

A TUMBLEWEED CASE STUDY

Tumbleweed Email Firewall™ solution provided The Center for Drug Evaluation and Research (CDER) with the ability to centrally create policies and control the flow of communications with pharmaceutical and biotechnology companies. This solution enabled drug approval applications and testing results to be submitted over e-mail and protect the CDER's infrastructure against virus, spam, and denial of service attacks.

Industry:

Government and
Pharmaceutical/Biotechnology

Geographies:

United States

Tumbleweed Solution:

Tumbleweed Email Firewall
Tumbleweed Secure Redirect

Deployment Summary:

- Created a network between the Center and the pharmaceutical companies using S/MIME encryption for all messages containing confidential information that pass between them
- Created security policies at the server level to encrypt all messages leaving the center going to pharmaceutical companies
- Utilized anti-virus capabilities at the gateway to protect center's networks from incoming virus attacks

Benefits:

- Reduced costs for the center and for pharmaceutical companies by replacing certain paper-based processes and expensive proprietary networks
- No end-user training within the Agency or pharmaceutical companies was needed
- Protected internal infrastructure against viruses, spam and denial of service attacks

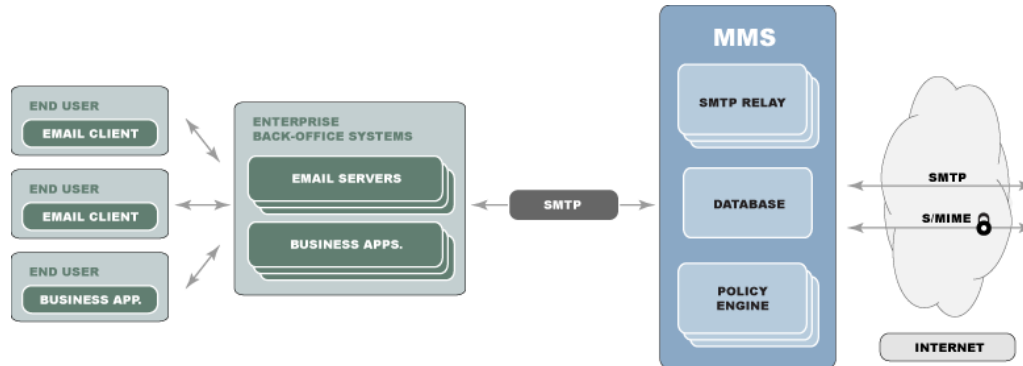
Profile

The CDER evaluates drugs before they can be released to the market. CDER ensures that prescription and over-the-counter drugs, both brand name and generic, work correctly and that the health benefits outweigh known risks.

Business Value

As the government agency acting as the consumer watchdog for America's healthcare system, the Center for Drug Evaluation and Research (CDER) within the FDA evaluates new drugs before they can be sold. CDER ensures that prescription and over-the-counter drugs, both brand name and generic, work correctly and that the health benefits outweigh the known risks. The FDA operates under the U.S. Department of Health and Human Services and is responsible for testing and approving many substances and products before they can be sold in the U.S., including food, human and animal drugs, medical devices and cosmetics.

CDER was seeking a solution to enable e-mail communications between itself and the various companies it regulated in the pharmaceutical and biotechnology industries. The drug testing approval process is an extended one that is traditionally paper-intensive, requiring numerous applications and clinical trials to be completed and documented with CDER. Previously, CDER had established an expensive Value Added Network (VAN), a proprietary system that allowed for e-mail communications of test results between itself and regulated companies. However, they were looking for a more cost-sensitive, practical approach that reflected the growing use of the Internet for communications, but incorporated the security they needed for their own networks and for the sensitive information they exchanged with their regulated companies. They came to Tumbleweed during their evaluation process and they were also evaluating PKI desktop solution alternatives, as well.



Server-based Encryption Facilitates Confidential Document Exchange

Tumbleweed EMail Firewall, installed at the server level within the FDA, served as the relay for e-mail communications entering and leaving the company. The pharmaceutical companies installed Tumbleweed’s Email Firewall as their mail relay or another S/MIME capable e-mail client and digital certificates were exchanged between the known parties. The CDER created policies specifying that all messages sent to the pharmaceutical companies domains must be encrypted using the CDER certificate and the pharmaceutical company’s certificate. All incoming messages from the pharmaceutical companies are encrypted and decrypted using the same process. The organizations had established a secure B2B exchange between the two of them—in essence an email VPN, known as the Tumbleweed Secure Redirect, without asking end-users to use a proprietary network, they simply used their existing e-mail client.

Tumbleweed Provided Simplicity for Users and Administrators

Because Tumbleweed Secure Redirect™ is installed at the server level, there is no end user training required for employees of the agencies or the pharmaceutical companies. This was in contrast to the PKI deployments the Agency looked at, which would require end users to encrypt forms and applications before submitting them—thereby relying on the end users to worry about security. In addition, Tumbleweed’s solution eliminated the costly, and time-consuming task of the administration of certificate management between entities, which was complex and left room for security breaches to occur. After conducting an exhaustive evaluation, CDER chose Tumbleweed because, “the Tumbleweed solution allowed us to have a minimal impact on our end users while not overtaxing our vital internal IT resources,” said Greg Brolund, Associate Director for the Office of Information Technology for CDER.

Reduced Costs and Protected the Network

Not only has “Tumbleweed allowed us to manage our e-mail communications stream,” added Brolund, “but it’s allowed us to facilitate a paper-based process over the Internet.” This has resulted in reduced

costs for both the CDER and the pharmaceutical companies, who previously would have needed to install a proprietary network or exchange confidential documents using overnight mail. Not only is e-mail less costly than paper, it is also more timely and companies awaiting results on clinical drug tests appreciate the efficiency with which results and submission can be turned around.

Finally, the CDER is able to protect their internal infrastructure from incoming e-mail with viruses, spam or denial-of-service attacks. This was a valuable addition to the benefits offered by Tumbleweed's Secure Policy Gateway and its protection modules, Anti-Virus and Anti-Spam. Recent virus attacks, such as ILOVEYOU, SIRCAM, PEACHY and others were prevented without needing a virus patch, the CDER simply implemented a policy quarantining .vbs messages—so messages never reached their employee's desktops to infect the systems.

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