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Krypsos Achieves FDA Compliance

AlpVision, supplier of authentication solutions based on image manipulation, has announced that its $Krypsos^{TM}$ server-based online authentication system has successfully achieved compliance with the FDA 21 CFR Part 11 requirements for Electronic Records and Electronic Signatures (ERES), issued by the Department of Health

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Screen shot of the Krypsos system in action

and Human Services of the US Food and Drug Administration (FDA).

Open Platform

Krypsos is an open platform that can integrate various levels of product security detection as well as delivering information about the product. The server-based authentication system can include the company's *Cryptoglyph*® covert security technology that uses standard inks and printing systems (offset, rotogravure, laser, inkjet etc) to apply digital encrypted marks (or glyphs) to paper or packaging.

It can also include *Fingerprint™*, a technology launched last year by AlpVision that creates digital codes from the intrinsic unique characteristics of the products that are being protected. Third party overt coding such as barcodes, 2D codes and OCR can also be included. All that is required for

verification is standard electronics equipment such as a flatbed scanner, digital camera or camera phone.

Pharma Inspection

Krypsos was originally developed to help field controllers or supply chain partners perform inspection of pharmaceutical products. According to the company, it enables brand owners to

provide their supply chain with a single point of contact for both fraud detection and genproduct authentication. It also provides logistics data, such as gray market consolidation, and can generate online notifications for mobile commerce.

The system meets FDA 21 CFR Part 11 requirements pro-

viding audit trail documentation, electronic records, advanced security controls and password protection, event reporting and notification (including: times, actions and users) and central data storage in a single SQL database.

AlpVision has also a full Quality Assurance (QA) system in place, which notably includes: development standards, document management, operational handbook, network and security management, risk analysis and contingency planning.

According to Roland Meylan of AlpVision, Krypsos is the first online authentication solution in operation for worldwide anti-counterfeiting applications, and is in line with the anti-counterfeiting requirements of the FDA Revitalization Act for medicines delivered in the USA.

Contact: www.alpvision.com