

CASE STUDY

LEO Pharma

**A smarter way to retire legacy systems:
How LEO Pharma reduced costs while
preserving GxP data for the long term**



Arkivum



Summary

Like many pharmaceutical organisations, LEO Pharma faced the challenge of preserving regulated GxP data for decades while modernising its application landscape. Historical records were dispersed across multiple systems, making governance difficult and preventing the retirement of costly legacy applications.

By implementing the Arkivum digital preservation solution, LEO Pharma established a central, GxP-validated archive for long-term retention of regulated information. The project delivered a return on investment in less than 12 months by enabling the decommissioning of redundant clinical systems, while creating a scalable, centralised and consolidated solution as a foundation for future application retirement and stronger enterprise-wide information governance.

About LEO Pharma

LEO Pharma is a global pharmaceutical company specialising in dermatology. Headquartered in Denmark, the company operates across more than 70 markets and employs approximately 4,000 people.

Like all pharmaceutical organisations, LEO Pharma has regulatory obligations to retain GxP data for decades, ensuring evidence relating to product quality, clinical research and patient safety remains accessible throughout a product's lifecycle and beyond.

The Challenge

As the organisation evolved, LEO Pharma recognised that while it had a regulatory obligation to preserve critical information, it lacked a dedicated enterprise archive.

Instead, individual departments had developed their own approaches to long-term data retention. Information was stored across multiple systems and locations, making it increasingly difficult to locate historical records years after projects had finished and personnel had moved on. Some regulated information was also being retained in environments that were not validated for GxP data, introducing additional compliance risk.

At the same time, several legacy business applications had reached the end of their operational life. Although they no longer delivered business value, they could not be retired because they still contained records that had to be retained for inspection.

"We realised that even without an archive, the need to archive data still existed. People simply became creative about where they stored it."

Jens Norin, Principal Process & Governance Specialist, LEO Pharma

LEO Pharma needed a dedicated archive that would centralise long-term retention, strengthen regulatory compliance and enable legacy applications to be safely decommissioned.



Building the Business Case

Rather than attempting to justify the project through estimated productivity improvements, LEO Pharma built its business case around measurable financial returns.

An agile project team identified two legacy clinical applications that had become redundant after the company took the decision to outsource much of its clinical trial activity.



While the applications themselves were no longer required, the regulated data they contained still needed to be preserved.

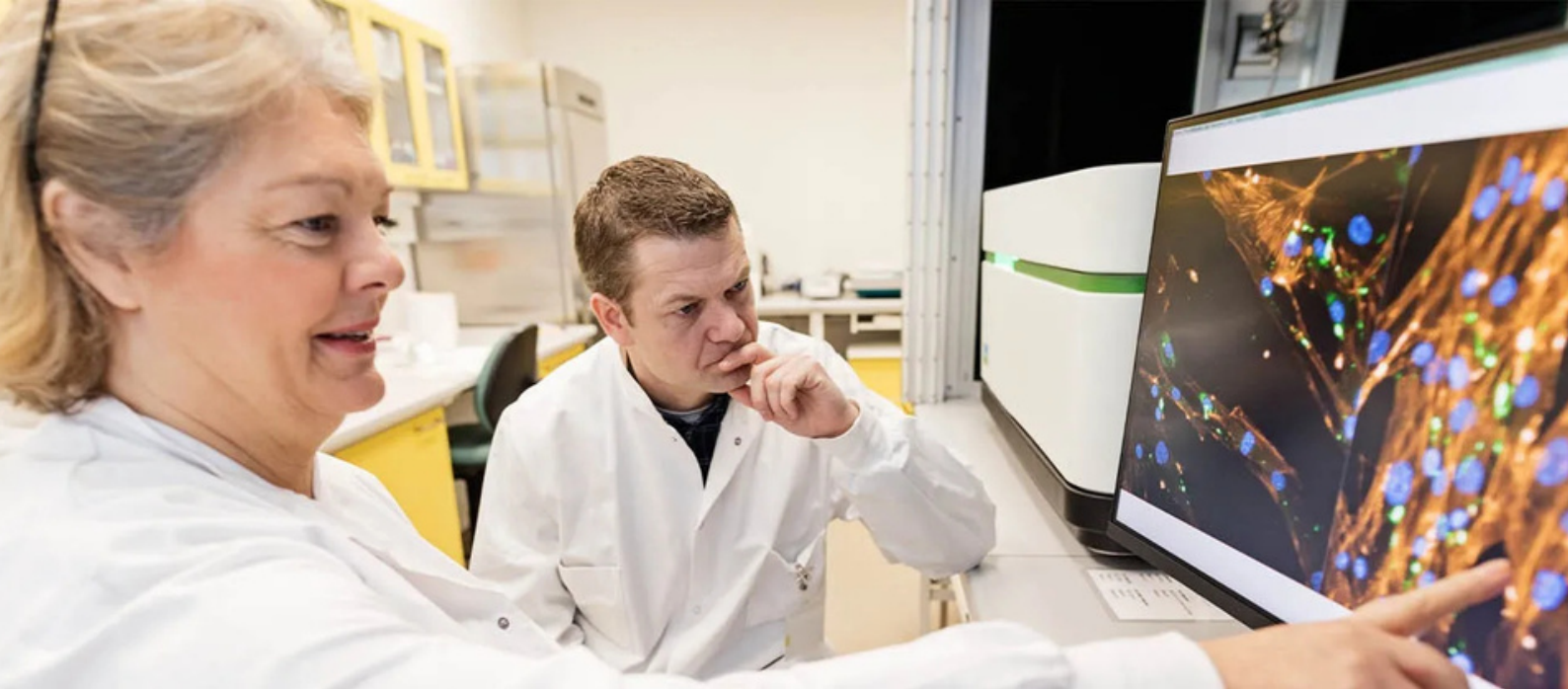
By migrating this information into a long-term repository, LEO Pharma could safely retire both applications while continuing to meet regulatory retention requirements. The financial case proved compelling.

The savings generated by decommissioning just these two systems exceeded the cost of implementing the archive, allowing the investment to pay for itself in less than twelve months.

This early success also demonstrated how a dedicated archive could become a strategic enabler for future application retirement programmes across the organisation.



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Choosing the Right Archiving Solution

During procurement, one of the biggest challenges was helping stakeholders understand the difference between an electronic archive, an Electronic Document Management System (EDMS) and traditional backup technologies.

LEO Pharma evaluated both archive platforms and document management systems before concluding that the organisation's requirements centred on long-term preservation rather than document lifecycle management.

Arkivum's solution aligned closely with these needs, providing secure long-term preservation, retention management and reliable retrieval of regulated information without the complexity of a full EDMS.

The availability of comprehensive validation documentation also reduced implementation effort, enabling the project team to focus only on organisation-specific qualification activities identified through a targeted gap analysis.

Building Strong Information Governance

LEO Pharma recognised early that technology alone would not guarantee long-term success. To ensure the archive remained sustainable as it grew, the organisation established a comprehensive governance framework around the platform.

Standard Operating Procedures (SOPs) were developed to define archive processes and responsibilities. Ownership of the archive was assigned to the Quality organisation, ensuring appropriate oversight of regulated information.

LEO Pharma also introduced a dedicated "Head Librarian" role responsible for maintaining archive standards, metadata quality and governance across the platform. Local librarians were appointed within business units to support individual archive projects and ensure consistent application of governance policies. This operating model ensures archived information remains searchable, consistent and inspection-ready as adoption continues to expand.



Driving Organisation-wide Adoption

The project team worked closely with business units to explain the role of the archive, understand departmental requirements and identify additional opportunities for application retirement.

These conversations quickly generated a pipeline of new migration projects as teams recognised the opportunity to reduce infrastructure costs, improve governance and simplify long-term compliance.

Today, the archive is becoming an important enabler of wider IT modernisation across the organisation.

Results

Although still in the early stages of deployment, the implementation of the Arkivum solution has already delivered significant business value to LEO.

Key outcomes include:



Return on investment achieved in less than 12 months.



Safe **retirement of legacy clinical applications** while preserving regulated GxP data.



Reduced software licensing and infrastructure **costs**.



A **centralised enterprise archive** for long-term regulated information.



Improved governance through standardised processes and dedicated archive ownership.



A **scalable platform** supporting future application retirement programmes.



Looking ahead

By combining a purpose-built digital archive with a clear governance framework and a business case centred on measurable financial value, LEO Pharma has established a sustainable foundation for preserving regulated information for decades to come.

Having demonstrated rapid ROI through its first application retirements, the organisation is now extending its archive strategy across additional business systems, using Arkivum as a strategic platform for long-term compliance, legacy application retirement and ongoing IT modernisation.

About Arkivum

Arkivum is a leading digital archiving and preservation solution provider. Supporting a diverse and global customer base, the Arkivum solution guarantees that customer data is secure, findable, accessible and usable for as long as it is needed.

Built upon the foundations of good practice for Long Term Digital Preservation, the ALCOA+ and FAIR principles, the Arkivum solution combines innovative technology with digital preservation expertise and services.

By providing certainty and confidence in data retention, energy can be redirected where it's needed most: innovating in the present.

Future-proof the past. Focus on the present.



Arkivum

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