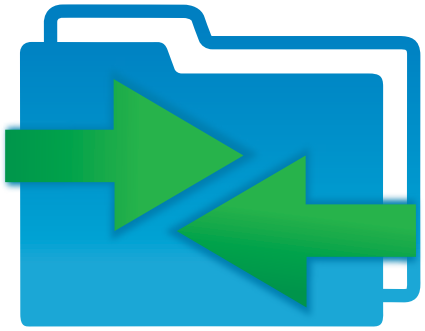
e-Submissions Follow Extensive Medical Regulations with Large File Exchange

Complicated Data Movement Became Simplified



When drug companies require approval for a new or enhanced drug, large amounts of critical data must be submitted to various healthcare regulatory organizations. These include the Federal Drug Administration (FDA), the European Medicines Authority (EMA), and the Japanese Ministry of Health, Labour and Welfare (MHLW). In the past, these organizations accepted data in either printed files or on multiple CDs or DVDs. In 2005, the FDA began testing an Electronic Submissions Gateway (ESG) as the backbone for receiving drug submissions from pharmaceuticals and other healthcare organizations. The EMA and the MHLW were already using a similar gateway for these submissions. By 2006, the FDA finalized their standard, which enabled two methods for receiving submissions: WebTrader and AS2.

WebTrader is a basic web portal that allows users to submit drug information in a very manual, tedious, and time-consuming process. While this system is functional, it does not work for larger, high-volume submissions, especially those submissions where the amount of data may be up to 100 GB.

The secondary option was to use the AS2 protocol standard for automated submissions. This allows companies to properly package, encrypt, validate, and audit submissions. It also allows large file transfers, as well as the automation of preparation and retries.

In May 2013 EMA mandated that all submissions go through the eSubmissions Gateway (http://esubmission.emea.europa.eu/esubmission.html). DVDs, CDs, or any other physical media were no longer accepted, with the new regulation becoming effective March 14, 2014.

It was at this time that a prominent worldwide pharmaceutical approached Globalscape®, requesting a solution that met the demand for all agencies using the eSubmission system.

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Globalscape® Offers Excellent Solution

Globalscape EFT™ platform supports a vast array of protocols, including SFTP, FTPS, HTTPS, and AS2. The latter was the desired protocol sought after by regulatory agencies, as well as the pharmaceutical company. Using EFT as a standardized method for drug submissions, the pharmaceutical company was able to quickly meet demands of multiple agencies by using a wide range of modules that helped group or package required drug information files. In addition, what was once a manual process to prepare submissions, EFT could now automatically integrate with backend eCTD systems and databases in order to gather necessary documentation, clinical results, and corresponding files that were needed, package them into a properly formatted TGZ file, and deliver them to the FDA.

The EFT platform not only met the pharmaceutical's secured and detailed requirements, but also met stringent requirements of the FDA and other regulatory agencies ahead of schedule. This also effectively supported the pharmaceutical company's mission by shifting resources that previously were spent preparing submissions and redirecting their ultimate focus back to saving lives.

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