Blood Plasma Pharmaceutical Manufacturer with Cold Storage and Sterile Manufacturing Requirements

TEGO

Powering Assets with Intelligence

Blood Plasma Pharmaceutical Manufacturer with Cold Storage and Sterile Manufacturing Requirements

Industrial Digitization that Survives Sterilization

Life science companies and medical device manufacturers can maximize operational efficiencies when critical product data and information is readily available throughout their value chain -from manufacture to distribution to end use. Tego's Asset Intelligence Platform (AIP) is the first solution that enables such data to be securely embedded directly on products and also rugged enough to withstand the most demanding manufacturing environments, including radiation sterilization processes. Tego's AIP solution benefits pharmaceutical companies, medical device manufacturers and healthcare service providers by providing unprecedented visibility and availability of product and regulatory compliance data.

The Traceability, Visibility and Recall Challenge

The main challenge for a global biopharmaceutical manufacturer was cradle-to-grave traceability for its biologic product with an annual running inventory of 20 million units. Each container must undergo gamma or e-beam sterilization, long-term deep freeze cold storage and be transported between third-party vendors as well as their own facilities worldwide.

Each container must be traceable in the event that a recall is triggered during the manufacturing process. How do you do that when you have 20 million containers stored in giant freezers located in multiple facilities and countries? How do you locate and extract a singular recalled container with a precise level of efficiency without disrupting the entire business operation? Can this be done without implementing a very costly and lengthy IT project?

Historically this problem was addressed with complex, expensive, inexact set of processes based on an outdated and inefficient barcode system. The barcode reading process alone is labor intensive and susceptible to reading errors due to the harsh manufacturing and storage environment resulting in the loss of traceability and subsequent loss of high value product.

Tego's Asset Intelligence Platform— Every Asset Tells its Story

The Tego AIP and its core capability to store data on a product itself has enabled this company's highly complex product manufacturing process to become more efficient, safe and cost effective. Tego's AIP creates smart assets by powering those assets with intelligence. To meet the challenge of this biopharmaceutical manufacturer, the AIP enabled the container to maintain its own unique 'storyline' consisting of all critical manufacturing and regulatory details - events and processes endured at a certain time and date - gathered sequentially during manufacturing, and accessed when needed in the supply chain, to validate processes, guidelines and manufacturing compliance. The TegoChip is both the physical and digital foundation of the AIP solution as it enables each container to be embedded with digital memory management capability. The physical embedded intelligence is durable enough that digital

information survives radiation, cold storage, and extreme heat. No other wireless platform solution has this capability. The TegoChip does and so this solution has wide application in medical manufacturing and industrial applications as well.

The TegoChip's digital architecture dramatically increases the data and intelligence capability of the asset. The chip uses Tego's patented archival capability for acquiring more information and data files over time as the containers are processed. Today's standard technology includes only enough memory for an identification number and little more. That ID number is static, available to be read only; it cannot be updated when changes or events occur to the product tagged with that ID. TegoChips carry an identification number and also carry additional large amount of free memory capability, that can store, save and manage information over time. By using this additional memory capability, whenever the bottle goes through a new process or state, that information is accounted for on the bottle itself, in a digital archival database. This means that wherever the bottle goes, data and information about its contents, it processes completed and regulatory compliance goes with it. The product is smart enough to tell any stakeholder in the value chain where it has been and what has been done to it so the availability of specific product information can be achieved without relying on an external networked database.

The Tego AIP is powered by the TegoOS software that gets installed on each device throughout the value chain's predetermined check points. The TegoOS platform supports all major mobile and desktop operating systems, including iOS, Android, Windows and OS X. For this medical application TegoOS embeds digital information about an asset directly onto the asset itself–

such as product specification and configuration, manufacturing event history, intended use and compatibility. The open OS also operates across all RF gateway protocols and handheld readers.

Financial and Operational ROI

With the full AIP solution, the company unlocks many significant benefits. Many are dramatic improvements over their old barcode system, and many are new enhancements to their business that were not previously possible.

Improvements in workflow efficiency come from a number of places in this application. Previously, barcode labels were applied after the bottle-manufacturing step. This has been replaced with automating and embedding the data capture capability and encoding the tags, all during container production. Previously, information about the container contents required printing and applying several barcode labels. This step has now been removed entirely. With the Tego solution, as the product undergoes real-time manufacturing events, that information is added to the existing product's digital history and storyline, which exists on the container itself. Data is then accessed and synced by workers throughout the process chain.

A much more significant work reduction comes from the scanning process. A barcode system that is used to keep track of each asset's location relies on frequent scanning, and with assets such as these, that meant significant manual intervention by work crews. Since traceability is required down to the individual container, that meant at some locations pallets had to be broken down and cases opened so that workers could manually scan containers one at a time. Using Tego's solution it is now possible to read all product information inside a case without opening the lid. This results in measurable improvements to a factor of 20. Not 20%, but a

reduction to one twentieth of the original time and effort. **A shipment that used to take eight hours to process can now be received in roughly 30 minutes.**

Smart Asset Solution More Flexible and Less Costly than Enterprise Software

While traditional barcode solutions require a centralized database, where ID numbers correlate to the data files associated with the product, Tego's distributed data solution foregoes this necessity. This is ideal since a corporate-wide, networked software environment is a costly and time consuming endeavor. With Tego's solution product information is stored directly on the product itself for its entire lifecycle. Manufacturing details, regulatory compliance files, even details about how to use the product - all of this can be stored, maintained and accessed on the individual product. When product is inspected, either by quality assurance personnel or by government agencies, all important information is at their fingertips, instantly available for use as well as syncing the information to any database as it travels throughout the world.

With Tego's solution companies can explore new revenue models made possible by enabling data on products and assets alike. Useful process metrics have already led to workflow improvements in the production environment. But there are novel ways to improve vendor and customer relationships based on the amount and types of data made available with the Tego solution.

Tego's Innovative Solution in Life Sciences

In summary, Tego has brought to market the world's only Asset Intelligence Platform solution, which provides data at your fingertips, rugged enough to survive sterilization and other manufacturing processes. This breakthrough technology is bringing the benefits of the Industrial Internet of Things (IIoT) to new industries such as life sciences and healthcare. As demonstrated here, the benefits come in many forms, including dramatic increases in process efficiencies and reduced production costs.

About Tego, Inc.

Tego powers assets with intelligence. Tego's Asset Intelligence Platform makes businesses smarter by embedding digital information in components and assets for the aerospace, life sciences, healthcare and manufacturing industries. Insights about assets' lifecycle history, regulatory compliance and integrity drive operational excellence and new revenue models. Smart asset data is available for the right people and systems, including IoT, EAM, ERP, and Analytics applications.

Tego is an architect and co-author of the aerospace ATA Spec2000 Ch9-5, has 30+ granted patents, has dozens of global customers including Honeywell, Parker Aerospace, and B/E Aerospace, and serves as a healthcare leader with the Industrial Internet Consortium (IIC).

Follow Tego on **LinkedIn, Twitter** and **YouTube**