

Astellas Pharma Inc.

Global pharmaceutical company uses Adobe® Acrobat® to accelerate completion and submission of new drug applications



Astellas Pharma Inc.

www.astellas.com

Industry

Pharmaceutical

Challenges

- Accelerating document production and improving collaboration
- Reducing printing, shipping, and handling costs
- Improving compliance with regulations

Solution

- Electronic submissions

Astellas Pharma is using Adobe Acrobat software to accelerate the completion of new drug application forms with a dynamic digital process that replaces more expensive, time-consuming paper-based processes.

Results

- Reduced paper documents by 66%
- Saved tens of millions of yen per year in printing and shipping costs
- Accelerated completion and submission of new drug application forms
- Enhanced security of documents
- Improved accuracy of data collected
- Standardized software operation worldwide
- Established a cost-effective system to serve as a foundation for future business practices

Systems at a glance

- Adobe Acrobat

Putting resources to work

To accelerate the delivery of new drugs to patients as soon as possible, Astellas Pharma Inc. (Astellas) has established its therapeutic area research strategy to focus on the five areas of urology, immunology and infectious diseases, oncology, neuroscience, and diabetes complications and metabolic diseases.

In recent years, Astellas acquired Agensys, Inc., a bio venture in the United States, and later acquired OSI Pharmaceuticals Inc., which has strengths in the oncology and diabetes fields. The company also established a new Bio-Imaging Laboratory at the Tsukuba Research Center and has built a global research network in three strategic regions—Japan, the United States, and Europe—boasting one of the top facilities for drug discovery research in Japan.

A movement toward digital drug application forms and pressure from regulatory authorities throughout the world has pushed companies toward streamlining and standardizing processes. Astellas adopted Acrobat to standardize its digital document generation globally for new drug applications and other business-critical documentation. The company considered and reviewed other PDF tools, but determined that free PDF creation tools would be too risky for business purposes since free PDF tools frequently lacked support from vendors. The company also was uncertain whether other PDF creation tools would create PDF files that fully comply with the rules and regulations for new drug application forms.

"PDF is a file format that was originally developed by Adobe Systems. With Adobe Acrobat, we can create files that comply with the rules required for new drug applications, and can also check them after they are created. In addition, Acrobat handles languages other than Japanese, and the ability to use it in the same way in every country is yet another reason why we chose it," says Mr. Katsuya Tamamoto, Senior Manager of R&D Informatics—part of the Corporate IT Department—who is managing the digitalization of the Research and Development Division.

Standardizing on Adobe Acrobat

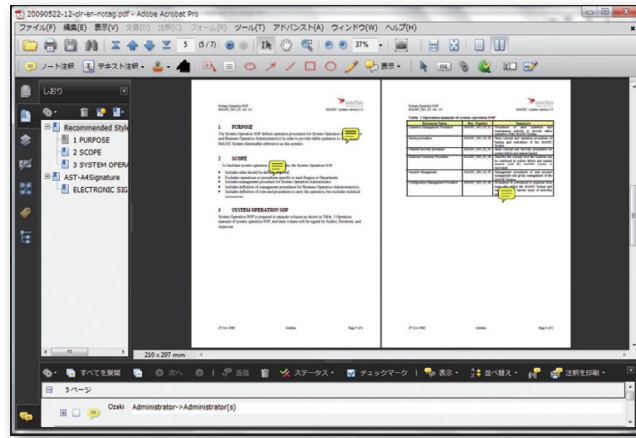
Across the enterprise, company work stations all have the same OS and applications, which are scheduled to be upgraded shortly. In addition, the company is planning to upgrade approximately 7,800 licenses worldwide to the latest version of Acrobat.

"We introduced Acrobat via the Adobe Volume Licensing program, which best suits large purchases, and achieved cost reductions and centralized license management. At the same time, we included an Upgrade Plan with a Maintenance Option Agreement within which we can upgrade without incurring any other charges when a new version is released during the agreement term. This is extremely valuable to us," says Mr. Shuichi Hiraki, Associate Manager of Infrastructure, Information Systems.

Greater efficiency and cost savings

In the United States, the company submits new drug application forms in PDF and is working to digitize the process in Japan as well, aiming to realize the same major cost reduction benefits.

Astellas Pharma adopted Adobe Acrobat to streamline the process of and reduce costs associated with submitting new drug applications for approval.



Tamamoto estimates that digital processes could help reduce the amount of paper documents submitted by about two-thirds, helping save tens of millions of yen per year, including the printing and shipping expenses incurred for paper. "In the past it was necessary to submit the equivalent of 100 cardboard boxes full of documents to the United States Food and Drug Administration (FDA), but now only a DVD is needed for the submission. If new drug application forms are 100% digitalized in Japan as well, we can expect huge cost reductions and greater contributions to eco-friendly practices."

Moreover, the company has established a global network that includes its overseas branches, and has put into place an enterprise-wide information sharing environment that leverages EMC Documentum Server, a robust content management system. By integrating Adobe Acrobat with Documentum the company can achieve significant reductions in review time for new application documents and research reports.

Tamamoto stresses the benefits of using Adobe Acrobat. "When creating new drug application documents, it is necessary to have the contents of the application and report documents reviewed by the in-house researchers in each country, and accurately reflect the feedback of the review when making the final submission. If we had to go through this process with paper documents, it would take a week or even longer, as we would have to send them to our overseas branches by mail. On the other hand, with PDF documents, we can attach them to an e-mail to deliver it to reviewers on the same day. By leveraging the Documentum system and Acrobat together, several reviewers can conduct the review while referencing each other's comments and the comment history can also be left on the server," he says.

In addition, Acrobat helps enhance the security of sensitive information with advanced functions such as the ability to enable document access to only pre-approved users, and to prevent unauthorized edits to existing documents. And, because authorized users can always review the same, latest version of the PDF document, communication errors can be reduced.

New tools to help ensure compliance

New drug applications are required to meet strict standards for quality. For example, fonts and screen resolution must meet particular guidelines in order to maintain the quality of each PDF document that is submitted. Documents that do not meet established standards might be returned by regulators. Because of this, maintaining consistent quality throughout each PDF document to be submitted has become one of the most important issues in the pharmaceutical industry.

For Astellas, the built-in preflight function in Adobe Acrobat helps the company avoid such issues. It automatically checks for font and format settings established definitions and identifies any discrepancies.

"When there are several PDF documents, it requires a lot of time and manpower to check the quality manually, and it is very easy to miss things when checking. The preflight function in Acrobat is extremely useful," says Tamamoto.

"If we had to go through this process with paper documents, it would take a week or even longer, as we would have to send them to our overseas branches by mail. On the other hand, with digital PDF documents, we can attach them to an e-mail to deliver them to reviewers on the same day."

Katsuya Tamamoto
Senior Manager, R&D Informatics,
Information Systems,
Astellas Pharma Inc.

In addition, Acrobat enables the company to search multiple PDF files simultaneously. For example, since Acrobat enables searching across multiple documents, a developer can find necessary information quickly by using a keyword to search past research documents.

Hiraki notes that with the free Adobe Reader® software, employees can access and read PDF files from any computer or operating environment, regardless of which one was used to create the file. "At our company, creating and managing in-house documents using Microsoft Office has become standard. When we handle PDF files, creation as well as active use of the PDF files is needed. Active uses such as page insertion, merging, adding a footnote, electronic signatures, and setting printing permissions are the primary uses of Acrobat to share PDF files with users outside the company."

With Adobe Acrobat, Astellas has been able to significantly shorten the time needed to complete new drug applications and reduce its paper costs. It is expected that additional gains in productivity and cost savings as the solution is extended to other parts of its operations with Acrobat Pro.

For more information
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