

Automation, Digitalization and Analytics for Quality Control & Aseptic Manufacturing







Tego's platform solution delivers an automated, end-to-end solution with real-time reporting of business process flow, location tracking and analytics.

Tego is the inventor and provider of the only sterilization proof RFID chip/tag capable or surviving:

- Gamma sterilization
- eBeam sterilization
- Ethylene oxide sterilization
- Cold storage (-80C)

The Challenge

Today's Quality Control (QC) laboratory is reliant on manual processes that are cumbersome, labor intensive and prone to inconsistency and error. Moreover, when manufacturing teams are bound by manual data recording and transfer, Quality Assurance teams lack the means to review and resolve exceptions in the moment. Instead, they often discover exceptions weeks or months after they occur, necessitating a time-consuming and expensive paper trail to determine the root cause and address the impact.

Scope of the Problem

The need for automated visibility, and real-time quality information has never been more pertinent. Only an estimated 15 percent of the environmental monitoring programs utilize even basic methods like bar codes. Lack of automated solutions and reliance on paper and pencil means the manufacturing floor is error-prone, and that the most critical monitoring activities are time and labor intensive.

Solutions that automate, digitize, and provide real-time tracking information for sterilized materials and products being used in the manufacturing process can greatly assist the efforts of Quality Assurance programs. In an industry where risk is synonymous with heavy financial impact and potentially even the risk of human life loss, all measures that facilitate accurate environmental monitoring and improve operational excellence are of first-order importance.

The Solution

Tego's award-winning Asset Intelligence Platform (AIP) is uniquely suited for success in this challenging production environment. With the world's only sterilization-proof ultra-high frequency (UHF) Radio-Frequency Identification (RFID) chip, Tego's platform solution provides a touchless sample tracking and real-time location solution able to meet the rugged requirements of aseptic manufacturing and CGMP. The platform manages real-time tracking of samples throughout their lifecycle, provides a complete digital history, chain of custody and automated reporting. The platform integrates with LIMS, ERP systems or Data Lakes for enterprise-wide integration and analytics.

See Tego Connect Mobile and TegoHub in action.



The Solution

Automated digitized platform providing visibility with enterprise-wide analytics, traceability and contextualized data sharing through the quality process

Tego provides a single, comprehensive, scalable solution enabling automation, visibility, and traceability of the materials, the processes and the people inherent in production of injectable drugs.

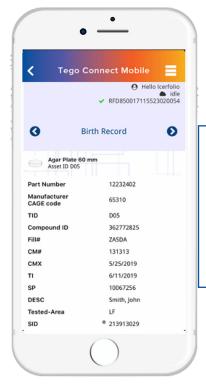
The solution integrates laboratory processes, quality management and quality assurance measures to deliver a real-time report of the materials, the data, and the people directly responsible for activity across the production floor.

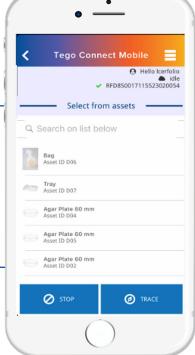
The solution provides enterprise-wide analytics addressing manufacturers and suppliers need for identifying process bottlenecks, reporting quality metrics, and sharing data and information throughout the production team.

- Digitalization of manufacturing room logbooks
- Real-time alerts to thwart operational errors
- Enterprise-wide visibility

- Detailed location maps for track and trace and chain of custody
- Media lifecycle for use during contamination event (used or unused media)
- Automated collection of contextual data







TegoConnect Mobile™

TegoConnect Mobile™ provides local apps running at the point of use for floor workers, providing visibility and traceability for the materials, processes and workforce associated with production runs



TegoHub is the system-level portion of the solution, running on an internal network or hosted in the cloud, enabling reporting of key performance indices and essential business metrics. TegoHub provides real-time location and process control with automated alerting capability. TegoHub is where the storage and management of all the metadata exits related to workflow activity, including raw materials, design, quality, production stages, finished goods and everything in between.



TegoHub is where all automated information related to the people, the parts, and the processes, critical to every production floor, flow into for higher level Al analysis. Tego's Software as a Service (SaaS) solution is standalone or can be integrated with other LIMS, manufacturing execution systems or enterprise software solutions.



Benefits

QUALITY CONTROL



Automate data collection from devices and people



Eliminate redundanct data entry and transcription errors



Gain direct traceability of QC Micro programs



Improve worker efficiency



Improve regulatory compliance



Make sound product and quality release decisions

OPERATIONAL

- Accurate, secure, and automated digitized data flowing directly from the manufacturing room floor into LIMS, BMS, MES, etc
- Automated alerting and event reporting based on workflow movement of aseptic materials, samples, and assets
- · Personnel monitoring in real time

ROI

50%

Digitizing materials, samples and asset results in a fifty percent reduction in labor intensive sample collection activities



Improved regulatory compliance and reduced risk in turn reduce financial penalties



Better reporting for FDA speeds time to market

WITHOUT TEGO'S SOLUTIONS

Manual paper and pencil process steps burden QC programs with paper scheduling, market labeling of sample media, manual reconciliation, paper log book entry, and manual notification of deviations. Moreover, test results are stored in shelves of paper binders — a challenge to navigate in an audit.

Solution Components



TegoHub[™]

- A configurable, scalable, platform with industry specific templates for rapid deployment and a crossplatform library.
- Supports all major mobile and desktop operating systems including iOS, Android, Windows, and OS X.
- APIs allow simple plug and play integration with IoT, EAM and ERP systems.

TegoConnect[™] **Mobile and Auto**

- Easily and securely manage critical data directly on the asset through TegoConnect, a mobile or fixed device application to deliver supply chain intelligence, business analytics, workflow/process management at the edge.
- TegoConnect supports iOS, Android, Windows and OS X and integrates with TegoHub and enterprise applications.

Tego Tags [TegoChip™ inside] or other Auto-ID Inputs

- Suitable for disconnected, rugged, and/or field assets, with the ability to support diverse multimedia file types such as images, documentation, spreadsheets, and other types of files or unstructured data.
- First of its kind that is Gamma/E-Beam sterilization-proof and is rated for 30+ year data retention and durability through extreme temperatures, vibration and shock.
- Blockchain on a chip first verifiable edge ledger on a chip.
- → Get in touch to find out what Tego can do for your company.