Tego Digital Environmental Monitoring

Solution Briefs and Use Cases for CGMP

To be competitive and viable, today's CGMP-regulated manufacturers face more pressure than ever to comply with requirements for providing evidence of facility cleanliness. The risk of financial and market loss goes up with every single deviation.

The Challenge

The FDA requires manufacturers operating under Current Good Manufacturing Practices (CGMP) to certify that every batch of drug, vaccine, or biologic be produced in a high-quality controlled environment. There is no leeway. A carefully planned and executed environmental monitoring (EM) program provides increased assurance of sterility for aseptically produced products.

Environmental monitoring is key to confirming contamination-free production processes. It ensures that products are fit to be released and manufacturers can meet regulatory obligations. From clean room validation to testing of utilities and monitoring of microbiological and pharmaceutical processes, achieving effective environmental monitoring faces various challenges:

Environment Monitoring Challenges

- Implement continuous environmental monitoring that is harmonious with CGMP
- Produce full traceability back to a specific exposure event
- Limit instances of human contact and error-prone recording

Equipment Inspection Challenges

- Inspect passive and active air monitoring equipment without introducing contaminants

Sterilization Process Challenges

- Guarantee data survivability through Gamma & eBeam sterilization processes

Compliance and Batch Tracking Challenges

- Validate cleaning procedures for CGMP compliance reporting
- Correlate between specific numerical environmental monitoring data and batch sterility

Digital Environmental Monitoring Solution

How can manufacturers monitor the state of the manufacturing process without introducing unnecessary touchpoints or contamination risks? The answer is to digitize records and embed data directly on the asset, all while communicating via touchless RF.

Digital Environmental Monitoring (EM) removes human factors and provides significant process improvement opportunities. These digital, data-driven solutions must survive sterilization, however.

Digital EM with sterilization-proof technology allows CGMP manufacturers to write data directly onto:

a) products and materials that must be tracked and verified before, during and post-production

b) products and materials that monitor sterility

More importantly, digitized environmental monitoring makes data available via touchless, sightless procedures.

The digital traceability and visibility provides a full compliance solution as well as an early warning system.

How it Works

A sterilization-proof, passive UHF digitized label captures the necessary data under sterile conditions. The data it houses survives gamma and eBeam irradiation to enable downstream monitoring of:

- finished drug components
- finished lots
- agar exposure plates
- cleanroom airflow monitoring filters
- any other raw materials and components used to monitor the environment under CGMP

For the first time, manufacturers can attach readable, writeable, and sterilization survivable data enriched memory directly to assets in the sterile lab.

Data includes:

- Date stamping - production date, due date, expiration date
- Culture ID
- Manufacturing center
- Test station

Benefits

Secure and Reliable

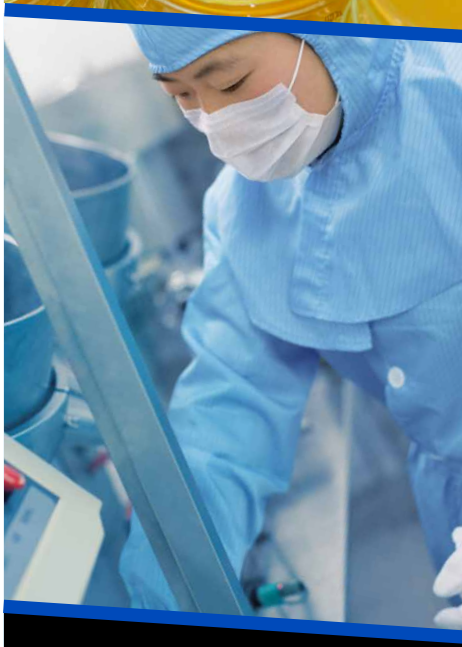
- **Passive UHF digital data:** for sightless, paperless transport of information
- **High memory chip:** with data retention capability for chain of custody tracking and complete lifecycle monitoring
- **Rugged, sterilization-proof solution:** built for rugged, complex and highly-regulated environments. Gamma-survivability of data means no further touchpoints and minimal risk of introducing contamination.

Convenient

- **Multi-environment use:** data stability under refrigeration, incubation, room temperature and high heat; storable at site-of-use

Flexible

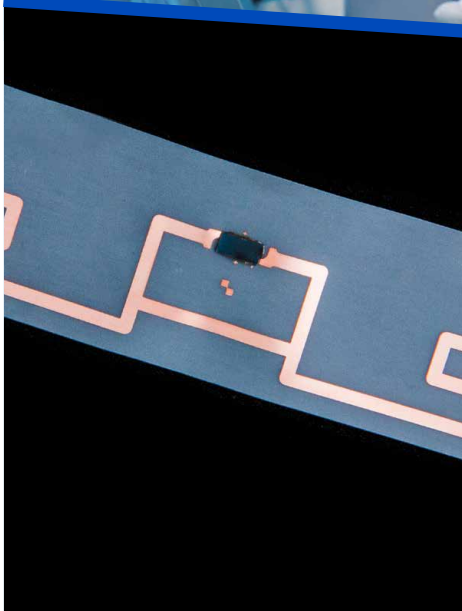
- **Multiple use cases:** suitable across all components of facility and cleanroom monitoring systems in CGMP
  - No touch automation for agar plate tracking; aggregate multiple agar plates for batch readings
  - Personnel monitoring
  - Automated active and passive air quality monitoring; e.g. digitally tagged HEPA filters
- **Production tracking at an item or batch level**



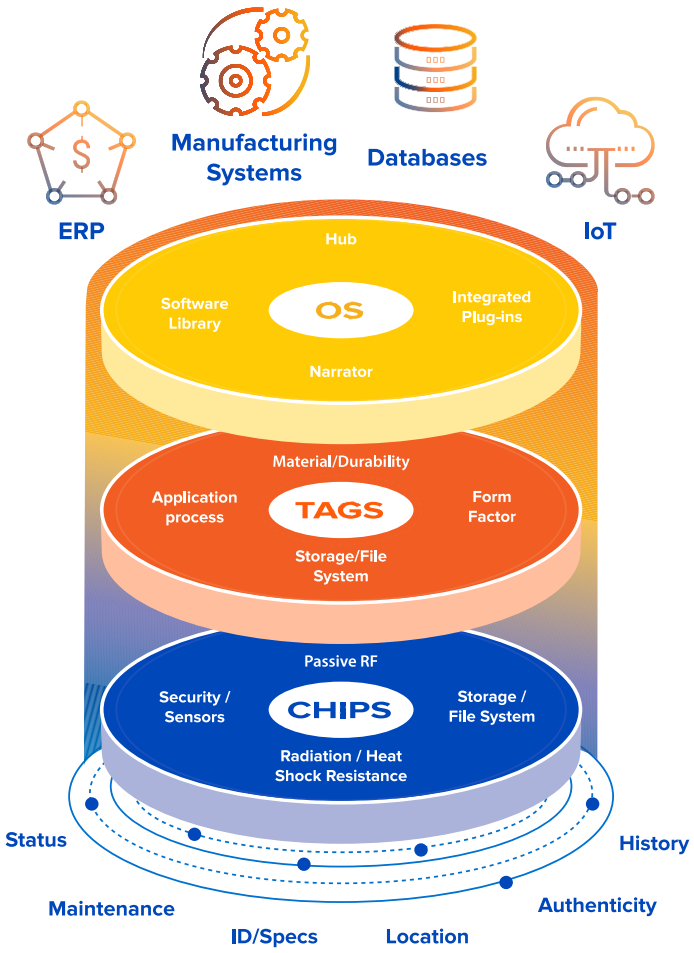
Use Cases

Ideal for CGMP-regulated manufacturers that must abide by environmental monitoring (EM) mandates to detect microbial and particulate content.

- Eliminate risk factors of human contact, and error-prone recording during inspection processes
- Track and pinpoint potential introduction of contaminants at any point of the process
- Prove batch-by-batch compliance with FDA contaminant regulations
- Eliminate burdensome post-sterilization labeling processes



Tego AIP Components



Tego Digital EM Leverages the Tego Asset Intelligence Platform (AIP)

- Tego's AIP embeds data and documents on the asset itself, connecting your physical world to the digital, using high-memory, rugged, sterilization proof chips and tags
- It enables the capture of data in every step of the manufacturing process and throughout an asset's life cycle
- The data travels with the asset wherever the asset may go
- This distributed, secure data approach enables unsurpassed visibility, local analytics and action on the spot

Software Operating System (OS)

- The built-in operating system is the engine underneath the Tego Digital EM Solution
- The operating system software allows the data to be read using any standard RF protocol and reading devices in a secure manner
- The data and documents can be captured and presented on a smartphone or tablet
- Open and multi-platform, TegoOS supports all major mobile and desktop operating systems, including iOS, Android, Windows and OS X
- TegoOS enables distributed data to sync with any cloud-based IoT platform, ERP, EAM, or BI*

Solution Features

- COTS (Commercial Off The Shelf) ease-of-deployment
- Platform agnostic - interoperable with all major ERP, EAM, IoT and BI technology stacks
- Smartphone and tablet-ready
- Data security controls
- Universal acceptance and interoperability via standard RFID protocols
- Unique component location feature picks individual components out of crowded groups

* ERP - Enterprise Resource Planning, EAM - Enterprise Asset Management, BI - Business Intelligence

TEGO

Powering Assets with Intelligence

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