

Case Study

CryoXiltriX Integration at Cryoport Systems' GMP Validated Site in Belgium



CRYO
Solutions

XILTRIX
MONITORING-AS-A-SERVICE

In November 2024, Cryoport Systems opened its new IntegriCell® Center of Excellence in Villers-le-Bouillet, Belgium. This facility expands the company's global cryopreservation capabilities and underscores its commitment to advancing cell therapy supply chain management. The site is designed to support clients in delivering lifesaving treatments worldwide, reinforcing Cryoport Systems' dedication to innovation and GMP-compliant solutions for the cell therapy supply chain. This new, custom-built 13,401 square-foot facility is fully GMP-compliant and purpose-designed for the cryopreservation of leukapheresis starting materials, which are critical for a variety of cell-based therapies. With an annual capacity to cryopreserve up to 1,100 leukapheresis products, this facility provides a valuable, reliable resource for clients who need consistent, high-quality cryopreserved materials for their clinical and commercial cell therapy programs.

The Story of Cryoport Systems' IntegriCell®
IntegriCell® by Cryoport Systems is more than just a cryopreservation service; it is a comprehensive solution tailored to meet the evolving needs of the global cell therapy industry.

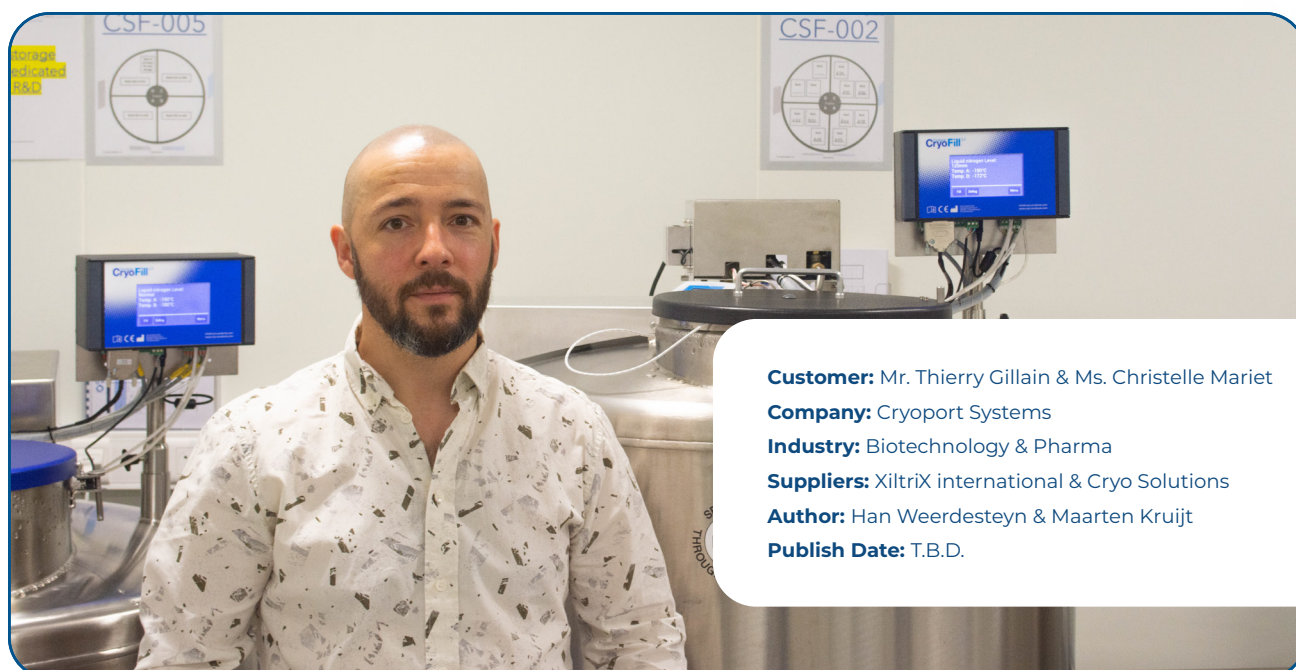


IntegriCell® combines standardized bioprocessing and cryopreservation with advanced logistics and distribution services, providing clients with a seamless and reliable solution for maintaining the viability and quality of critical cellular materials. This solution helps address a pressing need in the industry: ensuring the stability and integrity of cell therapies as they move from research and development to commercialization.

By expanding its IntegriCell® capabilities into Europe with the new Belgium facility, Cryoport Systems did not only enhance local access for clients but also established an interconnected network of facilities that can consistently deliver high-quality, manufacture-ready cryopreserved leukopaks. As a Center of Excellence, the Belgium site will also serve as a resource for sharing optimized preservation processes across facilities worldwide, reinforcing consistency for global cell therapy programs.

***Sources:**

www.cryoport.com/cryoport-systems-expands-integricell-cryopreservation-services-with-european-center-of-excellence-in-belgium/



Customer: Mr. Thierry Gillain & Ms. Christelle Mariet

Company: Cryoport Systems

Industry: Biotechnology & Pharma

Suppliers: XiltriX International & Cryo Solutions

Author: Han Weerdesteyn & Maarten Kruijt

Publish Date: T.B.D.

Stages of the Implementation Process

The new facility was designed to be implemented in an already existing building, according to the box-in-a-box principle. By using modular cleanrooms, a clean environment could be implemented without having to completely redesign the facility. Additionally, the cryogenics storage facility did not exist and needed to be integrated within the existing facility. Alongside that, the facility needed to provide a warehouse area and be futureproofed by providing space for expansions later in the process. All of this needed to be completed in record time adhering to the most stringent accreditation standards in the industry. Mr. Thierry Gillain, Facility and Equipment Supervisor for the Cryoport Systems Belgium site, commented,

“I am very impressed with the whole process. Everyone, the project team, the commercial team, the technical and the support team from both companies XiltriX International, as well as Cryo Solutions were very responsive. They adapted to changing requirements quickly and faced challenges head on by thinking outside the box and providing a good solution on time.”

During the execution of the process, the design of the system needed to be changed due to changing requirements. Process changes are never easy, but in a project with various stakeholders and in a GMP accredited environment, it's even more challenging. The project team had to work closely with Ms. Christelle Marlet, Senior CQV Expert & QA Lead of the Cryoport Systems' team, to make sure the change process was followed and all design and qualification documents were signed off correctly. Mr. Han Weerdesteyn, CCO for XiltriX International, said,

“This Cryoport Systems project was a fun but challenging one. Installation of a new system and partially retrofitting XiltriX onto existing sensors and cables, whilst working together with project and IT teams on two continents is something that requires



experience. Being able to work together with the Cryo Solutions team really helped in making this project a success. Our companies provide seamlessly integrated solutions, without the customers having to invent the wheel.”



Cryoport Cryogenic Storage Vessels with CryoFill in the Lab

A major part of the project comprised of the cryogenic storage facility. Cryo rooms are notoriously difficult to optimize and integrate into Environmental Monitoring System (EMS) solutions because the commercial systems provided by existing suppliers usually do not digitally integrate. Since the samples stored in the vessels are irreplaceable and the GMP accreditation require absolute control, all parameters need to be measured. Cryo Solutions engineered and installed the complete piping infrastructure and the control system for the cryogenic vessels, enabling seamless communication between the storage vessels and the central control system. This integrated approach improved both the safety of the Cryoport Systems staff and the efficiency of cryogenic operations.

What makes this approach unique is that XiltriX can monitor and visualize the entire cryogenic ecosystem built by Cryo Solutions. Every critical parameter, including vessel liquid levels, filling cycles, room oxygen levels, differential pressures, and freezer performance, is tracked in real time.



XiltriX Communication and Measurement Substations

By combining robust cryogenic engineering with continuous monitoring, the system not only safeguards compliance but also significantly reduces the risk of sample loss or operational failure. Mr. Maarten Kruijt commented,

"It was a great honor to be able to provide our unique services to Cryoport Systems. Our CryoFill controller, available in an MDR-certified variant, demonstrates compliance with the highest regulatory standards while offering retrofit capability across all vessel types. In this project, the cooperation with XiltriX International was instrumental in providing the right solution with the right accreditation level".

Having control over the cryogenic storage process is imperative because you are working with fresh human materials. The process needs to be performed quickly,



within 24-48 hours. After that, the quality of the material deteriorates, and important properties of the material are lost. The faster the material is frozen after collection, the greater the flexibility for pharmaceutical manufacturers to deliver high-quality final products to patients.



Cryoport Automatic Filling Station for Small Dewars

Mr. Thierry Gillain shared, ***"I am really happy with the insight provided by CryoXiltriX for the whole facility. Having real-time information on all critical room and equipment parameters helps the Operations team and me to do our jobs more effectively and provides complete control."***

Why Cryoport Systems chose CryoXiltriX

In the beginning of the project, the system has 2 existing EMS systems, none of which could integrate with the cryogenic storage facility that needed to be built. CryoXiltriX was able to integrate with the new cryogenic storage facility and was flexible enough to take over all functionality of the existing EMS systems, eliminating the need to keep 3 systems running. In order to be successful, the end result needed to be signed off on by the QA department. Ms. Christelle Marlet shared her experience,

“During the change and qualification process I was in frequent contact with the XiltriX team. All my questions regarding the documents and requirements were quickly answered and all requirements were met. This resulted in me successfully commissioning the system in a GMP validated state.”



Cryogenic Storage Vessels with CryoFill Retrofitted



How Cryoport Systems uses XiltriX

The facility in Belgium needs to continuously monitor all critical parameters in all rooms and equipment. CryoXiltriX is used for the monitoring of temperature and relative humidity in all rooms, as well as safeguarding the temperature, door, and power status of all equipment used. This includes fridges and freezers. All critical parameters of the cryo room are seamlessly integrated in the solution, including filling cycles, temperature, liquid level and oxygen depletion protection. On top of that, all differentials pressures in the clean room areas are being measured in real-time and are sent to the XiltriX secure cloud server that has a redundant power and internet connection. Deviations of any kind are immediately sent to the appropriate staff in a cascading manner, utilizing both local physical alarms as well as email and SMS notifications. The whole systems receives 24/7 support from the XiltriX technical support team, providing absolute control.



C-Stic Pressure Vessel Measurement Sensor

The Results and what's next

Having successfully finished this project, the CryoXiltriX team has spent the last months with the Cryoport Systems team in fine-tuning the systems and providing the right level of training. Given the fact that the facility is already expanding, the validated state will need to be maintained. All expansions will need to be integrated and signed off on by the QA team to maintain the highest level of quality. Mr. Maarten Kruijt noted,

“It is important for us to continuously learn from each project. By working closely together with the Cryoport Systems team, our solutions will be improved for future projects and customers to benefit from our experience.”

Being a global company, Cryoport Systems has a need for information to be digitalized and integrated with third party systems. XiltriX has already built an API that can be used for exchanging data with, for example, Building Management Systems (BMS) or Laboratory Management Systems (LIMS). Furthermore, XiltriX also has digital integration with continuous particle counters. Supporting the facility's growth through scalable solutions is a critical aspect of futureproofing. Mr. Han Weerdesteyn commented,

“Having a secure and flexible globally available XiltriX cloud platform is a must for global providers today. We are looking forward to growing with the Cryoport Systems organization in every corner of the world.”



Acknowledgements: I would like to extend my gratitude to Mr. Thierry Gillain and Christelle Marlet for their continued support and hospitality during the installation and qualification process. We hope that our solution will help you stay in control!

Han Weerdesteyn, CCO, XiltriX International
Maarten Kruijt, CCO, Cryo Solutions

Contact Cryo Solutions

☎ +31 (0)73 620 54 50

✉ info@cryosolutions.nl

🌐 www.cryosolutions.nl

📍 Hambakenwetering 17,
5231 DD, 's-Hertogenbosch, NL