

## **ELECTRONIC RECORDS; DIGITAL SIGNATURES FOR LIFE SCIENCES**

### **Who We Are**

Since 1995, Kyberpass has been helping organizations to overcome the challenges of building and deploying high-trust applications for corporate enterprises. Kyberpass recognized two very important issues. First, building high-trust applications should not be a one-off integration of a series of security technologies done on a custom basis for a specific customer. Rather it should be a highly integrated, re-useable platform, which hides the details and complexity of the underlying technologies. Second, trust is only as good as the underlying party providing the trust. For this reason, Kyberpass was one of the first companies to recognize and implement the Identrus™ business integration solution. Identrus banks are trusted third parties (TTPs), which underpin the entire trust infrastructure.



### **21 CFR Part 11**

In response to the increased use of electronic records to maintain information subject to the FDA (and other global regulatory agency review), the FDA made effective Title 21 of the Code of Federal Regulations Part 11 (21 CFR Part 11) - Electronic Records; Electronic Signatures. This regulatory compliance policy defines the technical and procedural requirements to ensure the integrity of the information contained in an electronic record throughout the life of the record. 21 CFR Part 11 also defines the requirements for signing electronic records where the signature may be either an electronic signature, or a physical signing that is linked to an electronic record.



There are several sections to 21 CFR Part 11 including:

- 11.10 Controls for Closed Systems
- 11.20 Controls for Open Systems
- 11.50 Electronic Signature Manifestations
- 11.70 Signature/Record Linking
- 11.100 General Requirements
- 11.200 Electronic Signature Components and Controls
- 11.300 Controls for Identification Codes/Password

### **TrustPlatform**

The Kyberpass Life Sciences TrustPlatform enables Part 11.100 - General Requirements to be met in a completely electronic, *legally admissible* format.

(a) "Each electronic signature shall be unique to one individual and shall not be reused by, or assigned to, anyone else." This requirement is accomplished through a trusted third party (TTP), (e.g. an Identrus bank) issuing digital certificates and signing keys.

(b) "Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual." This requirement is met by the Kyberpass Life Sciences TrustPlatform linking the application to the TTP, who verifies the individual is who they say they are.

(c) "Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system are intended to be the legally binding equivalent of traditional handwritten signatures." This requirement is underpinned by the TTP, the Kyberpass Life Sciences TrustPlatform and the trust established between the utilizing company and the TTP.

#### **Problem**

To provide a means for legally enforceable digital signatures in an end-to-end electronic submission.

#### **Solution**

Kyberpass Life Sciences Trust Platform - bringing high-trust to document management.



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