CASE STUDY

Idorsia

Decommissioning GxP Systems: Best Practices and Lessons from Idorsia

Arkivum

Why Decommissioning GxP Systems Matters

In the pharmaceutical industry, much of the focus falls on implementing new digital solutions and meeting evolving compliance standards. Yet every system eventually reaches the end of its life. For GxP computerised systems, decommissioning is far more complex than shutting down a server or copying files into storage. It is a structured project that safeguards data integrity, regulatory compliance, and long-term accessibility. Mishandling it can compromise audit readiness and, ultimately, patient safety.

At the 2025 ArkFest virtual conference, Jean-Maxime Pommery, Associate Director at Idorsia, explained how his team approaches this challenge. Drawing on years of experience, he described decommissioning as a "recipe" a repeatable but adaptable methodology designed to balance compliance obligations with practical execution.

The Regulatory Framework for Decommissioning

System retirement in a GxP environment is tightly governed by international regulations and guidance. GAMP 5 provides the framework for computerised systems, ALCOA+ outlines principles of data integrity, and 21 CFR Part 11 regulates electronic records and signatures. OECD guidance further reinforces these principles. Together, they make clear that organisations must not only preserve data but also guarantee its authenticity, completeness, and readability throughout the retention period.

Documentation is therefore non-negotiable. Every stage of the process must be logged, from planning and execution through to reporting, so that auditors can verify the integrity of both the data and the process itself.

"Decommissioning is not just turning off a system. It requires meticulous planning, risk assessment, and rigorous documentation to ensure compliance and data integrity."

Jean Maxime Pommery - **Idorsia**

A Structured Decommissioning Process

According to Jean-Maxime, decommissioning unfolds in three main phases:

1. The first is **planning**, where the team defines scope, identifies risks, and clarifies responsibilities across IT, quality, and business functions.

2. Next comes **execution**, where systems are frozen, data is extracted under controlled conditions, and integrity is verified.

3. Finally, a **retirement report** is produced, documenting all actions taken and providing the evidence needed to confirm compliance.

This structured approach ensures that decommissioning is not treated as a housekeeping task but as a full-scale project requiring rigorous quality oversight.

Handling Static and Dynamic Data

One of the greatest challenges in retiring systems lies in the type of data involved. Static data, such as reports or PDFs, can usually be exported and archived with minimal difficulty. Dynamic data, however, may depend on proprietary viewers or the original application environment to remain interpretable.

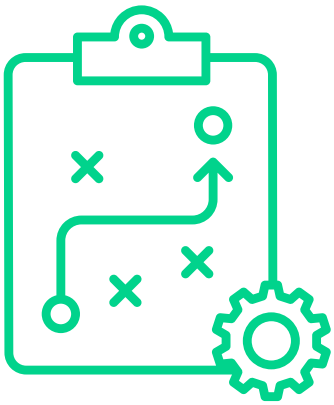
To address this, Idorsia sometimes uses virtual machines, preserving both the data and the software environment in which it was created. This approach ensures that years later, regulators or scientists can still open the system, view the data, and confirm results exactly as they appeared originally.

Lessons Learned in Pharma System Retirement

From his team's experience, Jean-Maxime stressed several key insights. First, organisations must understand what constitutes "raw data" for each system, so that only essential information is archived. Second, decommissioning should be considered as early as system selection, with vendors asked about exit strategies upfront.

Finally, companies must think beyond data storage and create documentation for future users. Without clear instructions, even well-preserved data may become meaningless to colleagues who are unfamiliar with the original system.

Decommissioning as a Strategic Project



The central message is clear: decommissioning GxP systems is not an afterthought. It is a strategic project in its own right, requiring time, resources, and collaboration across functions.

When done properly, it preserves data integrity, ensures regulatory compliance, and guarantees that the scientific story contained within a system remains complete, secure, and accessible for as long as it is needed.

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.

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