CASE STUDY

Global Pharma Modernises Archiving with CARA Platform and fme Life Sciences Expertise

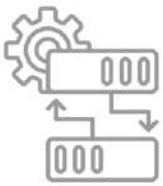
A global pharmaceutical company needed to modernise its document archiving infrastructure to reduce costs, eliminate system redundancy, and meet evolving regulatory requirements.

Industry	Employees	Location	Use cases
Pharma	50,000+	Germany	Document Archiving

The Challenge

The client was operating with outdated architecture across two separate legacy platforms that had been in place for many years. This created significant challenges:

High maintenance cost



System redundancy

Increasing regulatory risk

As their business evolved, they needed a modern, unified solution that could support their compliance requirements while providing the scalability and efficiency that legacy systems couldn't deliver.

The Scale

13 terabytes

of content across two repositories

65 million

documents and records requiring migration

Ongoing

archive requests continuing during migration

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Why the CARA Platform

The client selected the CARA Platform for its cloud-native architecture, regulatory compliance capabilities, and ability to provide a unified archiving solution. Key drivers included:

1 System Consolidation

CARA enabled the consolidation of multiple legacy systems into a single, modern platform, eliminating redundancy, simplifying operations, and reducing costs.

2 Cloud-Native Architecture

Built on AWS, CARA provided the dynamic scalability and modern infrastructure needed to support both current requirements and future growth.

3 Regulatory Compliance

Purpose-built for life sciences, CARA delivers the GxP compliance, audit trails, and retention management essential for pharmaceutical operations.

4 Low-Code Configuration

The platform's low-code approach enabled rapid deployment without custom development, accelerating time to value.

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Solution Requirements

Selective Archiving

Archive specific data selections flexibly.

Lifecycle Automation

Trigger-based retention enforcement

Divestiture Support

M&A and contractual compliance

Integrated Search

Efficient discovery and retrieval

The project needed to address several critical GxP and regulatory requirements. The client required comprehensive system decommissioning support with robust records archiving capabilities. They needed selective archiving functionality to archive specific sections or areas of data and documents with flexible organisation options.

The solution had to support divestiture management for M&A activities while maintaining contractual compliance. Lifecycle based archiving with automated retention enforcement based on trigger points was essential, ensuring records management aligned with regulatory schedules.

Integrated search and retrieval capabilities were critical for efficient content consumption and discovery. Finally, the client needed a standardised archiving framework on an adaptable, cloud-ready platform.

The Solution

Archive Structure and Security

CARA's flexible archive structure combines the familiarity of traditional folder navigation with powerful modern search capabilities. The platform implements an "archive area" model that functions like secure cabinets, where each area represents a line of business or functional area with specific security controls. Within these areas, hierarchical folder structures organise content using metadata-driven classification.

This approach allows different departments to maintain their own archive areas with appropriate permissions while all content resides in a unified platform. Security permissions are applied at the archive area level, ensuring that users only access content relevant to their role and function.

Search and Retrieval

CARA delivers both quick search and advanced search functionality across the entire archive. Users can search by individual properties, all attributes, or perform full-text content searches. This dual approach—structured navigation and powerful search—ensures users can find information efficiently regardless of their preferred method.

Compliance & Audit Capabilities

The platform maintains comprehensive audit trails for all content, whether migrated from legacy systems or newly archived. Users can generate audit trail reports in Excel format for regulatory submissions or internal reviews. CARA automates retention policy enforcement, manages legal holds, and handles content dispositioning according to established schedules—all critical requirements for pharmaceutical operations.

User Experience and Roles

CARA implements four distinct user roles that align with typical pharmaceutical archive operations:

Standard Consumer

- Search and access assigned archive areas
- View and export content and audit trails
- Self-service information retrieval

Archivist (Business Power User)

- Archive content to existing or new structures
- Promote content to archive status with retention
- Update metadata for documents in draft status

IT Archivist

- Create archive areas and manage permissions
- Adjust metadata with full audit tracking
- Apply legal holds and manage user groups

Archive Administrator

- Platform-level administration
- System monitoring and logging
- Legal hold management

Implementation and Migration

Generis partnered with long-time migration specialist fme Life Sciences (fme-LifeSciences.com) to execute this large-scale implementation and migration. fme brought over 15 years of partnership with the client and deep expertise in migrating content at enterprise scale.

The migration leveraged fme's migration-center® platform (migration-center.com), which provided the scalability necessary to handle 65 million documents and 13 terabytes of content. The process followed a rigorous methodology with discovery, design and development, verification, and production phases, all executed with the validation and documentation rigor required for GxP environments.

The implementation approach balanced business needs with technical requirements. The fme team used CARA's low-code configuration capabilities to rapidly design and deploy the solution without custom coding. They incorporated both phased migration and big bang elements, allowing the client to begin using the platform at technical go-live while legacy content migration continued in parallel.

Throughout the project, the team provided comprehensive change management support, including training programs, SOP updates, and user guide development. Post-deployment, ongoing support and hypercare services ensured smooth adoption.

Results and Benefits

Unified, Modern Archive

The client successfully consolidated two legacy platforms into a single, unified archiving solution on CARA, eliminating system redundancy.

Cloud Scalability

The AWS-based architecture provides dynamic scalability that adapts to changing business needs. The platform fully leverages AWS services for provisioning, scaling, and performance.

Rapid Deployment

CARA's low-code configuration approach and purpose built metadata accelerators enabled faster implementation compared to traditional development approaches.

Regulatory Confidence

The platform provides audit-ready processes, automated retention enforcement, and comprehensive compliance capabilities essential for pharmaceutical operations. All changes to archived records are tracked and audited, with legal holds properly managed.

Cost Efficiency

By consolidating legacy systems and moving to a modern cloud platform, the client reduced maintenance costs and eliminated the expense of supporting outdated infrastructure.

Future Plans

CARA's AI capabilities offer potential for further improving ongoing archiving processes, with the goal of enhancing the end-user experience for on-demand content archiving and providing additional value through intelligent document processing.

About Generis

Generis provides the CARA Platform, a modern, cloud-native content management and archiving solution purpose-built for regulated industries. CARA combines powerful compliance capabilities with the scalability and efficiency of AWS cloud architecture, enabling regulated organisations such as life sciences, financial services, public sector, manufacturing, and more, to modernise content management while meeting stringent regulatory requirements.

About fme Life Sciences

fme Life Sciences helps clients worldwide drive digital transformation through cloud, business intelligence, collaboration, and content management solutions. With a focus on the life sciences, financial and industrial manufacturing industries, fme's experts deliver vendor-independent consulting and proven best practice implementations that enhance quality, compliance, and competitiveness. fme's global teams in Germany, the US, Romania and India manage international projects and provide cost-effective bestshore support. Learn more at **www.fme-LifeSciences.com**