

# 10 Ways IoT Devices Can Help You Achieve Good Laboratory Practices (GLP)

## Overview

Meeting regulatory compliance is key for many laboratories across a variety of industries. Internet of Things (IoT) sensors, combined with data storage, retrieval and reporting capabilities, can make your job a lot easier. In this piece we highlight ten ways in which the use of IoT sensors can help you to achieve GLP. Elemental Machines' sensors and system are designed to be used in regulated environments by meeting FDA regulations 21 CFR Part 11B Electronic Records, 21 CFR Part 58D GLP Equipment and 21 CFR Part 1271 Human Cells and Tissues. Our sensors are factory calibrated and can be calibrated to NIST-traceable standards.

## About 21 CFR Part 11B Electronic Records

Elemental Machines Platform securely collects electronic records as part of an FDA 21 CFR 11 compliant process in food, drug, medical and science-based research environments.

FDA 21 CFR 11 compliance requires that a system meets certain controls to ensure authenticity, integrity, and confidentiality of electronic records. Elemental Machines Insights platform:

### Meets Electronic Record Authenticity Requirements:

21 CFR Part 11 requires that the system be accurate and reliable, and give the ability to discern invalid or altered records. Elemental Machines sensor data is encrypted in transit using HTTPS protocol, redundantly stored, and is not able to be modified by users once recorded. All data is recorded with a time-stamp and data authenticity is verified upon ingestion, storage and there-after. Data is stored by Elemental Machines without limit in time or quantity, and is regularly backed up across distributed databases.

### Meets Electronic Record Integrity Requirements:

21 CFR Part 11 requires that human readable copies of records can be generated while protecting the original record. Elemental Machines sensor data can be inspected from a browser in the form of historical graphs, time-stamped copies generated in standard reports, and data manually exported in spreadsheet/text form, or programmatically exported using a secure API. In all forms, data is accessible to authenticated users in a readable and standard format.

### Meets Confidentiality Requirements:

21 CFR Part 11 specifies that only authorized users can access the system. Elemental Machines authenticates users according to this standard (or better), with a username and password as the minimum requirement, and provides roles-based access to authorized users that restricts actions to approved functions. Unauthorized users are not granted access to stored sensor data. Customer data is partitioned by account to ensure users from one customer do not see the data of another.

*Note: In order to be completely 21 CFR Part 11 compliant, an organization's entire system of data collection and recording must meet regulations. This system extends beyond the use of Elemental Machines equipment to manual procedures, user training, and validation.*



## 21 CFR PartT 58D GLP For Lab Equipment

Elements & Dashboard features are designed to report temperature and environmental data for customer's study protocol in a variety of methods: dashboard view, logfile export, PDF report, API.

### Wireless Elements Can Be Attached in a Variety of Ways

(No-tool magnetic attachment, removable adhesive strips, etc.) that affords access for inspection, cleaning and maintenance.

### Elements are Factory Calibrated

Available with NIST-traceable calibration, and can be easily be calibration verified in-field.

### Detailed Product Sheets

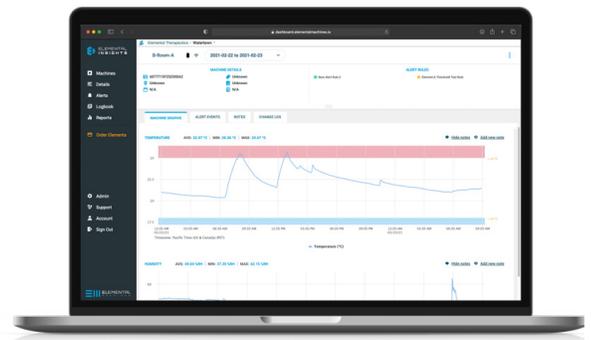
Describing inspection, cleaning, maintenance, testing, calibration for sensor Elements are available.

### Element and Platform Operation and Troubleshooting Information

Is available online and through customer support.

### Elemental Insights Dashboard

Provides dedicated, traceable fields for calibration date, installation date and other user operations including documentation of non-routine repair and corrective actions. These can be exported via reports into a customer's QMS system.



## 21 CFR Part 1271 Human Cells, Tissues, and Cellular & Tissue-Based Products

The Elemental Machines sensors and platform can be used in support of compliance with FDA 21 CFR Part 1271.

### Meets Alerts & Monitoring Requirements:

- Elemental Machines sensors and platform can be used to continuously monitor, document, and maintain records of, monitoring activities in freezers, refrigerators, cold rooms, and other storage areas.
- Alert thresholds can be set to pre-defined acceptable limits and proactively notify when exceeded, creating an audit trail and capturing related corrective actions.
- Cloud-based storage provides sufficient readable access in excess of 10 years.
- The Elemental Machines system stores and can reproduce electronic records on demand through log download and reports.

### Meets System for User Generated Records Requirements:

- The Elemental Machines system provides annotation fields that allow users to document cleaning, disinfection, maintenance and inspection activities related to Elemental Machines sensors. This information can be collected into Reports ready to enter into the customer's QMS system.