

# Digital Transformation in a Blood Plasma BioPharmaecutical Company

Industrial Solution Survives Sterile Manufacturing Requirements, while the Product's Digital Thread Delivers Operational Precision



## **Enhancing Operational Efficiency in Life Sciences**

Life science, biopharmaceutical, and medical device manufacturers can enhance operational efficiencies by ensuring that critical product data and supply chain information is easily accessible throughout their value chain. Key areas of interest include visibility during manufacturing processes, when items are stored at distribution centers, and when they are ready for use at the point of care. Tego's solution allows wireless UHF RFID data to be securely integrated directly onto products or within their packaging, and it is robust enough to endure rigorous processes, including gamma and eBeam sterilization. Tego's comprehensive solution offers unparalleled visibility, analytics, and accessibility of product and quality data at every point of need.

#### THE CHALLENGE OF CRADLE TO GRAVE TRACEABILITY

A significant challenge faced by a global biopharmaceutical manufacturer is ensuring cradle-to-grave traceability for its biologic products. Each collection unit is comprised of a serialized container that must undergo gamma or e-beam sterilization before it collects a patient's blood plasma. Following this, each container is subjected to long-term deep freeze storage, after which it is transported between third-party vendors and stored throughout several of the manufacturer's facilities worldwide.

In the event of a quality recall, it is crucial for these containers to be removed. The question arises: how does a global manufacturer accomplish this when managing twenty million collection containers annually stored in large freezers across multiple facilities in various countries? Furthermore, how can one efficiently locate and retrieve a single recalled container without disrupting overall business operations? Is it possible to achieve this without embarking on an expensive and lengthy IT project? This was the challenge faced by the customer.

#### An Automated Real-time Solution Delivering Operational Precision

The customer selected Tego's solution in part due to the company's distinctive hardware component, TegoChip™, which fundamentally possesses the ability to store, manage, and report lifecycle event data in an automated yet disconnected manner when embedded upon the product itself. TegoChip serves as both the physical and digital cornerstone of the solution, granting each container the capability for digital memory management. This durable embedded intelligence can withstand radiation, extreme cold, and high heat. As a result, the biopharmaceutical manufacturer can digitize, collect, and report data on each container as it progresses through their intricate product collection in real-time. The automated data gathering and reporting significantly minimizes manual labor, enhancing the efficiency, safety, and cost-effectiveness of the entire internal supply chain.

The enterprise software aspect of the solution provides an automated digital twin for each collection container, detailing its internal supply chain and manufacturing events for informed operational decision-making. To address the challenges faced by this biopharmaceutical manufacturer, every enabled container was required to maintain its own digital thread, encompassing all crucial manufacturing and regulatory information. This entails that every event and process occurring at specific times and dates—sequentially collected during manufacturing and accessible as needed in the supply chain— be documented and reported to ensure compliance with operational guidelines and manufacturing standards.

The customer chose Tego for its comprehensive end-to-end solution, which integrates edge devices, intelligent software, and hands-on services specifically designed for the challenges of their rugged and disconnected operations. Tego's offering stands out from other platform solutions that only automate and collect manufacturing data; TegoHub also facilitates data exchange with other systems (e.g., ERP, MES, WMS, and more), providing a fully integrated digital solution complemented by robust real-time analytics and genuine business insights. This integration allowed for IT/OT convergence with minimal disruption during deployment.

### Financial and Operational Return on Investment

With the solution implemented, this biopharmaceutical manufacturer has unlocked remarkable advantages. The initial, significant benefit stem from transitioning from a manual barcode system to a fully automated, wireless, and battery-less UHF RFID tracking solution that can withstand sterilization and provides enterprise-wide data reporting.

Workflow efficiencies have dramatically improved, as the automatic capture of each production event occurs across multiple locations, resulting in a substantial reduction in labor involvement. For instance, this manufacturer experienced a 20-fold measurable enhancement in their supply chain processes—not a mere 20% improvement, but a process that is 20 times more efficient with minimal errors. Essentially, the automation transformed what used to be an eight-hour process into a 30-minute task, all without errors.

Tego's solution creates a digital thread. As the product undergoes real-time manufacturing processes and events, information is automatically captured, stored, and reported both on the container and in the Cloud. This capability generates immense value for the business, both financially and operationally. The data is accessed, synchronized, and reported, leading to significant operational efficiency gains and real-time quality reporting. By capturing data in aggregate and providing real-time visibility and traceability for individual containers, the solution contributes to a substantial return on investment. Quality risks are effectively managed in real-time, thus eliminating considerable financial expenditures one possible adverse events. Finally, leveraging real-time data facilitates improved resource management throughout the entire supply chain, ensuring a more balanced allocation of efforts, time and money.



CONCLUSION

#### Visibility through Manufacturing

Tego has unveiled an innovative solution that tackles a major challenge encountered by life science and biopharmaceutical companies. The TegoChip™ is the only UHF RFID hardware globally that can endure gamma and beam sterilization. Its true value lies in providing automated visibility throughout even the most rigorous manufacturing processes. Additionally, Tego offers a comprehensive software solution that collects real-time data from each plasma collection container, relaying it through an enterprise-wide digital twin. This enables manufacturers to react quickly and effectively in the event of a recall. This groundbreaking solution presents significant benefits, including considerable enhancements in process efficiency, reduced production costs, and the ability to respond in real-time to minimize quality risks.

