Compliance, Risk and Cost of Ownership Comparisons for Critical Laboratory and Facility Continuous Monitoring - Wired, Wireless and Standalone Systems

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Worldwide, there is growing concern about how to protect public safety and increased cooperation among regulatory agencies to audit laboratories and facilities subject to GLP and GCP guidelines. As agencies focus inspection resources on risk-based areas, there is greater scrutiny to existing regulations such as the US Food and Drug Administration's review of how the storage of electronic data, 21 CFR Part 11, is being applied in the laboratory environment and elsewhere. Recently, the FDA has considered amendments to GLP regulations to include enforcement of sites that were previously excluded from GLP inspections.

Moreover, the ever-increasing costs for R&D efforts to create medicines the clinical studies that prove them out, and the post-marketing tests to validate quality are such that the economic costs of failure in the totality of monitoring systems are greater than ever before. All monitoring methods, whether wired, wireless or standalone instrumentation, need to be evaluated for systemic weaknesses that allow human error to compromise product quality, system failure probabilities and overall costs of ownership.

This paper discusses six approaches to monitoring critical environments such as refrigerators, freezers, incubators, rooms, and other controlled storage areas for specimens and products: 1) wired systems with UPS power backups; 2) wired systems with UPS and use of PoE (Power over Ethernet); 3) wireless WiFi; 4) wireless mesh; 5) non-networked/standalone data loggers; and 6) chart recorders.

Briefly, chart recorders are the oldest technology - paper-based, powered either by AC or batteries. Standalone non-networked data loggers also use either AC or batteries, and require manual downloading of data at regular intervals. Wired networking technology has been around for decades. While this technology continues to evolve and remains the mainstay of most life science operations, wireless has fast become an interesting alternative. Each method of communicating data has its advantages and disadvantages. When it comes to regulatory-compliant applications involving public health, however, the criteria for using one method over the other should be well understood. The following two charts provide an overview of risk factors and cost-of-ownership differences between the continuous monitoring modalities.

Risks	Chart Recorders	Standalone Data Loggers	Wired—UPS only	Wired—PoE	Wireless WiFi	Wireless Mesh
Power outage risk impacts to data loss	Moderate (3-yr battery) to High (AC only)	Moderate—3-yr battery and data storage capacity	Low—dependent on device battery maintenance	Low—dependent on device battery maintenance	Low to Moderate—dependent on device and radio battery maintenance	Low to Moderate—dependent on device and radio battery maintenance
Human error risk—Adhering to maintenance schedules	Highest—charts, pens, batteries need frequent attention	High—data downloading before overload capacity and battery life	Lowest	Lowest	Low (if AC-powered)—Higher (dependent on battery replacement frequency)	Moderate—unpredictable drains on battery life require more frequent attention
Data security risks	High—paper chart data can be manipulated	Low	Low	Low	Moderate—access to data possible from outside facility	Low—proprietary networks prevent easy access
Risk of gaps in data records due to network downtime	Not Applicable	Not Applicable	Low—with redundant data capability, otherwise high risk	Low—with redundant data capability, otherwise high risk	Low—with redundant data capability, otherwise high risk	Low—with redundant data capability, otherwise high risk
Risks of IT training gaps and breakdown in IT staff turnovers	Not Applicable	Not Applicable	Low—Ethernet protocols widely understood	Low—Ethernet protocols widely understood	Low—WiFi protocols widely understood	Moderate—proprietary networks requiring additional training
Combined sources of human error posing risks to quality	High—frequent staff hours required to stock supplies, change paper & pens; check readings; retrieve records	Moderate—adherence to data download schedules required and to check for excursions and/or change batteries	Low—requires adherence to schedule of changing device batteries	Lowest—system least dependent on battery maintenance	Low—requires adherence to schedule of changing device batteries	Low to Moderate—requires adherence to schedule of changing device batteries and IT training on proprietary protocols

Figure 1. Risk Factors - Continuous Monitoring Modalities

The following chart provides general guidelines only to risks associated with meeting GxP requirements.

Cost of Ownership	Chart Recorders	Standalone Data Loggers	Wired—UPS only	Wired—PoE	Wireless WiFi	Wireless Mesh
Inventory costs required for operation	High—paper, pens, batteries	Moderate to Lowest with 3 to 10-year battery systems	Moderate to Lowest with 3 to 10-year battery systems	Moderate to Lowest with 3 to 10-year battery systems	Moderate to Lowest with 3 to 10-year battery systems	Highly variable depending on need to change batteries
Labor required for operation	Highest—daily or weekly maintenance	High—frequent data downloads	Low	Low	Low	Variable—dependent on need to change batteries
Costs for adding AC power or network cabling	Low	Low to Moderate	Low to Moderate	Low to Moderate	Lowest	Lowest
Labor costs for audit compliance	High—deviation reporting and manual retrieval & compilation of records	Moderate to High—deviation reporting and labor to show complete records	Lowest (with redundant data capability) to High (without redundant capability)	Lowest (with redundant data capability) to High (without redundant capability)	Lowest (with redundant data capability) to High (without redundant capability)	Lowest (with redundant data capability) to High (without redundant capability)
Energy and/or battery costs	Low to Moderate—dependent on battery type	Low to Moderate—dependent on battery type	Low to Moderate—dependent on battery type	Lowest—no local battery or AC, power required for PoE devices	Low to Moderate—dependent on battery type	Low to Moderate—dependent on battery type
Potential costs from human error	Highest—requires frequent human intervention	High—requires frequent human intervention	Low with redundant data, remote alarming & infrequent battery changes; High without these capabilities	Low with redundant data, remote alarming & infrequent battery changes; High without these capabilities	Low with redundant data, remote alarming & infrequent battery changes; High without these capabilities	Low with redundant data, remote alarming & infrequent battery changes; High without these capabilities

Figure 2. Costs of Ownership Factors - Continuous Monitoring Modalities

The following chart provides general guidelines only for some of the more salient factors affecting costs of ownership related to the six monitoring options. Varying facility sizes and scale of operations affect the impacts of various cost factors.

We will now examine each of the six modalities with their respective challenges and advantages.

Paper-Based Chart Recorders

In the last decade, leading life science companies - pharmaceutical, biotechnology, medical devices - and their suppliers are replacing paper chart recorders. Most quality managers consider this obsolete technology due to the obvious risks of handling paper-based records and limited or no alarm notification.

Chart recorders rely on humans for daily or weekly checks to replace paper, check pens and write deviation reports. In addition, regulatory agencies encourage the move away manually intensive processes to more automation with the purpose of tightening up quality systems, and make better use of quality resources.