



SOLUTION OVERVIEW



VeriSign Security Solutions

to Support Compliance with FDA 21 Code of
Federal Regulations (CFR) Part 11



Where it all comes together.™

**KEY BENEFITS*****Supports Rapid, Cost-Effective Compliance***

VeriSign security solutions help pharmaceutical companies, medical-device manufacturers, and other organizations achieve compliance with §11.10 – §11.100 of FDA 21 CFR Part 11.

Minimizes New Security Investments

VeriSign security solutions reduce the costs of planning, developing, and implementing the digital certificate services infrastructure to help achieve 21 CFR Part 11 compliance.

Establishes Flexible, Extensible Security Program

VeriSign security solutions establish policies, procedures, guidelines, and technologies that help in complying with other regulations and achieving business priorities.

Pharmaceutical companies and medical-device manufacturers are increasingly using the Internet to automate business processes such as clinical trials, drug research collaboration, and drug approvals. As a result, there is renewed interest in compliance with the Food and Drug Administration (FDA) standard for electronic records and electronic signatures.

The FDA issued the Final Rule on Electronic Records and Electronic Signatures in March 1997 (21 CFR Part 11). In February 2003, the FDA issued its Guidance for Industry, stating its intention to define the scope of 21 CFR Part 11 more clearly. However, the agency noted that the basic provisions of 21 CFR Part 11 would not be changed: “We intend to enforce all other provisions of Part 11 including, but not limited to, certain controls for closed systems (§11.10), the corresponding controls for open systems (§11.30), and requirements related to electronic signatures (§11.50 – §11.300). We expect continued compliance with these provisions, and we will continue to enforce them.”

VeriSign offers a suite of services to support pharmaceutical companies and medical-device manufacturers in complying with 21 CFR Part 11:

- **VeriSign® Managed Public Key Infrastructure (PKI)** – Enables compliance with access control, authentication, encryption, and digital signature requirements (§11.10, §11.30, §11.50, §11.70, and §11.100)
- **VeriSign® Managed Security Services (MSS)** – Support compliance with §11.10 (d) and (e) through 24/7 management of the network security infrastructure
- **VeriSign Secure Sockets Layer (SSL) certificates** – Enable compliance with access control, authentication, encryption, and digital signature requirements §11.30 and §11.50, for application-to-application integration
- **VeriSign® Global Security Consulting** – Enables enterprises to conduct risk assessment and implement risk management measures, consistent with 21 CFR Part 11, Guidance for Industry, Part C

+ Assessing Compliance and Risk

Identifying vulnerabilities, assessing potential threats to electronic protected information, and evaluating the effectiveness of current safeguards is a complex task. VeriSign leverages deep expertise, proven methodologies, and state-of-the-art tools to thoroughly assess the current state and vulnerability of existing network security implementations, including policies, technology, operations, use, performance, and physical security. VeriSign identifies immediate security concerns and pinpoints gaps between the current infrastructure and identified requirements for compliance with 21 CFR Part 11, overall system security, and projected growth. Using the assessment and gap analysis, VeriSign provides prioritized recommendations for improving performance and mitigating risk.

+ Secure Communications, Transactions, and Data Exchange

VeriSign digital certificate services, based on VeriSign Managed PKI, provide mechanisms to support compliance with §11.10 – §11.100. Using digital certificates, pharmaceutical companies and medical-device manufacturers can perform:

- **Authentication** – Validates the identity of employees, partners, and applications
- **Encryption** – Ensures that information is not viewed or tampered with during transmission
- **Non-repudiation** – Establishes an irrefutable, time-stamped audit trail
- **Digital signing** – Attaches legally binding electronic signatures to documents and forms



CASE EXAMPLE OF 21 CFR PART 11 COMPLIANCE

A Fortune 500 pharmaceutical manufacturer uses VeriSign Managed PKI to provide a secure environment for exchanging clinical test information with the FDA, physicians, and business partners.

In addition, Managed PKI provides out-of-the-box integration with leading messaging programs (e.g., Microsoft® Exchange, IBM® Lotus Notes®, and AOL® Instant Messenger™), enabling organizations to send and receive digitally signed and encrypted messages. With VeriSign solutions, organizations can rapidly strengthen security and compliance while minimizing the costs associated with developing, deploying, and maintaining in-house digital certificate services.

The 21 CFR Part 11 mandate also applies to automated data-sharing among applications. To comply with these regulations, pharmaceutical companies and medical-device manufacturers must ensure that application-to-application communications can reliably secure data, validate the identity of applications, check the integrity of data, and log and archive system activity. VeriSign SSL certificates enable organizations to extend application integration initiatives to partners and suppliers with complete confidence that valuable data is protected from end to end.

+ Authentication and Access Control

To protect sensitive information against unauthorized access (§11.10), pharmaceutical companies and medical-device manufacturers must be able to control not only who accesses networks, applications, facilities, and other resources, but also which resources each user can access. VeriSign® Unified Authentication enables organizations to significantly reduce the risk of unauthorized access. Along with its technology partners, VeriSign enables organizations to easily deploy and manage a variety of strong authentication solutions such as digital certificates, smart cards, universal serial bus (USB) tokens, and biometrics. In addition, VeriSign solutions can be seamlessly integrated with leading access control and directory applications.

+ System Protection and Audit Trails

To comply with 21 CFR Part 11, pharmaceutical companies and medical-device manufacturers must limit system access to authorized individuals (§11.10 [d]). In addition, they must be able to maintain audit trails for all significant activity and system events (§11.10 [e]). VeriSign MSS enables organizations to delegate security infrastructure management to a team of experts whose core business is security. The suite of services (e.g., firewalls and intrusion detection systems), which can be used individually or as a set, includes assessment, monitoring, management, and reporting. Working from globally linked VeriSign Security Operations Centers (SOCs), VeriSign security teams use sophisticated tools to monitor, correlate, and analyze data across multiple levels of the organization in order to rapidly identify and prevent attacks. Organizations maintain full control of security policies and decisions and can access network data 24/7 via the Web-based VeriSign® Enterprise Security Portal.



+ Learn More

For more information about VeriSign® Security Services, please call 650-426-5310, email enterprise_security@verisign.com, or visit us at www.Verisign.com.

+ About VeriSign

VeriSign, Inc. (Nasdaq: VRSN) operates intelligent infrastructure services that enable and protect billions of interactions everyday across the world's voice and data networks. Additional news and information about the company is available at www.verisign.com.

This Solution Overview provides only a general description of VeriSign services for informational purposes and does not comprise a legal opinion or representation regarding the status or sufficiency of VeriSign services under any applicable law. Customers should obtain independent legal advice on the scope and applicability of any legal requirements to which they may be subject.

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00017475 06-07-2006