



Environmental Monitoring in CGT

A Guide to Monitoring Strategies for Cell and Gene Therapy Facilities



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Introduction: Environmental Monitoring in Cell and Gene Therapy

Cell and gene therapy is transforming medicine, offering life changing hope to patients with conditions that once had no treatment options. These therapies bring the potential for cures where only symptoms were managed before, opening doors to treatment strategies once considered impossible. But with this promise come new challenges: therapies that are highly personalized, manufacturing processes that push the boundaries of technology, and evolving regulatory expectations that continue to shape the landscape.

In this demanding environment, environmental monitoring is more than a regulatory obligation, it's critical for patient safety, product quality, and operational excellence. The integrity of these therapies depends on tight control of vital parameters at every stage, from personalized cell collection to manufacturing and long-term storage. A single deviation in temperature, humidity, or pressure can compromise years of research and, more importantly, a patient's treatment.

Cold storage, including cryogenic, ultra-low, and other critical temperature-controlled solutions are more than just equipment; they're lifelines. A single freezer failure could impact therapies for hundreds of patients, with consequences that extend far beyond financial loss. These therapies can't simply be replaced by making another batch. Cleanrooms, incubators, and specialized equipment like automated cell processors demand constant oversight to maintain

consistency and sterility, protecting the therapies that patients and families depend on. Facilities need environmental monitoring systems that demonstrate control and readiness for audits while meeting regulators' expectations for real-time, validated data. As cell and gene therapy expands into outpatient settings and commercial production grows, the need for robust, adaptable monitoring systems has never been greater. Relying on manual checks or periodic data logs is no longer enough. Facilities must invest in systems that provide immediate visibility, proactive alerts, and defensible records, systems that turn data into actionable insights that protect both products and patients.



This guide is designed to help you understand the critical role of environmental monitoring in cell and gene therapy. It also outlines how to build a strategy that supports your scientific mission, regulatory requirements, and, ultimately, the patients you serve.

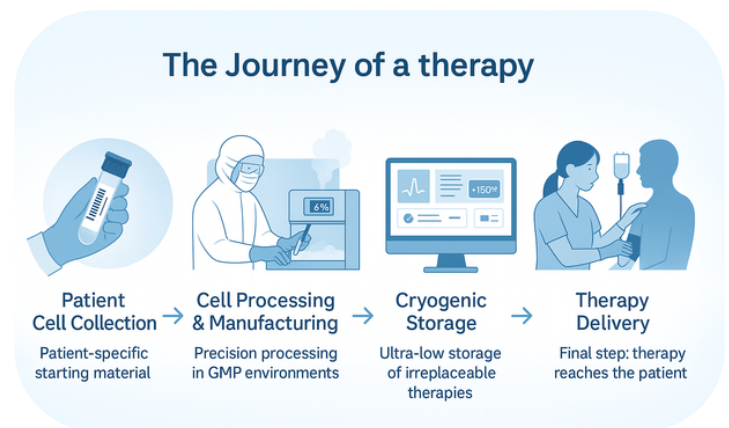
Why Monitoring Matters in CGT

Environmental monitoring in cell and gene therapy isn't just a routine task, it's an essential part of ensuring that therapies remain viable and reliable, often representing a patient's last hope. Each therapy is unique, derived from a patient's own cells, making it irreplaceable. Unlike standard pharmaceuticals, where a lost batch can be remade, the loss of a cell therapy batch means the loss of a patient's treatment, and sometimes their only chance at recovery.

Consider the journey of a therapy: starting with patient cell collection, continuing through complex manufacturing, and culminating in long-term storage until administration. Every step carries its own set of risks and demands consistent oversight. A single temperature excursion in a cryogenic freezer can compromise therapies stored for hundreds of patients. These therapies can't simply be replaced by pulling a new product off the shelf. For many patients, this therapy represents months of preparation, collection, and processing, and in some cases, their best hope for survival.

That's why monitoring every step, from cell collection and processing to storage and distribution, is essential. Tight control of critical parameters like temperature, humidity, pressure, and device status ensures that every batch meets the highest quality standards. Real-time alerts and continuous oversight give facilities the ability to catch deviations early, respond quickly, and protect both therapies and patients.

In an industry where patient-specific therapies are the standard, monitoring is the bridge between groundbreaking science and safe, reliable treatment. It's the assurance that therapies meet the highest standards of quality and safety, every time.



Understanding Risk: Storage, Manufacturing, and Beyond

Risk management in cell and gene therapy is a constant balancing act, and no area presents more risk than storage. Unlike traditional pharmaceuticals, cell and gene therapies are often patient-specific and cannot be replaced. A single cryogenic freezer might hold therapies for hundreds of patients, each representing a treatment that can't be replicated.

A failure in that freezer could mean the loss of irreplaceable treatments and devastating consequences for patients waiting for hope. Beyond storage, manufacturing introduces its own set of complexities. Cell and gene therapies often require around-the-clock production processes involving specialized equipment in cleanrooms and GMP suites.

Any environmental deviation, such as a shift in room pressure, a fluctuation in temperature, or a spike in humidity, can compromise batch quality or halt production altogether. Continuous monitoring of these parameters is essential to ensure every therapy batch is produced within the required specifications.

The regulatory landscape adds yet another layer of challenge. Agencies like the FDA (21 CFR Parts 11), EU GMP bodies, WHO, CDC, and MHRA each bring specific expectations and interpretations of compliance.

A system that satisfies one regulator may not meet the requirements of another, creating a dynamic and sometimes unpredictable compliance environment. Facilities must be prepared to navigate these varying demands, ensuring they have the systems and processes in place to demonstrate control and readiness at all times.

Understanding these risks, and proactively planning for them, is essential to safeguarding therapies and protecting the patients who depend on them.

Core Parameters to Monitor

Monitoring the right environmental parameters is the foundation of producing safe, consistent cell and gene therapies. Each parameter plays a crucial role in protecting therapies that are often irreplaceable and ensuring that processes align with regulatory expectations.

Freezer Temperature and Status Indicators

Cold storage, including cryogenic, ultra-low temperature, and other temperature-controlled solutions, are essential for safely storing therapies. Continuous temperature monitoring ensures that therapies remain viable, while status indicators such as power status and door closure provide added assurance that equipment is functioning as intended. This layer of monitoring helps facilities respond quickly to potential failures and avoid catastrophic losses.

CO₂ and O₂ in Incubators

Cell growth and viability hinge on stable incubator conditions. CO₂ levels regulate pH in culture media, and even small deviations can compromise cell health and

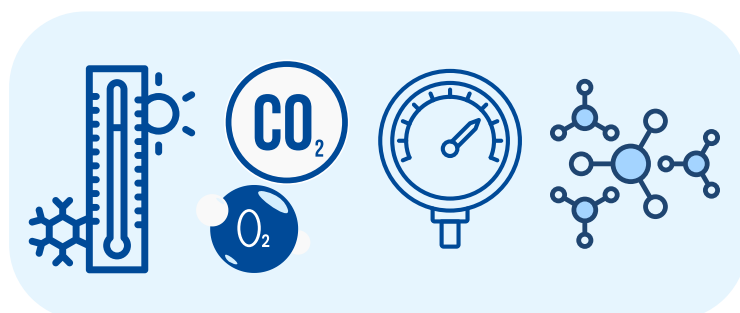
affect therapy quality. O₂ monitoring supports specific oxygen requirements during cell expansion and genetic modification processes.

Air Exchanges and Differential Pressure in Cleanrooms

Proper airflow and pressure differentials prevent contamination and ensure sterile conditions. Monitoring these parameters helps facilities maintain regulatory compliance and product integrity.

Live Particle Counting

Airborne particles can carry contaminants that compromise product sterility. Real-time particle counting provides immediate feedback on air cleanliness, supporting proactive risk management and audit readiness.



Additional Equipment Status Monitoring

Monitoring equipment status, such as power, door closures, and operational readiness, provides valuable insights into equipment health. This proactive monitoring helps facilities detect small issues before they escalate into serious problems that could affect therapy production.

A comprehensive monitoring approach builds confidence that every therapy produced meets the highest standards of quality and safety.

Building a Monitoring Strategy for CGT

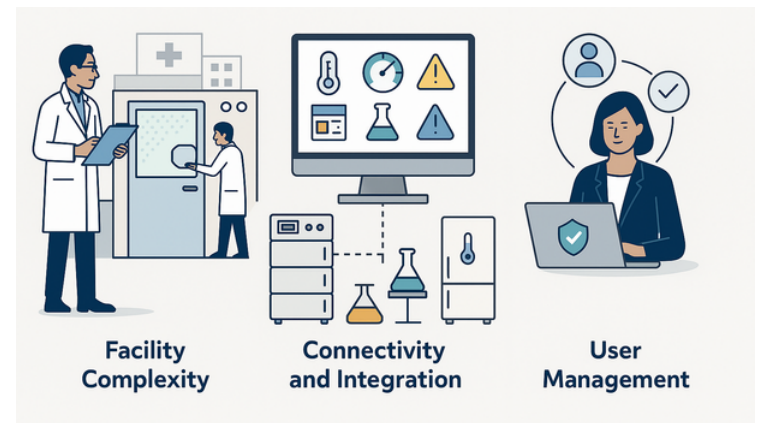
Developing a successful monitoring strategy for cell and gene therapy facilities requires more than placing sensors; it requires a holistic approach that addresses the unique complexities of the field.

Facility Complexity

CGT facilities often span GMP labs, cleanrooms, preclinical development areas, and even outpatient therapy centers. Each environment has different risk profiles, regulatory expectations, and operational challenges. GMP suites require strict control over differential pressure and particle counts, while preclinical labs might focus on flexibility and process development. A one-size-fits-all approach doesn't work. Instead, monitoring strategies should be tailored to each environment's needs, ensuring continuous oversight and defensible records.

Connectivity and Integration

Monitoring extends beyond temperature and humidity. In CGT, equipment status and process continuity are equally important. Integrating data from diverse equipment, sensors, and systems into a centralized monitoring platform ensures that facilities can see the full picture, allowing them to respond quickly and effectively to potential issues.



User Management

User management is a key focus area, particularly as regulators demand stronger controls over data integrity and access. Facilities must ensure that only authorized personnel have access to monitoring data, and that user roles are clearly defined and documented. A robust user management strategy not only supports regulatory compliance but also fosters confidence during inspections.

Building a strong monitoring strategy means weaving together elements of facility complexity, connectivity, and user management. The goal is to create a system that supports operational continuity, regulatory compliance, and, most importantly, patient safety.

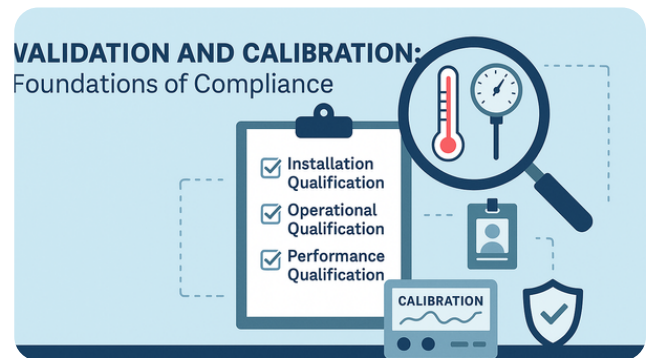
Validation and Calibration: Foundations of Compliance

In the regulated world of cell and gene therapy, an environmental monitoring system is only as reliable as the validation and calibration that stand behind it. Compliance with standards like 21 CFR Part 11 and global requirements from agencies like the EU GMP, WHO, CDC, and MHRA, isn't just a regulatory checkbox; it's a critical element in protecting therapies and ensuring patient safety.

Validation is the process of confirming that your monitoring system performs as intended, consistently and reliably, under the real-world conditions of your facility. This includes Installation Qualification (IQ), Operational Qualification (OQ), and, where applicable, Performance Qualification (PQ). For cell and gene therapy facilities, where therapies are often patient-specific and irreplaceable, validation provides confidence that every alarm, sensor, and data point contributes to a reliable, audit-ready system that stands up to regulatory scrutiny.

Calibration is equally important. Sensors that measure temperature, humidity, differential pressure, and other key parameters must provide accurate, traceable readings. Even minor drifts can create significant deviations in environmental conditions, potentially compromising the quality of therapies in storage or during processing. Calibration should be performed using standards traceable to NIST or equivalent, and documented according to ISO/IEC 17025 where applicable.

Missed or overdue calibrations are among the most common findings in regulatory inspections. They can raise questions about data integrity, equipment performance, and overall compliance. In cell and gene therapy, this risk is magnified by the fact that a single deviation can affect a therapy that may not be replaceable.



A robust validation and calibration program is more than just meeting regulatory requirements. It's a key part of a monitoring strategy that protects product integrity, ensures audit readiness, and safeguards the therapies that patients rely on. A strong calibration program includes scheduled, documented calibrations using equipment traceable to national or international standards (such as NIST), performed by qualified personnel. It ensures that sensors for temperature, humidity, pressure, and other critical parameters remain accurate over time. The program should also include procedures for identifying drift, handling out-of-tolerance conditions, and maintaining detailed calibration records to support audits and inspections.

Leveraging Data: Real-Time Alerts

In the world of cell and gene therapy, where each treatment is highly personalized and critical to a patient's care, real-time data is a non-negotiable requirement. Monitoring systems must provide immediate visibility into conditions that can affect therapy quality, from freezer temperatures to cleanroom pressure differentials.

Equipment Status Monitoring

Effective environmental monitoring includes equipment status indicators, covering critical aspects like power, door closures, and operational readiness. Real-time notifications, via alarms, emails, texts, and interactive phone calls, help staff respond immediately to potential issues. This proactive approach can prevent small problems, like a door left ajar, from escalating into major failures that put therapies at risk.

Supporting Critical Equipment

Specialized equipment like the Prodigy, a fully automated cell processing device, often runs continuously, supporting overnight and multi-day therapy production. While environmental monitoring systems typically do not track the internal process of such devices, they play a critical role in ensuring that the surrounding environment remains stable, compliant, and GMP-ready. Monitoring parameters like temperature, humidity, and power supply within GMP suites helps protect product integrity and supports continuous production.

Harnessing data effectively means more than just reacting to alarms, it means having the insights needed to act decisively, maintain compliance, and ensure therapies reach the patients who depend on them.

What's Next: The Future of EMS in CGT

The cell and gene therapy landscape is evolving rapidly, bringing new opportunities, and new challenges for environmental monitoring. Outpatient therapies are poised to become more prominent, shifting elements of manufacturing and administration closer to patients. This shift will require monitoring systems that can adapt to decentralized production and delivery models, ensuring consistent oversight even outside traditional GMP facilities.



As gene therapies continue to expand, facilities will need monitoring strategies that can handle a growing portfolio of therapies, each with unique storage and production requirements. This demands systems that are both scalable and flexible, capable of integrating with diverse equipment and processes.

While AI-powered predictive analytics remains an emerging capability, the potential to detect early trends, such as freezer drift or shifts in environmental conditions could enable facilities to address issues before they impact product integrity. Although still evolving, AI could play a key role in enhancing data analysis, supporting preventive maintenance, and driving operational efficiency in the years ahead.

Meanwhile, regulatory agencies are increasing expectations for data integrity, real-time monitoring, and audit readiness. Monitoring systems must evolve to integrate seamlessly with other quality systems, laboratory information management systems (LIMS)

and manufacturing execution systems (MES). These integrations will not only support compliance but also enable facilities to manage growing complexity as therapies move from clinical trials to commercial production.

Facilities that invest now in adaptable, future-ready monitoring systems will be best positioned to deliver safe, effective therapies to the patients who depend on them, regardless of where or how those therapies are produced.

Choosing the Right Monitoring Partner

Implementing a successful environmental monitoring strategy for cell and gene therapy facilities requires more than just reliable sensors and software. It demands a partner who understands the unique regulatory, calibration, validation, and operational challenges that define this complex field. Your monitoring system must be precise, validated, auditable, and supported by experts who know what's at stake.

That's where Rees Scientific comes in.

With decades of experience in regulated environments, Rees brings deep knowledge of GMP manufacturing suites, clinical labs, cold storage, and cleanroom operations. Our regional service coverage, the largest in the industry, ensures that you have trained Rees technicians who understand your facility, your workflows, and your regulatory obligations.



Whether you're implementing a single unit or managing a facility-wide rollout, we're there with hands-on support before, during, and after implementation.

Our systems are designed to meet your unique requirements. We offer multiple deployment options, hardwired, wireless, WiFi, or hybrid, so you can choose the best solution for your infrastructure.

Systems can be hosted on your own network or in the secure ReesCloud, with full data traceability and access control.

Our offerings help you meet the highest compliance standards, including 21 CFR Part 11, FDA, WHO, CDC, MHRA, and other global requirements.

- ISO 9001:2015 certified and ISO/IEC 17025 accredited systems and services
- End-to-end validation support, including IQ/OQ protocols, requalification, and mapping studies
- NIST-traceable calibration services performed by industry-trained technicians
- Real-time alerts via SMS, email, and interactive phone calls for immediate deviation response

- Flexible system designs that scale across equipment types, buildings, and global sites
- Documented excellence, supporting clients through regulatory inspections and internal audits
- 24/7/365 expert Product Support to keep your systems running, compliant, and your team confident

At Rees, we don't just provide monitoring solutions, we provide confidence. Confidence that therapies are protected, operations are audit-ready, and patients receive the treatments they rely on. In a field where every therapy matters, Rees is committed to being there for you, every step of the way.

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