



Utilizing CipherShare within Pharmaceutical and Biotechnology Industries

Table of Contents

Table of Contents	2
1. Securing High-Value Intellectual Property.....	3
2. Regulatory Pressure to Secure Privacy and Confidentiality.....	3
3. The Challenge – Securing Research Collaboration	4
4. What is CipherShare?	4
5. CipherShare R & D Case Study.....	5
5.1 The Company	5
5.2 The Need	5
5.3 The Solution – CipherShare.....	6
6. About Proven Security Solutions	6

1. Securing High-Value Intellectual Property

Pharmaceutical product development, drug discovery and biotechnology research are extremely demanding, highly skilled and highly proprietary endeavors, resulting in very high-value intellectual property. The demand for new and innovative products continues to grow exponentially and consequently, the pharmaceutical industry must engage in a highly productive program of research and drug discovery¹. In fact, over the next 10 years, the pharmaceutical industry:

*“will see patent expiries of drugs currently generating some US\$91 billion in sales. In order to remain competitive, these **companies** need to pursue strategies that will offset the sales decline and see robust growth in shareholder value. A big **pharmaceutical** company with sales of US\$16 billion today would need to be selling products worth some US\$37 billion 10 years from now. This poses a huge challenge.*

*Big **pharmaceutical companies** are now looking for products that can generate at least US\$1.62 billion of new sales every single year. That equates to up to four blockbusters a year products with sales of between 500 million and one billion a year. To achieve this, big **pharmaceutical companies** are consolidating to create a bigger R&D capability and forging strong alliances (about 426 alliances were created in 2000) by merging with **biotechnology companies**.”*

Not only is the research necessary, but also the intellectual property derived from that research must be held completely confidential. It is currently estimated, for example, that the cost to bring a new drug to market is \$500 to 900 million USD. A significant portion of this is spent within the preliminary research and discovery phases.

That cost can only be offset by the degree to which information concerning the drug can be kept proprietary and patentable. If disclosure occurs to the public or a competitor prior to the securing of the associated intellectual property, the investment is lost.

This need for a high level of research activity is clearly coupled with an equally high need for collaboration among those involved in the research. It is clear that the dominant mechanism through which collaboration is supported will be electronic file and data exchange.

2. Regulatory Pressure to Secure Privacy and Confidentiality

Two regulatory measures affecting both healthcare and biotechnology are in effect within the U.S. and are exerting significant regulatory pressure to provide for confidentiality, privacy, strong authentication, and digital and electronic signatures. These measures

¹ Nitin Naik, Brave New Biotechnology Word Revisited,
http://www.pharmabriefing.com/businessbriefing/pdf/drug2_2002/reference/ref19.pdf

are the FDA's CFR Part 11² and the Health Services HIPAA³. CipherShare's PKI and digital rights platform are perfectly suited to meet these standards within the areas of data and document submission and securing clinical trial information.

3. The Challenge – Securing Research Collaboration

Electronically mediated collaboration raises a second significant challenge for pharmaceutical and biotechnology firms: the need to secure all collaborative activity, information and data. This problem, which characterizes the pharmaceutical and biotechnology research industry, is exacerbated under the following conditions:

- R & D teams may be distributed around the world
- R & D team members may be very mobile, carrying much of the data with them on laptops or other mobile devices
- R & D team members may work for different organizations in different countries, with different networks, firewall configurations and security policies
- R & D teams may include 3rd parties that should only be privy to a very limited sub-set of the available information
- R & D teams need to be flexible and adaptable to changing priorities and mandates.

This need to securely bind a distributed group of collaborative participants together would represent a substantial challenge to meet using conventional software. CipherShare was designed from the ground up, to meet this challenge.

4. What is CipherShare?

CipherShare is a business application that offers Pharmaceutical and Biotechnology companies the ability to provide a *secure* communication and document/file collaboration channel for internal, external and client communications. It is an out-of-the-box solution that can be installed and deployed in hours with virtually no impact on a company's or clients' IT infrastructure. It does not compete with but rather complements and strengthens both a company's - and a company's clients' - existing security measures (e.g., firewalls, extranets and virtual private networks).

Providing state-of-the-art encryption within an easy-to-use, mature, commercial grade, and robust technology platform, CipherShare ensures that all documents, files, messaging and communication between a pharmaceutical and biotechnology team and the client are always securely stored and transmitted. CipherShare makes it safe and

² http://www.fda.gov/ora/compliance_ref/part11/frs/background/11cfr-fr_04.htm

³ <http://aspe.hhs.gov/admsimp/nprm/secnprm.txt>

simple for an organization to share information, and communicate and collaborate. Access to information is “granular” or limited to only specific personnel. Administrators have no access whatsoever to material unless stipulated by the author.

CipherShare provides a broad range of sophisticated collaborative services such as versioning, check-in/check-out, notes, tasks, scheduling and secured messaging. Providing support for all document, file and data types, it is a true global and roaming secure workspace that allows anytime and anywhere access to all relevant material – all that is required is a standard TCP-IP connection. In view of the complete collaboration solution that CipherShare provides, a company does not need to purchase separate collaborative software.

5. CipherShare R & D Case Study

The following is a case study of the way in which one of our customers has exploited CipherShare’s flexible framework to meet their specific needs.

5.1 The Company

An international manufacturer of scientific instruments with:

- Multi-national locations
- A wide range of third party partnerships
- Internationally distributed research and product development teams
- Multiple research and development groups and projects established on an “as-needed” basis
- A high degree of sensitivity to intellectual property protection including manufacturing methods and patents.

5.2 The Need

- Highly secure (encrypted) storage of all digital content both on and off-line
- Support broad range of R& D projects
- Allow for “roaming” access to secured content
- Bring together employees and third parties in highly controlled, secure, collaborative environment.
- Requires easily deployed, accessed and managed solution
- Must support multiple international encryption regulations
- Must be easily extended to include new projects, partners, and employees
- Must integrate into existing IT infrastructure

5.3 The Solution – CipherShare

- Internally hosted
- Deployed within one week
- Completely self-administered work-team creation and maintenance
- Full use of collaboration features including: version control, tasks, scheduling, threaded discussions, secure messaging
- Versioning and modification auditing
- Real-time notification and synchronization of all content
- Full control over access rights by author
- Ready access from anywhere though standard Internet connections
- Industry standard component technologies - Windows client/server, TCP/IP
- Very cost-effective

6. About Proven Security Solutions

Proven Security Solutions is a software development and consulting company specializing in highly secure and completely transparent applications of encryption and key management.

Proven Security's mission is simple - making state-of-the-art cryptographic security an invisible component of high value software applications.

For more information on, please visit www.provensecuritysolutions.com or e-mail us at info@provensecuritysolutions.com.