ALMAC

Partnering to Advance Human Health

Case Study

# Temperature Control Distribution

## EU Product Launch

# Temperature Control Distribution

## Challenges, solutions and results

A US biopharmaceutical company approached Almac to assist with the EU product launch of their high value, orphan drug product. As the drug product was temperature sensitive with minimal allowable temperature excursions a key deliverable of the project was to design and qualify a temperature controlled shipping solution to ensure delivery of the production optimum condition. Throughout this case study Almac will highlight the challenges that arose and will provide solutions on how these challenges were overcome to facilitate a successful product launch.

### Challenges

Almac have significant experience of the challenges that can arise with a temperature sensitive product launch and the requirements as laid out in the GDP (Good Distribution Practice) Guidelines. In this case, the drug product was a lyophilised powder in vial presentation which was for the treatment of an ultra-orphan indication (patient population of <1 in 50,000) which necessitated shipments of small quantities of finished packs.

The product was temperature sensitive and required storage and distribution conditions of 2-8°C which were further complicated by limited stability data for allowable temperature excursions.

A further challenge arose within the supply chain route, such that, the drug product was for the treatment of a niche oncology indication and therefore was to be administered in hospitals/clinics, requiring the establishment of a 3PL (Third Party Logistics) supply chain with orders being received directly from approved hospital pharmacies & clinics and then being shipped directly from Almac for delivery across Europe within 24 hrs; a "Just In Time" (JIT) product dedicated supply chain.

Almac were able to offer a 3PL supply chain with all the inventory held in the Almac facility. Through Almac's online, secure order portal requests are received in real time from the hospital/clinic and immediately processed by the dedicated Almac customer service team.

All orders received by midday are dispatched on the same day through an express delivery service. Utilising one entity and avoiding onward shipments through distributors the Almac distribution team coupled to its JIT supply chain provides our clients greater inventory control, ensures that product handling is kept to a minimum and gets product to patients as quickly as possible.

As the shipments were going direct to a hospital and not a wholesaler, the client company requested that the shipment solution be easily managed by a single person meaning no bulky containers.

Additionally the Client wanted to qualify a shipping system and supply chain which did not require temperature monitoring as it was felt that the hospital/clinic staff would not know how to download or interpret the data, meaning that the shipment solution had to be qualified to guarantee the drug product would arrive in optimum condition regardless of where in Europe the shipment was going.

A further challenge became apparent during detailed discussion with the Client. Whilst discussions were taking place on the shipping and distribution solution, the Product was acquired by a larger Pharma company which added another layer of complexity to the solution and eventually added significantly to project timelines.


## Almac Solutions

Almac initiated its solution by first assessing the product from a risk management and mitigation perspective. In line with section 9.2 of the EU Good Distribution Practice of Medicinal Products for Human Use Guidelines "Risk assessment of delivery routes should be used to determine where temperature controls are required.", the first action taken by the Almac team was the completion of a Failure Modes and Effects Analysis (FMEA), which assessed all factors that could impact the drug product during transit.

These factors included the following:

- Chemical Stability of the Drug Product
- Physical Stability of the Drug Product
- Typical shipment size & frequency
- Primary, Secondary & Tertiary Pack Formats
- Temperature Monitoring Requirements
- Temperature Control Requirements
- Consignee profile (trained professional in clinic or hospital or patient in home)
- Drug Value vs Shipping Cost
- Sustainability of the design
- Transit routes
- Carriers
- Customs regulations & lead-times

Upon completion of the risk assessment, it was determined that an "off the shelf solution" was not suitable, so the Almac team worked with an approved supplier to design a specific shipping solution.

The shipping system was designed and tested through rigorous thermal and vibration testing in a laboratory environment. When the shipping system design had been finalised a Performance Qualification (PQ) protocol was used to qualify the shipping system and to demonstrate it achieved the expected results.

The shipping system and supply chain were qualified utilising placebo product in PQ shipments made to destinations across the EU deemed to be worst case scenarios in terms of temperature (both high and low), transit route and overall transit time.

The final outcome of the project was a tailored insulated shipper, capable of holding six drug product kits, which was qualified to maintain a temperature of 2-8°C for 72 hours.

Central to the successful launch of the client company's product and the development of the tailored shipping solution, was the coordination and management of all activities by one of Almac's experienced Product Supply Managers, who led the multi-disciplinary team to ensure a timely product launch.

Following Almac's standard project management process, the Product Supply Manager generated a:

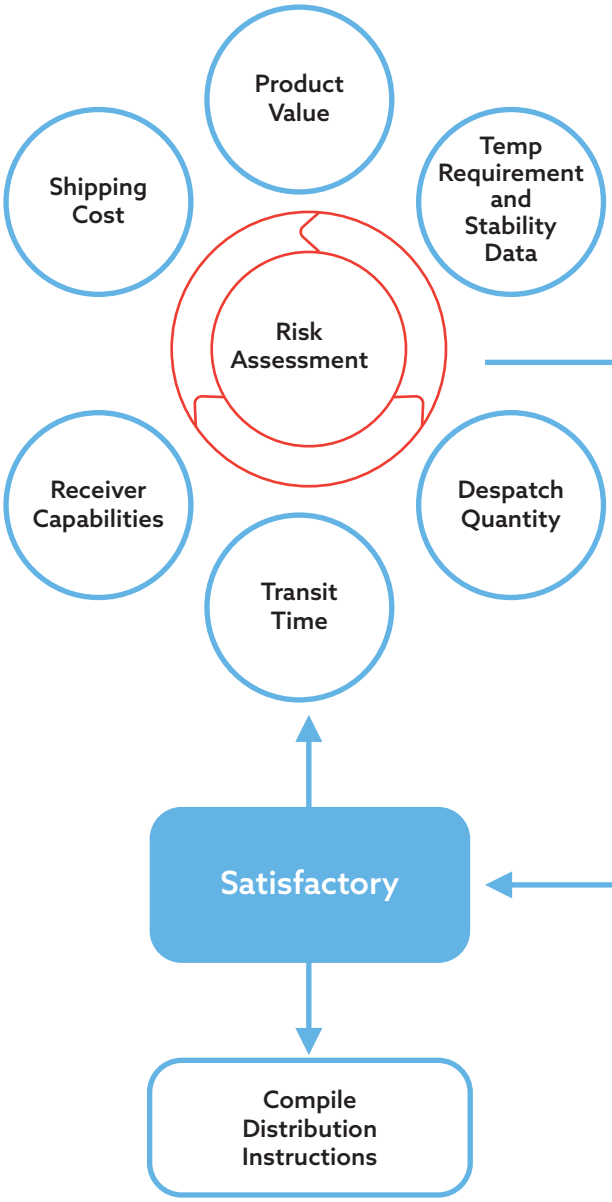
1. Communication matrix that defined roles, responsibilities and provided contact details of each member of the team within Almac, the client company and the shipping solution provider.
2. Documentation matrix that defined roles and responsibilities for generating, reviewing and approving GMP documentation.
3. Comprehensive live project plan that specified key deliverables and timelines.

The detailed project plan was paramount in driving weekly conference calls, across various time zones, and ensured the entire project team was kept informed of the project status and key next steps, to guarantee the timely qualification of the bespoke shipping solution and a successful product launch, upon MA approval.

## Results

Once the Risk Assessment and Performance Qualification were complete, a detailed Distribution Instruction was compiled with step-by-step instructions specifying how each outgoing shipment should be conditioned, packed, despatched and tracked. Each outgoing shipment was also labelled with the time by which the contents must be removed and placed into storage (i.e. pack-out time + 72 hours, in the time local to the final destination).

The solution has been in place for past 3 years, with thousands of shipments completed, with an On Time in Full (OTIF) KPI measure of > 99.9%.



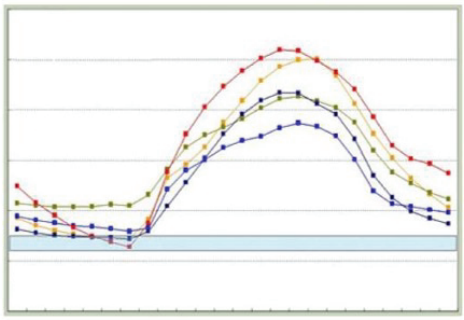

## Initial Selection

Ambient

Controlled Truck

Bespoke Shipping System

## Qualification



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