



Partnering to Advance Human Health

CASE STUDY

LARGE PHARMA COMPANY UTILISES ALMAC'S
EXCURSION MANAGEMENT SOLUTION TO
MEET NEW GDP REGULATIONS

BACKGROUND

As a result of updated GDP's regulations, a large pharmaceutical company started including temperature monitors into a large percentage of their clinical site shipments. The purpose was to monitor the shipment payload's temperature and determine if additional shipment controls were required. The company's plan was to review the results and manage excursions based on predefined stability criteria.

CHALLENGE

Many of the company's shipments employing the temperature monitors were processed utilising a cardboard corrugate shipper rather than a validated insulated shipper to conserve distribution costs. The products had a wide stability profile; therefore, an insulated shipper was not deemed necessary.

Once the temperature monitors were included in the cardboard shippers, a large volume of excursions triggered for the company to process. Although many of the excursions fell within the acceptable stability limits, the company found it difficult to process the excursions within a timely manner. Challenges included working in multiple time zones, providing ongoing updated communication to the sites, updating the Interactive Response Technology (IRT) system, and identifying which excursions would have patient impact and require expedited resupply.



ALMAC'S TEMPERATURE MANAGEMENT SOLUTIONS OFFER FULL EXCURSION ADJUDICATION OF CLINICAL SHIPMENTS, OFFERING OUR CLIENTS' PEACE OF MIND OF THEIR CLINICAL TRIAL SUPPLY.

SOLUTION

Almac provided assistance by processing the high volume of temperature excursions, which stemmed from in-transit or clinical site storage issues. The dedicated staff, available in multiple time zones, worked closely with the client and Supply Chain Managers to identify and expedite processing of an excursion when there was a patient or client impact. The temperature team, who are experts in analysing temperature data against a stability profile, ensured each adjudication was reviewed and verified by the Almac quality group. Upon completion of an adjudication, the temperature team updated the status of the supplies within the IRT. In the event that supplies required rejection due to the excursion falling outside the stability limits, the team triggered a replacement shipment and expedited the request through the distribution and logistics process.



RESULTS

Through the use of Almac's excursion management services, the average turnaround time for an excursion was improved to match the rapid pace of the study. In addition, the Almac Supply Chain team reviewed recruitment and dosing data to determine any upcoming patient visits to the site. The Logistics group utilised shipping lane analyses to select the most effective and efficient route for supply distribution. Almac was able to remove all out of specification supplies from the field and ensure replacement supplies were available in time for patients.



All our clients have unique needs.
That's why we develop unique solutions.

This is the **ALMAC TOUCH™**



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