monitor shipments, liaising with brokers where necessary to help keep shipments moving.

If a package is held by Customs, or other US government agency, then Biocair's operations experts will issue a 'manipulation'. As Biocair's Account Manager explains:

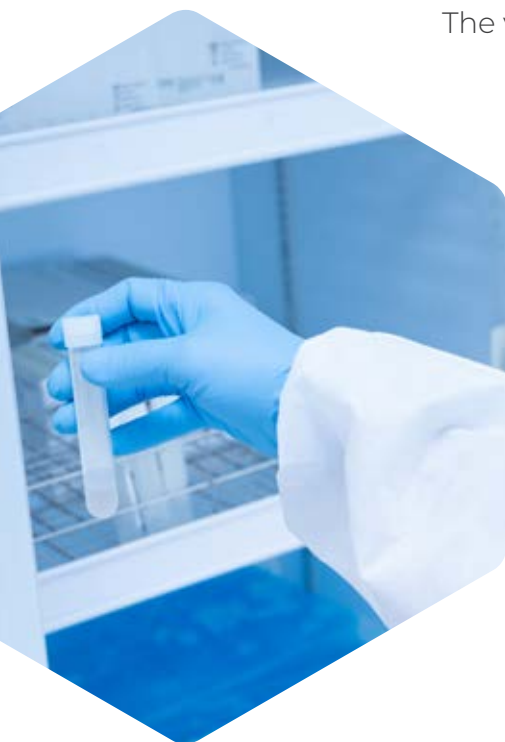


*A manipulation is a form submitted to customs that acts like a permission slip. Sign-off by Customs allows our team to come to the airline cargo facility, open the package, replenish the dry ice and document when this process has been completed.*

*Refreshing the dry ice is critical if a package sits longer than planned. This, along with the documentation, ensures the integrity of the product is maintained."*



## Expediting drug development



The vital drug development program initiated by NewbiePharm, and continued under MajorDrug, could not have progressed as quickly and reliably without Biocair's support and expertise. Biocair designed and implemented straightforward packaging procedures for both bulk API shipments and much smaller sample movements that remain in use within the program today.

These procedures coupled with personalized, expert support enabled the program to overcome significant logistics and regulatory compliance challenges. This ensured continuity and consistency of supply – even during periods of major corporate transition and key personnel changes.

Looking to the future, MajorDrug is now testing the Biocair packaging procedure originally developed for NewbiePharm for implementation with its other drug development programs.

Biocair's support wins a ringing endorsement from the drug development program manager:



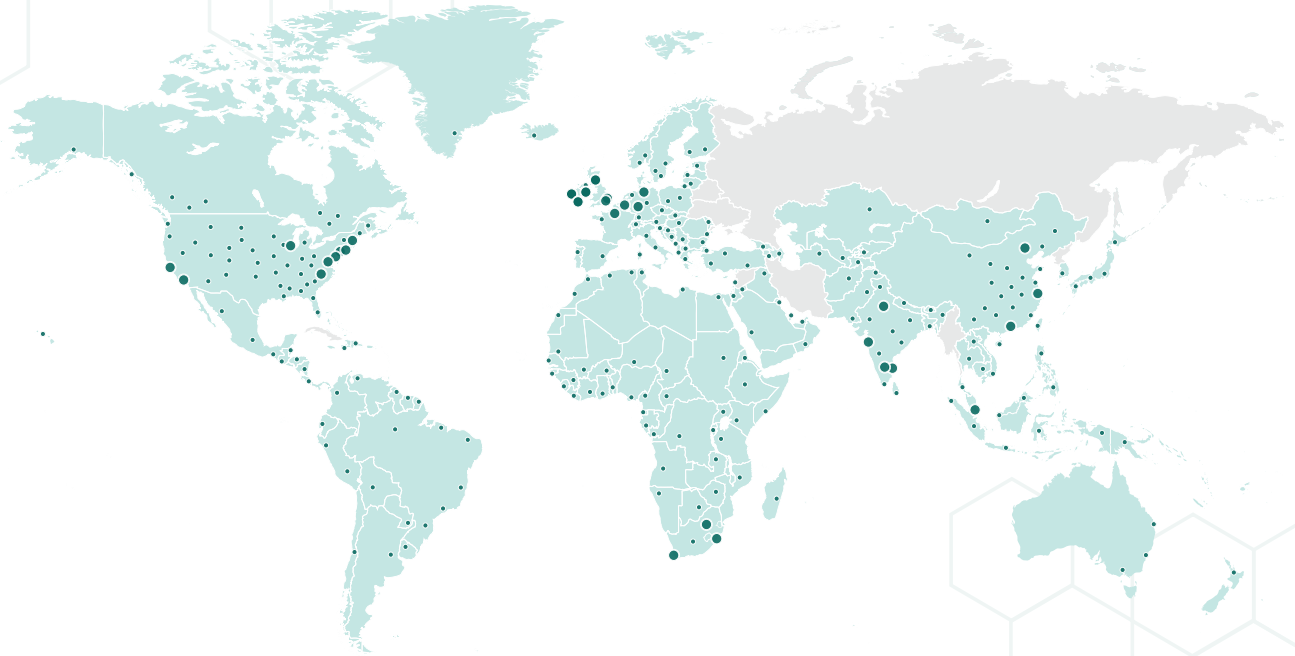
*In an expedited program with a global supplier footprint, we need a logistics supplier that can execute swiftly – our partnership with Biocair ensures critical program timelines are met. From early clinical trials through to commercial launch, Biocair's speed of execution, value-add services and critical cold chain maintenance are key contributors to success."*

**\* Company names have been changed to protect commercial sensitivities. Any similarity with real companies is coincidental.**





## About **Biocair**



Since 1986, Biocair has established a global reputation as a leading GDP logistics specialist within the pharmaceutical, biotechnology and life sciences sectors. Biocair has built up a unique, client-centric approach by employing scientists in front-line logistics positions and assembling a team of best-in-class industry experts in quality, cold chain and regulatory compliance. Biocair focuses on providing the most comprehensive time-sensitive and temperature-controlled logistics services available whilst delivering flexible, tailored, cost-effective solutions to all its clients. It is committed to delivering complete end-to-end logistics solutions through its 24/7 operation and global network spanning across Europe, Africa, Asia and the Americas.

Biocair employs over 550 people worldwide and provides specialist logistics services to more than 160 countries through a global network of partners. Biocair's offices are located in the UK, France, Belgium, Germany, USA, South Africa, China, Singapore and India.

In 2012 Biocair was acquired as an autonomous division by Geopost. Geopost is the largest parcel delivery network in Europe, which posted sales of €15.69 billion in 2023. Geopost is a holding company owned by Groupe La Poste.



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