Gimmal

CASE STUDY

PHARMACEUTICAL & LIFE SCIENCES

HOW A GLOBAL PHARMACEUTICAL TACKLED INFORMATION MANAGEMENT AFTER ACQUISITION

New records and information management system improved compliance and audit-readiness after global acquisition

CHALLENGE

Facing an acquisition by one of the largest pharmaceutical companies in the world, a US-based pharmaceutical company needed a formal, enterprise-class records management system, not only to handle the higher volume of records, but to also meet all FDA and GLP (Good Laboratory Practices) regulations.

Previously, the company relied on Excel spreadsheets and shared drives to manage its records and information. This created critical process and compliance challenges, such as:

- **Lack of automated** records management solution resulted in inability to handle high volumes of new records from new sources
- **Inconsistent processes** between users
- **Inability to search** all available records in a timely manner
- **Difficulty locating** the most up-to-date records due to lack of unified version control between users
- **Backlog** of inherited records due to rapid mergers, acquisitions, and divestitures (MAD)
- **Time-consuming and costly** validation process

SOLUTIONS

The client was searching for a sustainable product with a simple, scalable solution to improve the efficiency of their overall records management process.

Gimmal designed and implemented a system that allowed the client to track the status of records no matter where they were in the workflow.

BENEFITS

- **Ability** to track the status of records throughout the Quality Control process
- **Automatic updates** behind the scenes ensuring the most up-to-date information
- **Simple strategy** for adding all inventory items into one system
- **Optimized searching** capabilities
- **Timely access** to all records
- **Seamless 21-CFR Part 11** compliance with security features and complete, permanent audit trail
- **Barcoding strategy** to update barcodes that weren't unique or that were breaking inventory management rules

20,000+

number of **lab notebooks** to batch, scan, and track

2019 ACQUISITION

by one of the **largest pharmaceutical** companies in the world by revenue

A MODERN, COMPLIANCE DRIVEN SOLUTION

In recent years, many pharmaceutical companies have grown via mergers, acquisitions, and divestitures. This subsequently creates a myriad of records and information management challenges -such as classifying and locating tens of thousands of newly inherited records, originating from different locations.

Before the recent acquisition in 2019, the client acquired another bio-pharmaceutical company. Having experienced inheriting new records from other sources, it was important for the client to find an audit-ready solution that could automate the process of inheriting a high volume of new records, including lab notebooks.

Since GLP (Good Laboratory Practice) requires that all records be tracked at the item level (and provide an item-level manifest upon request), the client decided to mitigate future compliance challenges by moving off of the spreadsheet and to a secure, audit-ready solution that ensured precise tracking of every record.

VALUE OF A SOLUTION BUILT FOR PHARMACEUTICAL LANDSCAPE

With Gimmal, this client can now:

- **Maintain compliance** with FDA regulations and GLP (Good Laboratory Practices)
- **Have greater visibility and control** over all records, even during mergers, acquisitions, and divestitures
- **Track record status** throughout the entire Quality Control process
- **Improve** inventory workflow with bulk import and export functionality
- **Easily identify** status and location of all lab notebooks via mobile scanner devices
- **Seamlessly search, send, or ingest** new or existing documents securely and with a permanent audit trail

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