CUSTOMER SUCCESS STORY







LOCATION Montreal, Canada



INDUSTRY Pharmaceutical

Overview

Since its founding, the Pharmascience team has put significant value on the importance of collaboration. With this guiding principle in mind, Pharmascience approached the Montrium Professional Services team for guidance and advice on a GxP e-Signature tool that could modernize their environment. Pharmascience leveraged Montrium's Adobe Sign Fast Track Validation Toolkit to jump-start a transition to GxP and non-GxP use of Adobe Sign and support growing research, development, and manufacturing activities.

Challenge

With nearly half of its 1,500 employees moving to remote work, Pharmascience needed a faster way to transition to an e-Signature tool to keep productivity high while being away from the office. Some GxP signatures were being executed in Pharmascience's previous electronic signature system, and the remaining amount was using paper. If a document needed three signatures, it had to be printed, signed, scanned, and sent by all three parties. This led to many problems, delays, and bottlenecks that were only amplified at the start of the Covid-19 pandemic.

With a tight timeline, the team needed to validate and implement a tool that facilitated 21 CFR Part 11 compliant e-Signatures. However, the validation burden was too much for Pharmascience's internal bandwidth to do the validation work, leading them to consider leveraging outside expertise.

Highlights

THE CUSTOMER: Founded in 1983, Pharmascience Inc. is a full-service privately owned pharmaceutical company for over-the-counter generic drugs with strong roots in Canada and a growing global reach with product distribution of 2000+ products in over 60 countries.

CHALLENGE: Evolving to be a more distributed, collaborative, and efficient organization, Pharmascience's quality systems team was motivated to break free from paper-and-ink and ensure that all approvals for any GxP processes could be done with an e-Signature solution.

SOLUTION: With Montrium's Adobe Sign Fast Track Validation Toolkit, Pharmascience quickly validated Adobe Sign to benefit from specifically designed, intuitive functionality and controls for GxP purposes.



"My team was very excited to work with the system, and we've received great feedback so far. Because we're working remotely, everything has an added element of complexity, so people are very happy with the tool. With the pandemic, it was impossible to continue working the way we were."

> **Emmanuelle Rensonnet** IT Team Lead, Quality Systems

Solution

Montrium's Adobe Sign Fast Track Validation Toolkit is designed to help Adobe Sign life science customers who need to be up and running as quickly as possible with the e-Signature solution.

Over a period of two weeks, Montrium's experts provided the documentation that Pharmascience needed to validate their implementation of Adobe Sign for electronic signatures. Following a risk-based validation approach, validation tests were executed by Montrium on the Adobe Sign Validation scripts (available from Adobe), rather than Pharmascience having to adapt and perform the validation testing themselves. The validation was complete after two months.

Now used daily within the Pharmascience team, Adobe Sign's technical features and procedural controls allow for a faster, more streamlined signature process in compliance with FDA 21 CFR Part 11.

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"We chose to work with Montrium due to their expertise in the regulatory and technology landscape, understanding of our challenges, and quick responsiveness. We had less support when evaluating other companies."

> Isabel Brosseau IT Quality System Owner

Key Achievements

- The Adobe Sign Fast Track Validation Toolkit **saved Pharmascience two additional months of work** that they would have had to put in to validate the system internally.
- Internal teams now operate in a more collaborative environment where compliance and convenience go hand-in-hand.
- Considerable savings reported in printing costs and time saved to facilitate signatures. Most documents require a minimum of two or three signatures.
- Within four months of use since adoption, 4000+ documents have been shared and signed internally between 1,095 users at Pharmascience.
- All GxP processes, across all sites and departments, can now use Adobe Sign.
- Examples of Non-GxP documents using Adobe Sign at Pharmascience include contracts, SOW, legal documents, IT documents, and finance documents.
- Pharmascience is promoting more sustainable practices, there is no longer a need to print out each document, some more than 500 pages long.

