CASE STUDY

REES

ENSURING COMPLIANCE AND RELIABILITY IN A CELL & GENE THERAPY LAB

CLIENT PROFILE

A leading Academic Medical Center (AMC) operating a GMP cell therapy lab specializing in apheresis and advanced cellular products.

ROLE INTERVIEWED

Quality Manager overseeing the full Quality Management System, including SOP development, EMS validation, and regulatory compliance.

"What makes this different from other labs is that these products are irreplaceable. You can't just remake them... There's no price you can put on how much these mean to people."

— QUALITY MANAGER, AMC CELL THERAPY PROGRAM

OVERVIEW

A leading Academic Medical Center (AMC) is at the forefront of cell and gene therapy, operating a GMP-compliant laboratory where apheresis-derived and personalized cellular products are developed for life-saving treatments. These products are irreplaceable and require tightly controlled storage environments to ensure their viability and safety. In this setting, maintaining compliance with cGMP standards and FDA regulations—including 21 CFR Part 11 and 211—is not just a regulatory expectation, but a foundational element of their operational integrity.

The AMC's Quality Manager oversees the lab's complete quality management system, including more than 35 freezers used to store high-value cellular materials. For this team, reliable environmental monitoring and responsive technical support are essential to preserving compliance and minimizing risk. The Rees Monitoring System plays a central role in this effort, delivering the regulatory confidence, scalability, and service reliability needed to support cutting-edge therapeutic development in one of the most demanding areas of modern medicine.

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THE CHALLENGES OF PROTECTING IRREPLACEABLE THERAPIESS

Cell and gene therapy laboratories operate in one of the most sensitive and tightly regulated environments in modern healthcare. These facilities handle apheresis-derived and patient-specific cell therapies—products that are not only high in value but also irreplaceable. Unlike traditional biologics or blood products, once a personalized therapy is compromised due to a storage issue, it cannot be recreated. The consequences are significant, potentially impacting patient care and treatment success.

At this Academic Medical Center's GMP-compliant facility, the Quality Manager is responsible for over 35 ultra-low temperature freezers, each holding critical therapeutic materials. The operational demands are intense: maintaining continuous environmental monitoring, ensuring real-time alerting, and meeting FDA 21 CFR Part 11 and 211 compliance requirements are not optional—they are essential safeguards. Any delay in identifying or addressing a system issue could result in the loss of irreplaceable cellular products and severe regulatory consequences.

In this high-stakes setting, the lab needed an environmental monitoring partner it could rely on —not just for technology, but for responsive service, scalable infrastructure, and a deep understanding of the compliance landscape unique to advanced therapy environments.

OBJECTIVES

- MAINTAIN COMPLIANCE WITH FDA 21 CFR PART 11 AND PART 211
- CENTRALIZE MONITORING FOR DOZENS OF HIGH-VALUE STORAGE UNITS
- REGIONAL SUPPORT TEAM FOR SYSTEM MAINTENANCE AND OPERATIONAL CONTINUITY

THE REES MONITORING SYSTEM

To meet the rigorous demands of GMP operations in a cell and gene therapy environment, the Academic Medical Center selected the Rees Monitoring System as a foundational component of its quality and compliance infrastructure. Designed specifically for regulated life science environments, the system integrates seamlessly with the lab's quality management protocols while supporting both day-to-day operational needs and long-term compliance goals.

Regulatory Readiness

The Rees Monitoring System was fully validated to operate in accordance with FDA 21 CFR Part 11, ensuring that all monitored data is secure, traceable, and tamper-resistant.

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Key features such as electronic audit trails, user authentication, and system redundancy support a fully compliant data environment—critical in maintaining confidence during audits and inspections. The system also supports 21 CFR Part 211, ensuring that storage conditions for temperature-sensitive products meet established GMP guidelines.

Scalability & Centralized Oversight

With over 35 freezers in the facility requiring real-time oversight, the lab needed a solution that could scale effortlessly without compromising visibility or performance. The Rees Monitoring System provides centralized, unified access to all monitored equipment across the facility, enabling the Quality team to proactively track performance, respond to alerts, and generate compliance-ready reports across a wide device network—all from a single platform.

Responsive Regional Support

Beyond technology, the facility relies on Rees' 24/7/365 technical support and its responsive regional service team for prompt, knowledgeable assistance. Whether troubleshooting a device issue, scheduling a service visit, or supporting new system installations, Rees' localized support model ensures fast response times and minimizes operational disruptions. This combination of technical expertise and geographic accessibility is a critical differentiator for high-intensity lab environments where every minute—and every degree—matters.

"I love the Rees system... You guys have overall been really great to us and for us."

— QUALITY MANAGER, AMC CELL THERAPY PROGRAM

RESULTS

- **IMPROVED COMPLIANCE AND DATA INTEGRITY**
- **EFFICIENT MONITORING ACROSS A LARGE INVENTORY**
- **HIGH CONFIDENCE IN VENDOR RESPONSIVENESS THROUGH REGIONAL SERVICE SUPPORT**

For this leading Academic Medical Center, maintaining compliance with FDA 21 CFR Part 11 and 211 is essential to safeguarding the integrity of its cell and gene therapy program. The Rees Monitoring System plays a vital role in supporting this mission by providing a validated, scalable platform for continuous environmental oversight. Backed by responsive regional service teams and 24/7 support, the system enables the lab to operate confidently in a highly regulated space. This ongoing partnership has become a key element in the facility's ability to meet rigorous compliance standards while protecting irreplaceable therapies.