

Long-Term Security and End-to-End GMP Compliance for Critical Cell Banks

How a Leading European Biotech Secured Long-Term GMP Compliance and Accelerated R&D by Outsourcing Cell Bank Storage

EXECUTIVE SUMMARY

The Results

 Risk Mitigation	Secure, geographically-separated backup storage established	Critical cell banks safeguarded against single-site failure.
 Process Speed	Turnkey transport and storage solution implemented, saving crucial project time	BioKryo managed all logistics, ensuring seamless, end-to-end compliance.
 Compliance	Full GMP and GDP compliance secured for the entire storage lifecycle	Assurance of sample integrity and regulatory adherence for 5-15 years.

The challenge

A rapidly scaling biotechnology company faced a critical point in its R&D pipeline. They had successfully manufactured invaluable Master and Working Cell Banks via their Contract Development and Manufacturing Organization (CDMO). However, the CDMO's storage capacity was limited, and the biotech's internal risk strategy mandated moving these multi-million dollar assets—which must adhere to stringent GMP standards—to a secure, separate, and long-term facility.

The complexity was not just finding a compliant vault, but managing the secure, documented, and fully auditable **transfer** of highly-sensitive, cryopreserved material from one site to another under an urgent timeline. The company needed a true partner that could offer a **turnkey solution** to handle the entire chain of custody, from the CDMO dock to the final, long-term storage location, without the company needing to manage complex, multi-vendor **logistics**.

The Solution

The company selected BioKryo GmbH for its specialized focus on GMP-compliant storage and its proven ability to provide an end-to-end service. BioKryo provided a complete outsourced solution, moving the project from a complex logistical hurdle to a streamlined, single-source operation:

- ✿ **Turnkey Service:** BioKryo immediately took over the operational burden, providing the secure, long-term cryostorage capacity needed for the company's 5- to 15-year development horizon.
- ✿ **Logistics Management:** Crucially, BioKryo coordinated and managed the worldwide transport of the highly-regulated samples. This included selecting qualified logistics suppliers and managing the entire chain of custody documentation to maintain GMP/GDP integrity.

Technical Compliance and Expertise

BioKryo's facility is certified under the German Medicines Act (AMG, specifically §§ 20c and 52a) and holds a GDP (Good Distribution Practice) certificate, providing a non-negotiable foundation of quality. This commitment extends to:

- ✿ **Scientific Staff:** A highly trained staff, holding academic life science degrees, ensures stringent GMP compliance by capitalizing on their deep understanding of the samples for proper handling.
- ✿ **Operational Security:** Implementation of robust safety measures, including a redundant alarm system connected to a central notification system and an on-call duty team, backed by a comprehensive Business Continuity Plan.

Conclusion

For biotech and pharma, scalable, GMP-compliant backup storage is non-negotiable. Outsourcing to BioKryo transforms a logistical headache into a strategic advantage, providing the highest security through seamless, end-to-end service, robust compliance, and scientific expertise.

Next Step: Secure Your Long-Term Cryostorage Strategy

Contact our Business Development Manager



Federico Guillermo Gharzia

☎ +49 681 210 759 29

@ +49 176 234 804 90

✉ gharzia@biokryo.de

About BioKryo

As a spin-off of Germany's renowned Fraunhofer Institute, we deliver GMP-compliant solutions for safeguarding high-value biological assets across the entire temperature spectrum, from -196 °C to ambient. Backed by 15 years of proven expertise, BioKryo ensures uncompromising reliability, full regulatory compliance, and fast, secure handling of your most critical samples.