Excellos Ensures Reliability and Patient Safety with XiltriX



Summary

In 2023, <u>Excellos</u>, a leading provider of custom cGMP services for developing and manufacturing cell therapies expanded into a new GMP facility in San Diego. As part of their innovative solutions, they cryopreserve cancer patients' leukapheresis material before shipping it to the main manufacturing site – a crucial step in the cancer treatment process.

Before moving into their new facility, Excellos encountered a missed alarm at their previous location that revealed vulnerabilities in their monitoring processes. While missing alarms is a common occurrence for biotechnology and pharmaceutical companies, Excellos recognized the need for a robust monitoring solution. They partnered with XiltriX, a leader in real-time environmental monitoring with over 40 years of experience serving life science organizations. This partnership not only enhanced the reliability of Excellos' processes but also strengthened their commitment to delivering quality, accuracy, and patient safety.

Understanding The Process

Excellos plays an essential role in preserving the integrity of patient cells through precise cryopreservation, which begins with the apheresis collection of patient material. The outcome of this process directly influences both the physical and mental well-being of patients, making accuracy and reliability essential in every phase.

To achieve optimal freezing conditions, Excellos uses a controlled-rate freezer connected to a two-dewar switchover manifold that supplies liquid nitrogen to carefully freeze cells. The proper functioning of this equipment is crucial, as any interruption in cryopreservation can impact patient recovery and outcomes.

During one of the initial production lots, the controlled-rate freezer ran out of liquid nitrogen at a critical freezing step. Both tanks on the manifold were empty, and the local alarms on the equipment went unnoticed. Although the patient was able to reschedule the apheresis collection, this experience emphasized the need for a reliable monitoring solution to avoid similar risks in the future.

Solution

Following the missed alarm, Excellos partnered with XiltriX to implement a real-time environmental monitoring system that would keep a pulse on their critical equipment, mitigate risks, and enhance the reliability of their operations. With the assurance that their equipment is continuously monitored, the Excellos staff can dedicate even more time to focusing on their patients and delivering best-in-class cell therapies.

XiltriX engineers integrated the manifold and the controlled-rate freezer to the monitoring platform, ensuring that any fluctuation in liquid nitrogen levels would immediately trigger remote alerts to the manufacturing and engineering teams. In addition, the XiltriX system seamlessly connected with the freezer to provide real-time alerts with zero delay. Lastly, as a crucial layer of additional protection, the XiltriX SafetyNet team began monitoring Excellos' facility and equipment 24 hours a day, 7 days a week, ensuring any critical issues that arise are appropriately and promptly addressed.



"It's been over a year since the incident occurred, and now we have a system we can trust."

- Michael Tran, Sr. Principal Process Engineer



Conclusion

Since partnering with XiltriX, Excellos has mitigated risks and gained full confidence in their monitoring processes. The collaboration provides an added layer of protection and peace of mind.

With continuous, real-time monitoring in place, the Excellos team can fully focus on their work, knowing their equipment and facilities are always protected. More than a year has passed since the initial incident, with no similar issues, allowing them to provide cell therapies seamlessly to thousands of patients without interruption.

With aligned missions and a shared focus on quality, Excellos and XiltriX demonstrate how proactive collaboration increases operational reliability, safeguards patient outcomes, and supports the delivery of life-changing therapies with precision and care.

