Challenges and Practical Use Cases:

Biotechnology Challenges in Environmental Monitoring

Contents

Purpose of the whitepaper

The purpose of this whitepaper is to outline the key environmental monitoring challenges faced by the biotechnology industry and to explore best practices for ensuring data integrity, compliance, and product safety. It highlights how parameters such as temperature, humidity, and pressure directly influence product quality and regulatory outcomes in biotech environments. By examining issues like sensor reliability, calibration accuracy, and system integration, the paper aims to help readers identify potential risks and practical solutions.

Introduction to biotechnology

Biotechnology encompasses a broad range of scientific disciplines that utilize living systems, organisms, or derivatives to develop products and processes that benefit society. From the production of vaccines and biopharmaceuticals to genetic engineering, fermentation, and diagnostic development, biotechnology plays a pivotal role in modern healthcare and life sciences. These processes are often highly sensitive to environmental influences such as temperature, humidity, pressure, and contamination, all of which can affect the quality, stability, and reproducibility of results.

Given this sensitivity, environmental control and monitoring have become fundamental to maintaining product integrity and ensuring compliance with regulatory standards such as FDA 21 CFR PART 11, Good Manufacturing Practice (GMP) and EU GMP Annex 1 [1-3]. In biotechnology laboratories and manufacturing facilities, environmental parameters not only impact biological activity but also determine the validity of experimental outcomes and the consistency of production batches.

The rapid evolution of biotech technologies has intensified the need for precise and continuous environmental data. Accurate measurement and documentation of these parameters support not only regulatory audits but also scientific accountability. As a result, environmental monitoring has evolved from a compliance necessity to a core component of quality assurance and operational excellence.

Environmental monitoring in biotech: Why it matters

Biotech operations, from R&D laboratories to large-scale manufacturing facilities, depend on stable, well-controlled conditions to maintain the integrity of cell cultures, reagents, and finished products. Temperature shifts may denature proteins or inhibit cell growth, excess humidity can promote microbial contamination, and changes in differential pressure may compromise sterile areas. For these reasons, the physical environment in which biotech operations take place directly influences the safety and efficacy of the products being developed or manufactured. Reliable monitoring provides assurance that each step in the process occurs under validated conditions, protecting both scientific reproducibility and product quality. Proper environmental monitoring also offers traceability: when data are accurately collected and securely stored, deviations can be investigated and root causes identified with confidence.

Regulatory agencies, including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), emphasize environmental monitoring as an essential component of Good Manufacturing Practice (GMP). Guidance documents such as FDA 21 CFR Part 11, EU GMP Annex 1, and Annex 11 stipulate not only the need for continuous monitoring, but also the requirement for accurate calibration, secure data handling, and complete audit trails [1,4]. Compliance with these standards ensures that every environmental data can be traced, verified, and validated.
Beyond regulatory expectations, robust monitoring delivers tangible operational benefits. Reliable environmental data enable early detection of process deviations, preventing costly product losses and reducing downtime. Trend analysis of temperature or humidity profiles can reveal patterns that support predictive maintenance, energy optimization, and improved process stability. Moreover, real-time alerts and automated reporting systems empower quality teams to respond immediately to potential risks, reinforcing both data integrity and product safety.

However, implementing and maintaining such systems in a biotech setting is far from straightforward. The complexity of biological processes, combined with the stringent regulatory landscape and the diversity of laboratory and production environments, introduces a unique set of challenges. Issues such as sensor reliability, calibration accuracy, system integration, and scalability must all be addressed to ensure that monitoring data remain trustworthy and compliant. The next section explores these unique challenges.

Unique challenges in biotechnology

Regulatory landscape

Environmental monitoring in biotechnology is governed by a rigorous and evolving regulatory framework designed to protect product quality, patient safety, and data integrity. Authorities such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) require that all parameters capable of influencing product quality be continuously monitored and documented in a compliant manner. These expectations are formalized through globally recognized GxP guidelines.

Within the European Union, the EU GMP Annex 1 establishes detailed requirements for the manufacture of sterile medicinal products. It defines environmental monitoring as a core quality control activity, emphasizing the need for reliable sensors, continuous measurement, and immediate response to deviations. Annex 1 also underscores the importance of trend analysis and risk-based monitoring, requiring systems that not only capture data but also enable proactive assessment of environmental performance over time.

Complementing Annex 1, EU GMP Annex 11 focuses specifically on computerized systems used in GMP environments. It outlines the principles of validation, data integrity, and electronic record management, requiring that systems be designed to ensure accuracy, reliability, and consistent intended performance. Annex 11 mandates secure user access controls, audit trails, and periodic system reviews to verify that data remain complete and unaltered throughout their lifecycle.

In the United States, FDA 21 CFR Part 11 defines similar expectations for electronic records and signatures. It establishes that electronic data must be equivalent in trustworthiness to paper records and handwritten signatures. To achieve this, systems must implement measures such as unique user authentication, audit trails that capture all changes and deletions, and validated processes for data collection and storage. The FDA also expects organizations to demonstrate that their monitoring solutions can prevent, detect, and report unauthorized access or data manipulation.

Together, these regulations create a harmonized global standard: data must be accurate, secure, traceable, and readily retrievable. In practical terms, this means environmental monitoring systems must not only measure critical parameters but also guarantee the integrity of every data point before, during, and after acquisition. Compliance extends beyond hardware reliability to encompass software design, cybersecurity, and long-term data management practices.

Modern systems such as testo Saveris 1 are built in alignment with these expectations, incorporating validated software architectures, encrypted communications, and comprehensive audit trails to maintain full regulatory compliance. By adhering to these principles, biotech organizations can ensure that their monitoring infrastructure supports both operational excellence and global regulatory readiness.

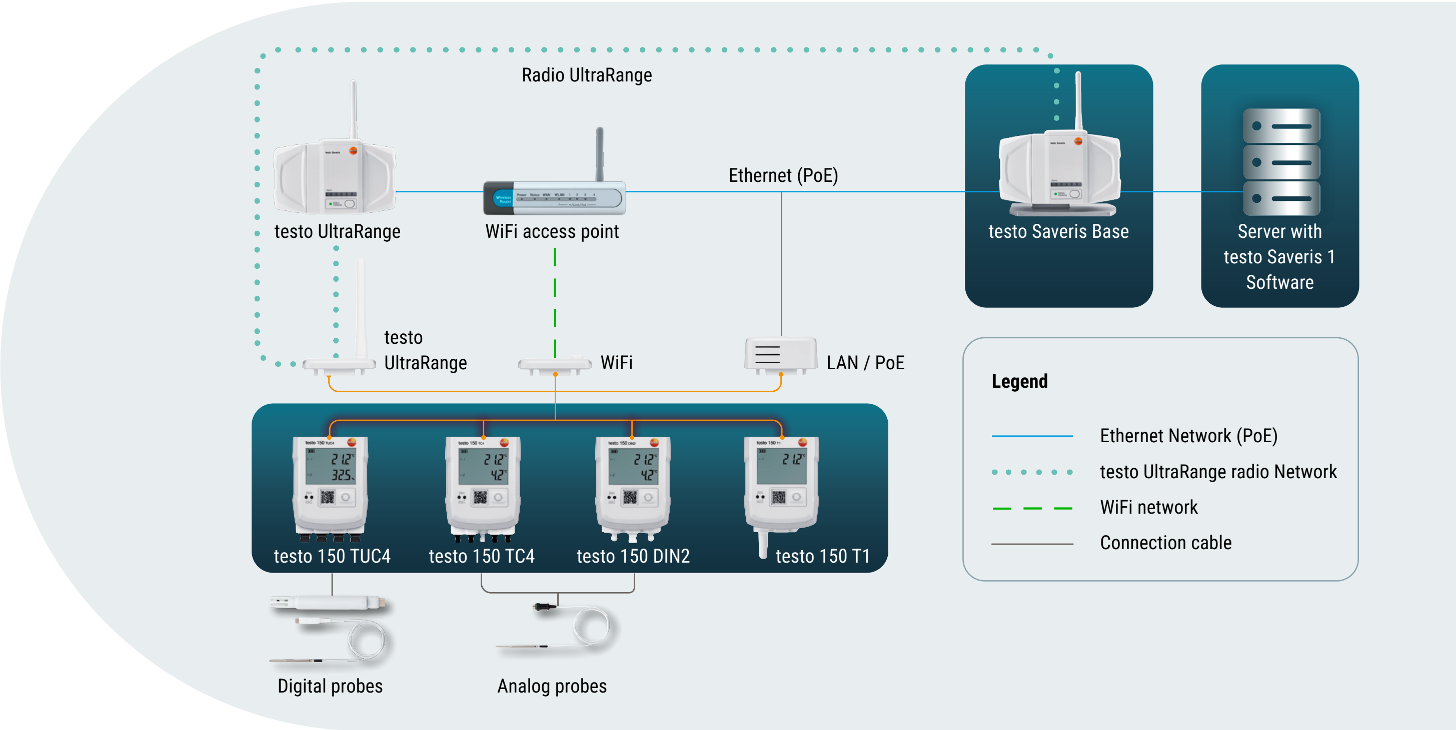
Data security and redundancy

The regulatory expectations outlined in Annex 11 and 21 CFR Part 11 make one principle abundantly clear: collecting data is not enough — it must be demonstrably trustworthy. For environmental monitoring systems, this means ensuring that data are protected against loss, alteration, or unauthorized access at every stage of their lifecycle. Any gap or inconsistency not only undermines process confidence but can also render entire batches or studies non-compliant in the eyes of regulators.

Data security in this context refers to the protection of environmental records against tampering or unauthorized access. To meet Annex 11 and 21 CFR Part 11 requirements, monitoring systems must implement controlled user authentication, encrypted communication, and complete audit trails.

Every change, whether a configuration adjustment or alarm acknowledgment, must be documented with timestamp, user, and action. This ensures that no data point can be modified without traceability.

Redundancy, meanwhile, protects against data loss caused by hardware failure, power outages, or network interruptions. In a non-redundant system, a brief communication loss could produce gaps in monitoring history that invalidate an entire qualification report or batch record. To avoid this, compliant systems employ multi-level data storage: measurements are temporarily buffered within the sensor or logger itself, then forwarded to a local base station or gateway, and finally synchronized with a central database or cloud environment. Even if one layer fails, the others preserve the complete data history.



testo Saveris 1 overview, with three-layer redundancy layers highlighted (blue box).

Modern solutions, such as testo Saveris 1, exemplify this principle by storing measurements in the data logger, in the base, and again in the server itself. This three-layer approach guarantees uninterrupted data continuity while enabling automated backup and disaster recovery procedures.

Ultimately, data security and redundancy are not optional features, they are embedded compliance requirements.

Integration with other systems

Due to the high need for operation automation modern operations grew to rely on a complex digital ecosystem. Most biotech operations have several data acquisition and/or data handling systems coexisting with each other. Good examples of such system are an environmental monitoring system, a Laboratory Information Management Systems (LIMS), a Building Management Systems (BMS), a Manufacturing Execution Systems (MES), a Quality Management Systems (QMS), or even various process control platforms. Each of these systems generates and stores critical data while operating independently, resulting in isolated data silos.

Integrating environmental monitoring data with other digital systems unlocks significant value. For example, linking temperature or humidity data from a monitoring system with LIMS sample records can provide a complete environmental history for each batch or experiment. Similarly, connecting with BMS allows for coordinated control actions such as adjusting HVAC parameters when deviations are detected, or automatically halting production until conditions return to validated ranges. Such integrations not only enhance process control and quality assurance but also reduce the risk of human error by minimizing manual data entry.

To achieve this level of connectivity, monitoring systems must be built with open communication interfaces that allow data exchange in standardized, secure formats. Two of the most common integration technologies are APIs and webhooks.

An Application Programming Interface (API) is a structured method that allows one software system to request and retrieve specific information from another. In environmental monitoring, an API enable a LIMS or QMS to automatically pull validated temperature data directly from the monitoring database for inclusion in batch records or audit reports. APIs provide flexibility, as they can support both real-time and scheduled data transfers while maintaining data integrity and access control.

Webhooks, on the other hand, enable event-driven communication. Instead of requesting data periodically, a webhook automatically sends information from one system to another whenever a predefined event occurs, such as an out-of-tolerance condition or alarm acknowledgment. This mechanism supports faster response times and more automated workflows, allowing quality teams or facility managers to be instantly informed through other connected systems when deviations occur.

Systems designed with these integration capabilities, such as the testo Saveris 1, allow organizations to consolidate monitoring data within broader digital ecosystems while maintaining full compliance with data integrity requirements under FDA 21 CFR Part 11 and EU GMP Annex 11. The result is a unified, data-driven infrastructure that enhances transparency, supports traceability, and empowers smarter decision-making across the entire value chain.

As the biotech industry continues to digitalize, integration is no longer a technical luxury but a critical enabler of operational excellence. Choosing monitoring solutions that support seamless interoperability ensures that data not only fulfill compliance obligations but also drive continuous improvement and innovation.

Scalability

The biotechnology sector is undergoing rapid expansion with a global market projection of 4.61 trillion USD by 2034 [5]. Roughly 11 – 14% compound annual growth [5]. As each biotech companies' business grows, expanding facilities, investing in more R&D labs, manufacturing and new operations, so do the amount of environmental measuring point grow. What begins as a modest monitoring setup in a single facility can quickly evolve into a multi-site network.

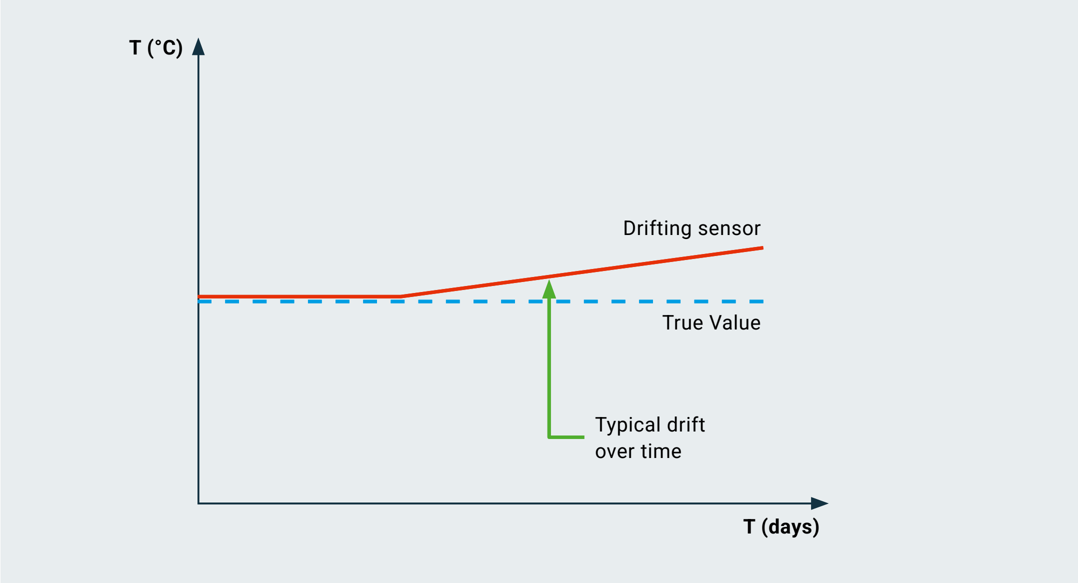
This acceleration creates a distinct challenge: how to ensure environmental monitoring systems remain reliable, compliant, and manageable as they scale. A system that performs well in a single laboratory may struggle to deliver consistent data integrity and centralized oversight once extended across multiple sites or regulatory regions. Fragmented solutions often lead to disconnected data, inconsistent calibration practices, and increased validation burden.

It is therefore important to choose environmental monitoring systems wisely. A truly scalable monitoring system must combine modularity, connectivity, and data management. Modularity allows the system to adapt to different infrastructures (e.g. Wi-Fi, Ethernet, or long-range radio communication, like the testo UltraRange) ensuring compatibility with diverse facility layouts and physical constraints. A second major feature of a scalable monitoring system is the capacity to add new measuring points (or data loggers) as the need increases. On the data side, scalability depends on a robust database architecture capable of handling large and growing volumes of environmental data while maintaining performance, security, and traceability. Databases like MongoDB can deliver this.

Equally important is a system's capacity to grow with the organization. Continuous software updates, aligned with evolving data integrity standards and cybersecurity requirements, ensure ongoing compliance with regulations such as FDA 21 CFR Part 11 and EU GMP Annex 11. Scalable monitoring platforms like testo Saveris 1 exemplify this approach offering modular hardware, centralized data storage, and flexible expansion paths that accommodate both current operations and future growth.

Sensor reliability and calibration

All sensors, regardless of design or manufacturer, experience drift over time. Drift describes the gradual deviation between a sensor's measured value and the true physical condition it is intended to capture. It often occurs so subtly that it goes unnoticed in daily operation. Some forms of drift are systematic, such as a probe that consistently reads slightly higher with each passing month, while others are random, manifesting as irregular fluctuations that make measurements less repeatable. In both cases, the result is the same: growing uncertainty that, if undetected, can compromise process decisions, regulatory compliance and ultimately, patient safety.



Representation of a sensor drifting overtime from the real value.

Several factors accelerate drift in biotechnology environments. Some examples could be repeated exposure to thermal stress during sterilization cycles can permanently affect the resistance of temperature probes; high humidity and condensation, common in incubators and cold rooms, may saturate sensing elements or lead to corrosion; disinfectants slowly deteriorate sensor surfaces, while mechanical strain on cables causes intermittent inaccuracies. Even under ideal conditions, electronic components naturally age, gradually shifting their baseline response.

Because drift is inevitable, it must be actively managed rather than ignored. While strategies like baseline comparison, trend analysis and self-diagnostic tools can help detect drift early. The only reliable way to prevent and correct drift is through regular calibration. This process compares sensor readings against certified reference standards and quantifies deviations. If a reading exceeds tolerance, action must be taken. Regulators make this expectation explicit, but the practical application can be summarized simply:

- Define acceptable deviation limits based on process criticality
- Verify sensors at defined intervals
- Calibrate against certified reference standards, ideally through ISO/IEC 17025 or DAkkS-accredited calibration providers [7-8]
- Document calibration results and trends, using them to detect early degradation before failure occurs

This lifecycle perspective is essential when evaluating environmental monitoring solutions. It is not enough to select accurate sensors at installation. Long-term integrity depends on how easily those sensors can be recalibrated, replaced, or requalified. A suitable monitoring partner must therefore provide both robust hardware and structured calibration services, supported by digital certificates, automated reminders, and seamless documentation workflows.

In short, drift cannot be eliminated, but it can be controlled. The difference between trustworthy data and questionable data lies not in how advanced a sensor is on the first day of use, but in how responsibly it is verified and maintained over time.

Use cases

The challenges outlined in the previous section are not abstract concepts. They manifest daily across real biotech operations, whether during active manufacturing or long-term product storage. To illustrate how these factors converge in practice, the following two case studies examine different points in the biotechnology value chain. The first focuses on regenerative medicine manufacturing, a field relying on sterile cleanrooms, multi-stage temperature control, and rapid alarm response. The second addresses large-scale deep-freeze storage under GDP conditions, where the challenge shifts from short-term process monitoring

to long-term stability assurance across thousands of units. Together, they demonstrate how an environmental monitoring solution like testo Saveris 1 addresses their main challenges.

Regenerative medicine manufacturing

Regenerative medicine production represents some of the most monitoring-critical environments in biotechnology. Unlike chemical or synthetic drug manufacturing, these processes rely on living cells, temperature-sensitive biological components, and multi-stage workflows that span cryogenic storage, controlled thawing, incubation, aseptic processing, and finished product storage. Each stage depends on narrowly controlled environmental parameters (e.g. temperature, humidity, and cleanroom pressure) and a single lapse at any point can compromise years of development or destroy irreplaceable patient-derived material.

What makes this challenge even more pronounced is that process risk increases as companies scale. Manufacturers still rely on fragmented monitoring setups: a mixture of paper records, standalone data loggers, and manual alarm notification chains. These approaches may be sufficient in small pilot operations, but they quickly become untenable when:

- Multiple controlled rooms and storage units must be supervised simultaneously
- Different temperature setpoints (e.g. −80 °C storage, 2–8 °C transport, +37 °C incubation) must be validated and tracked in parallel
- Alarm responsibility must be shared across teams rather than resting with a single operator
- Regulatory expectations move from documented readings to fully traceable, audit-ready data lifecycles

A practical illustration comes from Orthocell, a regenerative medicine manufacturer specializing in cell-based therapies for musculoskeletal disorders.
As demand for its products increased, Orthocell expanded its manufacturing capacity and faced a series of monitoring challenges typical of growing biotech operations:[9]

- Multiple temperature-dependent process stages, each requiring validated monitoring at different setpoints, often across separate cleanroom and storage areas
- Reliance on partially manual record-keeping, which increased the risk of transcription errors and limited real-time decision-making
- Single-point alarm notification, where only one operator received deviation alerts, creating dependency and delay during critical incidents
- Limited visibility across the site, making it difficult for operators to quickly assess the status of all controlled areas

To overcome these constraints, Orthocell transitioned to the centralized environmental monitoring testo Saveris 1, that consolidated all measurement points into a single, site-wide system. Instead of relying on individual displays or manual checks, real-time temperature and environmental data from storage units, cleanrooms, and production areas were visualized on a digital site map, giving operators instant situational awareness. Alarm notifications were no longer limited to one designated contact; alerts were distributed simultaneously via email and SMS to multiple qualified personnel, ensuring coordinated response even outside normal working hours. All measurements and user interactions were automatically logged within a 21 CFR Part 11-compliant audit trail, eliminating manual recordkeeping and strengthening traceability. Just as importantly, the system's modular architecture allowed new rooms and monitoring points to be added without reengineering the setup, supporting Orthocell's ongoing expansion without disrupting compliance or workflow.

The impact of these technical improvements was demonstrated during a facility-wide power failure. Due to distributed alarms and redundancy in data logging, multiple operators were notified simultaneously and initiated recovery procedures within minutes. As a result, over 15 years' worth of patient cell material was preserved without loss.

Beyond risk mitigation, the testo Saveris 1 system enabled Orthocell to transition from paper-based documentation to a fully digital, GMP-compliant monitoring workflow. This improved audit readiness and reduced administrative burden without requiring specialized IT or validation expertise during deployment.

Vaccine and biologics storage

Just as regenerative medicine manufacturing requires precise environmental oversight to protect cells during processing, vaccine and biologics storage facilities face a different but equally demanding challenge: maintaining constant conditions without interruption long after production has ended. The dominant risks shift from contamination or process deviations to thermal excursions, infrastructure failures, and traceability gaps across multiple ultra-low temperature units.

Ensuring quality in this phase requires far more than simply keeping temperatures low, it demands a validated cold-chain system capable of proving that conditions were consistently maintained at all times. These requirements become increasingly complex when scaling operations from a small number of freezers to hundreds or even thousands within a distribution facility. What may work at laboratory scale becomes unmanageable at industrial scale without a structured monitoring and qualification strategy.

A practical example comes from Simon Hegele, a global logistics provider that expanded into pharmaceutical distribution by converting an existing warehouse into a GDP-compliant deep-freeze storage hub in Karlsruhe, Germany [6]. The project involved commissioning 1,700 ultra-low temperature freezers for pharmaceutical storage at −75 °C, with an allowable corridor between −85.4 °C and −45 °C.[10]

The approach taken addressed several core challenges in pharmaceutical cold storage:

- Each freezer was equipped with an individual temperature sensor, qualified and calibrated to ISO/IEC 17025 and DAkkS standards.
- A dedicated radio network was deployed across the warehouse to allow gateways and loggers to communicate reliably despite insulation shielding.
- Warehouse environmental conditions were mapped in both summer and winter, first in the empty state (OQ) and later under full load (PQ), to establish validated temperature distribution limits.
- Monitoring extended beyond stationary storage, with transport trolleys equipped with integrated sensors to maintain traceability during internal movement.
- Alarm and escalation levels were defined collaboratively with operators, ensuring that notification workflows aligned with real-world response capabilities rather than arbitrary thresholds.

Once deployed, the monitoring system provided centralized visibility across all freezers and warehouse zones, with live status data accessible in real time. Automatic monthly reporting, user-specific documentation, and 21 CFR Part 11-compliant audit trails eliminated manual record assembly. Technical faults and temperature excursions could now be detected and acted upon proactively, with immediate alerts distributed to predefined personnel.

This implementation demonstrates a broader lesson for pharmaceutical logistics and biotech storage providers: scaling deep-freeze capacity is not merely a hardware exercise, it is a calibration, qualification, and data management challenge. Sensors must be validated, freezers must be qualified under real operating conditions, networks must be hardened against interference, and alarm strategies must match true operational response capacity.

By treating monitoring as an integrated infrastructure rather than a set of disconnected devices, Simon Hegele successfully converted an existing warehouse into a GDP-compliant distribution hub in under a year without compromising traceability or risking product integrity during transition.

Conclusion

The biotechnology sector operates under environmental constraints far more stringent than those found in most industrial settings. Whether in cleanrooms, incubators, stability chambers, and ultra-low temperature storage, control of the physical environment is not optional, it is fundamental to product viability and regulatory credibility.

This whitepaper identified several non-negotiable requirements for effective monitoring in biotechnology. Sensors alone do not constitute a reliable monitoring system; their readings are only trustworthy when supported by proper calibration, ongoing verification, and redundancy in data storage. Compliance is not achieved simply by recording values, it depends on being able to prove data integrity through audit trails, secure user access control, and validated software handling. System integration is no longer optional. When environmental monitoring platforms operate in isolation from LIMS, BMS, QMS, or MES systems, critical context is lost, and blind spots emerge. Scalability must be treated as a design requirement rather than a future upgrade. Solutions that work for a handful of freezers or a single laboratory often fail when replicated across multiple buildings or sites.

Finally, monitoring effectiveness is measured not by the precision of a sensor but by the quality of the response it enables. An alarm sent to the wrong person, or delivered too late, is functionally equivalent to having no alarm at all.

From the two use cases shown, we can learn that even competent manual or semi-digital monitoring methods eventually fail under scale. Orthocell's paper records and single-recipient alarm setup may have been acceptable, but as additional cleanrooms and cold storage units were added, the approach transformed from manageable to risky. Second, they demonstrate that alarm detection is meaningless unless paired with alarm delivery. A deviation is not truly captured until the right people receive it fast enough to intervene. Third, calibration and qualification effort does not scale linearly with device count, it explodes unless sensors, documentation, and mapping are managed through a centralized strategy. Simon Hegele's success with 1,700 freezers was not due to the hardware itself, but to the testo Saveris discipline of treating validation as a coordinated lifecycle.

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