

Cloudleaf Empowers a Global Pharmaceutical Company to Track Blood Plasma Samples with 100% Visibility

To meet the growing demand for life-saving plasma-based drug therapies, a global pharmaceutical company collects and transports over 8 million liters of blood plasma from 82 donor centers to its 5 plasma facilities around the world. Patients with a variety of rare, life-threatening, chronic and genetic diseases depend on the availability of high-quality drug therapies.

This is where Cloudleaf expertise came in. The company was losing tens of millions of dollars every year due to plasma sample spoilage, re-testing labor costs, and FDA compliance issues. The company turned to Cloudleaf to provide a complete system that provides real-time, accurate monitoring of the location, dwell times, condition, and movement history of the blood plasma samples.

Challenges in Tracking Blood Plasma Movement with Outdated Technology

The global pharmaceutical company is one of the top 10 largest pharmaceutical companies in the world by revenue, with research and development sites in Asia, North America and Europe. At their North American plasma facility is a new, 1.1 million-square-foot, state-of-the-art manufacturing space where they produce Albumin, which is used to treat rare, life-threatening, chronic and genetic diseases.

In order to produce Albumin, they collect and transport pallets of blood plasma samples from 82 plasma services centers to its North America facility every year. The beginning of the journey starts at the donor centers, where a plasma donation is put into a test tube sample bottle that is then put into a small freezer.

To ensure the safety and efficacy of the blood plasma, the company must comply with strict FDA regulations regarding the transportation of the samples. Plasma spoilage, re-testing, and waste cost the business millions of dollars every year.

CUSTOMER

Global Pharmaceutical Company

INDUSTRY

Pharmaceutical

OBJECTIVES

Reduce blood plasma re-testing, spoilage and waste, provide complete record of plasma movement history for FDA compliance, and increase visibility from 20% to 100%.

CHALLENGES

- Millions of dollars lost annually due to plasma sample spoilage, re-testing, waste and compliance issues.
- Manual method for tracking blood plasma samples resulted in a low Supply Chain Visibility Index of 20%.
- Manual tracking did not capture the complete movement history of the samples, which meant the company was not in 100% compliance with FDA regulations.

SOLUTION

Cloudleaf's solution provided end-to-end visibility and condition information of the plasma samples, from the arrival at the loading dock, to the pallets, and finally, to the freezer. Cloudleaf enabled the company to achieve 100% visibility into the flow of their plasma samples, with 100% count accuracy.

RESULTS

- **50x ROI**
- Supply Chain Visibility Index increased from 20% to **100%**
- **\$60M value** creation; saving millions in product losses
- Able to **track 25,000+** pallet movements



The illustration below depicts the journey of a blood plasma sample, starting from the donor center all the way to the plasma processing facility.

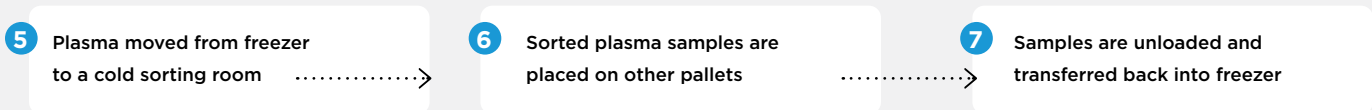
Plasma Sample Arrival



Plasma samples arrive at the facility and are unloaded and transferred to pallets, which must be immediately moved to the freezer to avoid spoilage. The loading dock is not refrigerated, so it's critical that the pallets are moved into the freezer as soon as they're unloaded to avoid being exposed to ambient temperatures. If the batch of samples are exposed to more than 60 minutes of ambient temperature, then those samples are quarantined. After the quarantine period, the samples must be re-tested for viability, which results in extra labor costs.

When the plasma is needed for Albumin production, the pallets are moved to a cold sorting room (+5 degrees C) for sorting by origin and profile. The sorted samples are then placed on other pallets and moved back into the freezer. There is a threshold (dwell time) for how long the samples can be out of the freezer — if the samples exceed that time, they are discarded.

Plasma Production



At the time of production, pallets are moved to a cold sorting room for sorting by origin and profile. The sorted samples are then placed on other pallets and put back into the freezer. In between, samples go on excursions where there is a threshold for how long they can be out of the freezer.

The processing facility, where plasma collected at remote donation sites is separated.



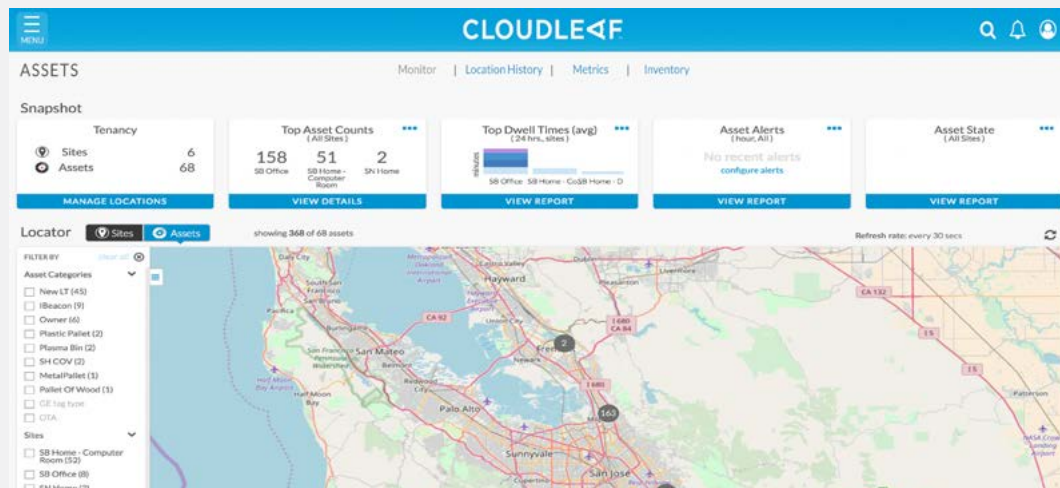
“ Cloudleaf gives us 100% visibility into the movement of our blood plasma samples, resulting in over 50x ROI. Now we can track pallet movements with 100% accuracy, and achieve 100% compliance with FDA regulations. ”

SVP Strategy, Global Pharmaceutical Company

Before implementing Cloudleaf’s solution, this global pharmaceutical company was relying on older, manual tracking methods which involved the use of hand-held RFID bar code scanners. RFID technology did not provide them with the timely, accurate data that they needed. As a result, a significant number of plasma samples spoiled due to temperature excursions — when samples are exposed to temperatures outside the recommended storage conditions. Fines and costs for each excursion top \$5M each.

100% Visibility with Cloudleaf Means Full FDA Compliance and \$60M Value Creation

Cloudleaf provides the pharmaceutical company with the ability to capture real-time product flow data within their plasma facility. The Cloudleaf solution, which included a software platform paired with 5,000 sensors and 60 gateways, enabled them to accurately monitor the plasma samples’ location, dwell times, condition and movement history, from the point when a truck pulls up to the receiving dock door to the end point when the final product is created. With the click of a button, the company can provide the FDA with a complete record of plasma movement history, resulting in significant cost savings.



Asset Monitor Dashboard – Insights

Cloudleaf enables the next generation of intelligent supply chains. We deliver continuous visibility and actionable insights across the supply chain, helping enterprises make the right decisions in real time, to increase revenues, avoid disruptions, improve customer satisfaction and increase sustainability.

To take the first steps in transforming your supply chain, reach out to **Cloudleaf**.

