

Precision, Compliance, and Efficiency: Abbott's Success with LogTag® Abbott



LOGTAG® ANALYZER

LogTag®



INTRODUCTION

Abbott is a global healthcare company specializing in diagnostics, medical devices, nutrition, and branded generic pharmaceuticals. In Colombia, Abbott delivers high-quality solutions across these sectors, focusing on improving public health.

NEED FOR A RELIABLE AND FDA 21 CFR PART 11 COMPLIANT MONITORING SOLUTION

Abbott required a comprehensive temperature monitoring solution that was accurate within $\pm 0.5^{\circ}\text{C}$, reliable, and robust, while ensuring compliance with industry regulations. As a healthcare leader, Abbott needed an easy-to-use, audit ready system that could seamlessly integrate into their existing operations and meet the stringent requirements of the United States Food & Drug Administration (FDA), specifically 21 CFR Part 11, which governs electronic records and signatures to ensure confidentiality, integrity, and authentication.

CHALLENGE:

- **Regulatory Compliance:** Ensuring adherence to FDA 21 CFR Part 11 for electronic records and signatures while maintaining data integrity and security.
- **Temperature Accuracy:** Accurate and reliable monitoring solution with precision better than $\pm 0.5^{\circ}\text{C}$ to safeguard temperature-sensitive healthcare products.
- **Temperature Monitoring:** Implementing a reliable temperature monitoring solution to safeguard temperature-sensitive healthcare products.
- **Operational Efficiency:** Streamlining compliance processes without disrupting day-to-day operations across Abbott's facilities in Colombia.

THE LOGTAG SOLUTION

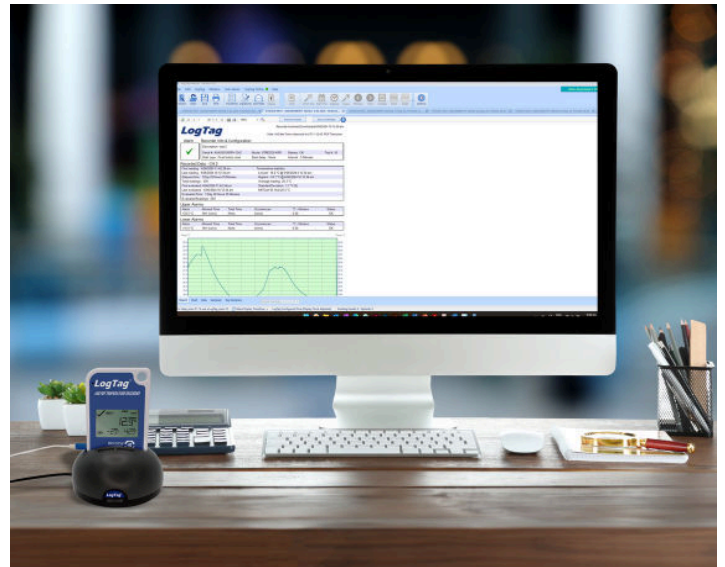
To achieve this, Global Sensors Colombia, LogTag's local distributor, worked closely with Abbott to identify the best solution for their needs. With local support, training availability, Spanish-language options, and responsive service, LogTag® was recognized as the ideal fit. Abbott adopted the LogTag® solution, utilizing the TRIX-8 temperature logger and LogTag® Analyzer software to achieve reliable, accurate, and efficient monitoring.

The TRIX-8 provided the high accuracy Abbott required, with better than $\pm 0.5^{\circ}\text{C}$ precision and industry-leading download speeds that saved valuable time during daily operations. More importantly, the solution integrated seamlessly into Abbott's workflow, making data collection and management for staff smoother and more efficient.

Installation was straightforward, with staff able to easily install LogTag® Analyzer and set up the user authenticator within the 21 CFR Part 11 Digital Signature Suite.

Minimal training was needed, and users quickly adapted to downloading data, setting up devices, and maintaining compliant records.

The LogTag® system made audits simple, with audit-ready information always available and secure stored. Abbott benefited from improved operational efficiency, saving time across multiple facilities in Colombia while ensuring compliance and maintaining confidence in the accuracy of their temperature-sensitive healthcare product monitoring.



CONCLUSION

Abbott's successful implementation of LogTag's solution has reinforced its commitment to regulatory compliance and product quality. LogTag® made it simple for Abbott to comply with 21 CFR Part 11, with staff easily capturing and securely storing data during audits. Compliance became straightforward, and information was always available and audit-ready. By utilizing LogTag® System, Abbott has enhanced operational efficiency while maintaining the highest standards for temperature-sensitive healthcare products.

