

CASE STUDY

# Design and Installation of an Environmental Monitoring System for MeiraGTx in Ireland



**CLIENT:** MeiraGTx

**INDUSTRY:** Biotechnology

**PRODUCT:** enVigil FMS



# I The Challenge

Having previously provided the Facility Monitoring System for MeiraGTx's London UK facility, Pharmagraph were commissioned to design and install the Monitoring System in their state-of-the-art, 150,000ft<sup>2</sup> manufacturing hub in Shannon, Ireland. Spanning multiple construction phases, Pharmagraph's scope of supply was to provide a comprehensive monitoring system to continuously monitor, log, and have alarms set for specific parameters, ensuring compliance across diverse facility functions.

FACILITY FUNCTIONS	PARAMETERS	COMPLIANCE REQUIREMENTS
Manufacturing Cleanrooms	Room pressure, temperature and humidity	EudraLex Volume 4
Warehouse Areas	Incubator, fridge, freezer and cold room temperature, humidity and CO <sup>2</sup> concentration	ISO 14644
Cryogenic Storage areas	Compressed air dew point	ISPE Baseline Guide: Commissioning and Qualification
QC and Product Development Laboratories		ISPE GAMP 5

To continue keeping their high standards in meeting global regulatory requirements, MeiraGTx requested a number of essential features for the FMS solution.



## REQUESTED FEATURES

- Full segregation from the Building Management System (BMS)
- Calibration of all sensors to traceable standards
- Data security / integrity / loss protection
- Indication of Alarm and Alert conditions
- Multi-user environment with remote user access
- Cleanroom compliant design and construction
- Standard Report outputs
- System future-proofing
- System validation



# I Pharmagraph's Approach

In response to MeiraGTX's User Requirement Specification (URS), we developed an initial Functional Design Specification for the system. Following our detailed Design Review and Qualification process, which included the client at each stage, the system design was finalised and built.

The system architecture followed a company standard approach utilising Pharmagraph's Series 2000 analogue I/O modules coupled with MX6001 Data Acquisition devices. These components, together with enVigil FMS software configured on a pair of Hot Standby Servers, provides resilience and robustness to ensure data integrity at all times. All system panels and servers were backed by Uninterruptible Power Supplies and local hardware level data logging to ensure uninterrupted operation with no loss of data even in the most disastrous of scenarios.

A distributed and modular approach to the system architecture provided a solution that can serve many segregated areas of the facility whilst allowing each area to be maintained separately. Moreover, MeiraGTX's system included, both in the electrical and the software design, full future proofing to allow additions to be made, whether that is a single temperature sensor or an entirely new manufacturing area.







## Key features of our solution included:

- Touchscreen display to allow instant access to locally measured temperatures, room pressures and air particle counts.
- Local audio-visual alarm indicators that immediately alert any out-of-specification condition.
- Network of more than 70 room pressure displays that give the operators an immediate indication of the air pressure differential between rooms of different classification.
- Integration of the system into the site network, allowing users to securely access the FMS from anywhere in the facility via a secure connection.
- Top-level facility overview allowing users to view, at a glance, the overall status of the facility.
- The system allows for navigating the hierarchical structure so users can focus their attention on individual rooms and then individual pieces of equipment within that room.
- Data Graphs, Tables and Alarm lists are all available and can be output to printed or electronic reports at the click of a button.
- Built-in alarm notification scheduler configured to send both SMS text messages and emails to the right personnel, at the right time, when out-of-specification events occur.
- Alarm inhibition that allows for certain areas of the facility to be temporarily removed from the alarm scheme whilst continuing to collect the associated data.

# I The Outcomes

Pharmagraph's exhaustive suite of test protocols and system documentation enabled MeiraGTx to fulfil the requirements of Installation Qualification and Operational Qualification. The Pharmagraph enVigil FMS provides end-to-end quality oversight of the environmental conditions, from goods-in, through manufacturing, to goods-out.

MeiraGTx benefit from our extensive service level agreement, granting them access to a dedicated support team who are on-hand 7 days-a-week to provide remote assistance, training, advice and incident triage via email and telephone. Backed by a local team of Engineers based in Northern Ireland, MeiraGTx can be assured that in the unlikely event that it is required, system repairs will be swiftly completed without delay.

## Key outcomes:

- Met all requirements of Installation Qualification and Operational Qualification.
- End-to-end quality oversight of the environmental conditions.
- Fully compliant and validated system.
- Fully scalable system.
- Support and guidance through Performance Qualification of the system.
- Access to a dedicated support team, on-hand 7 days a week.

*"Pharmagraph has been an invaluable partner to MeiraGTx at our Gene Therapy facility in Shannon. During our years of collaboration three significant installations have taken place, all of which are fully qualified to GMP standards.*

*The Pharmagraph role has spanned design, build and verification of the Environmental Monitoring Systems according to strict in-house compliance requirements.*

*Since then, the relationship has developed further into a rolling service level agreement covering maintenance and calibration services, technical support, as well as a highly proactive bulletin service to sustain GMP compliance and continuous improvement.*

*The personnel with whom I've worked, particularly in project management and servicing have demonstrated remarkable performance to navigate significant challenges particularly during COVID times as well as highly improbable fire damage to a haulier's truck, resulting in the loss of project materials which had to be remanufactured and replaced during an already compressed schedule.*

*Personally, I've found Pharmagraph staff to be very capable, adaptable to customer requirements, and fully committed to safety and quality requirements within our highly regulated site.*

*The Environmental Monitoring System (EMS) and enVigil platform provided by Pharmagraph are integral to our facility's operations, spanning cleanrooms, laboratories, controlled temperature equipment, and warehousing.*

*As our facility continues to expand, I look forward to sustaining and further developing the collaborative relationship with Pharmagraph. I would have no hesitation in recommending Pharmagraph for an EMS solution, confident in their expertise, reliability, and commitment to excellence."*

*Process & Automation Engineering Manager, MeiraGTx*

