



Partnering to Advance Human Health

# CASE STUDY

MAJOR PHARMA COMPANY IMPLEMENTS FDA RECOMMENDATIONS BY EMPLOYING ALMAC'S TEMPERATURE MANAGEMENT SOLUTIONS

## BACKGROUND

During a recent FDA clinical inspection of a major pharmaceutical company, the auditor placed a strong focus on temperature excursion tracking of study drugs, from manufacture of product through to storage at the clinical sites.

The inspector recommended **improving the timeliness** of excursion notifications to the sponsor and the **comprehensive tracking** of cumulative temperature excursions throughout their supply chain.

## CHALLENGE

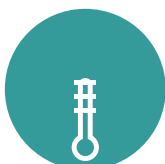
The pharma company did not have a robust end-to-end process established for managing and reporting cumulative temperature data for excursions.

The current practice was for their external supply chain partners to manage this work package. This process introduced the possibility that the sponsor would not be informed about excursions in a timely manner and drugs that had exceeded their cumulative time out of conditions could be administered to a patient.

The company was about to embark on several large Phase III studies and felt they needed to address the auditor's recommendation prior to starting these projects to avoid a 483 at future inspections.



ALMAC'S TEMPERATURE MANAGEMENT SOLUTIONS SERVICE CAN COLLECT AND MAINTAIN TEMPERATURE EXCURSION DATA AT THE LOT OR MED ID LEVEL FROM MANUFACTURE UNTIL THE DRUG IS ADMINISTERED TO THE PATIENT, SOLVING THE SPONSOR'S CHALLENGING NEEDS.



### SOLUTION

Data is collected from the manufacturer, Almac facilities, depots, and clinical sites at the following points: manufacture, receipt, production, storage, and shipment. This data, which is stored in **one secure database**, is made available to the client at the close of the study in a format that is suitable for regulatory submission.

The service also encompasses adjudication of temperature excursions, compliance management, and analytics. Using data provided by the sponsor company, Almac manages the process around replacing material that is determined to be out of specification. In addition, Almac follows up with sites to collect outstanding data.

### RESULTS

Through the use of Almac's temperature management solutions, the client received a full historical record of the temperature data in a single secure database. This was provided for the entire lifecycle of the clinical and commercial material used in their study.

This data allowed the company to remain compliant with current regulatory requirements. Through the rapid adjudication of excursions, Almac successfully made sure that the out of specification drug was removed from the field and not administered to patients.



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

This is the **ALMAC TOUCH™**



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