

The Internet of Things Provides Revolutionary Approaches to Satisfying GxP Requirements

INTRODUCTION

Strict requirements for adherence to Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) have been in place for decades now. Innovative tools to enable compliance keep advancing, making it easier to adhere to these practices. One good example is the emergence of Internet of Things (IoT) sensors and their associated platforms. Whether in a laboratory or manufacturing environment, IoT sensors provide an inexpensive and scalable method for tracking and recording data of interest, such as temperature, pressure, humidity, light, power consumption and other variables.

ALERTING AND MONITORING OF ASSETS AND THE ENVIRONMENT

Small sensors, like the Element-T (temp), Element-A (ambient) and Element-D (data from OEM equipment) can easily be deployed in any lab or manufacturing environment to track and record data from assets or the environment, giving operations teams valuable insights.

PEACE OF MIND

Monitoring assets daily is a fundamental GxP requirement. Monitoring 24/7 gives operations personnel peace of mind that everything is secure and protected, even when no one is there. An operations director from a large pharmaceutical company said, "We had an instance where a walk-in cold room had a catastrophic failure at about 1 AM. We got an alert and my main tech was able to go in and save over \$100,000 worth of media."

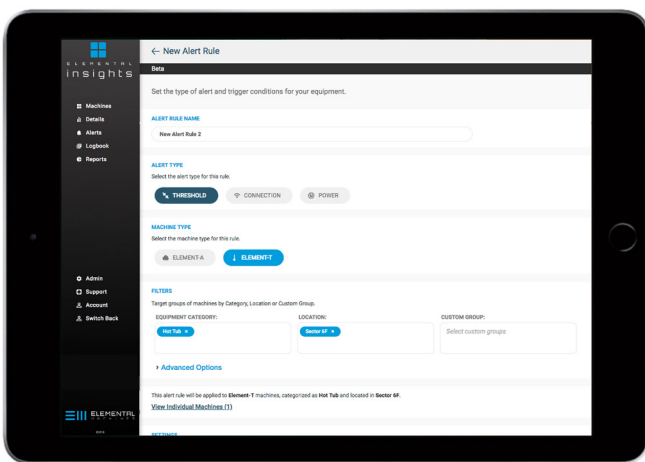
In another instance, a pharma lab was using IoT to monitor their incubators when they were alerted to an out of spec condition: "Just last night someone turned off an incubator because it was making a weird noise. Once it dropped 2 degrees outside of the allowed range, we got an alert, and could determine someone likely turned it off. We had the problem solved within 5 minutes, all while I was sitting on my couch at home," said the Lab Facility's Head of Operations & Safety.



PREDICTIVE MAINTENANCE

Collecting all this data also helps Operations see patterns in the data that might otherwise have been missed. One example comes from LabCentral, a life sciences incubator in Cambridge, MA.

“We had a refrigerator that was slowly increasing in temperature over a period of time. The average temperature was still inside the desired range, but the equipment clearly wasn’t functioning properly. We sent the temperature graphs to our service provider and they were able to make the diagnosis remotely and then order the replacement parts needed to fix it. This saved time and money for everyone involved” said Lyndsey Rissin, Sr. Manager, Lab Operations.



QUALITY AND COMPLIANCE CFR PART 11

IoT devices and platforms can enable CFR compliance in many ways. The FDA’s 21 CFR Part 11 establishes many requirements on electronic record keeping for industries that fall under its jurisdiction. CFR Part 11 has requirements around audit trails, user management, data security and user signatures. Cloud-connected IoT sensors allow you to meet data integrity requirements, such as redundant data storage, regular back up, time-stamped data records and an audit trail.

NIST-TRACEABLE

GMP facilities are required to regularly check the calibration of critical sensors. Typically this would be done by an ISO 17025 certified third party. If they find a temperature sensor (for instance) that does not correlate with their reading, the customer is left with two choices – replace the sensor or calibrate it in the field. It is typically best to recalibrate and adjust the sensor in the field.

The temperature reading of Element-T and Element-A sensors can be adjusted for slope and intercept based on the measurements taken during calibration. These adjustments are stored in the settings and applied to any future readings. In addition, a reminder will be set up to check the calibration again in one year.

One large analytical services laboratory made the switch to NIST-traceable sensors with in-situ calibration and estimated it saved them about two months worth of work each year calibrating their sensors.

DATA COLLECTION FROM OEM EQUIPMENT

Legacy equipment installed in labs and manufacturing facilities worldwide poses a challenge when it comes to data retrieval and storage. Extracting valuable data from this equipment has been challenging in the past. Element-D now automates this process for seamless integration. Element-D connects to standard equipment, such as lab balances, pH sensors, incubators, and other equipment. Analytical data and metadata can be merged in the Cloud, enabling monitoring, reporting and regulatory compliance.

One Manager of Lab Operations reports, "We are excited about Element-D and have deployed numerous devices on our incubators to track and record CO2 levels. Deployment was straightforward and all of the information is readily available to us on their cloud-based network. We are able to use this data to help simplify asset management, data collection and improve scientific best practices."



CONCLUSION

Cloud-connected IoT sensors provide an inexpensive way to continuously collect data from your equipment, environment and processes. Access to data, readily available in the Cloud, simplifies quality and regulatory compliance while also providing valuable insights into processes and equipment performance.

If you would like to learn more about IoT in regulated environments, please contact sales@elementalmachines.io.