

Krypsos Achieves FDA Compliance

AlpVision, supplier of authentication solutions based on image manipulation, has announced that its *Krypsos*[™] server-based online authentication system has successfully achieved compliance with the FDA 21 CFR Part 11 requirements for Electronic Records and Electronic Signatures (ERES).

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.

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

Contact: www.alpvision.com

Marking for Film Coated Tablets

DataLase has announced a key partnership with solid-dose specialist Colorcon to develop a new secure on-tablet marking technique specifically for film-coated tablets.

This technique is based on Datalase's *Pharmamark*[™] - an edible on-tablet non-contact marking system that can be used to record information such as barcodes, logos, patient details, dosage information or use-by dates. Certain additives, which meet FDA and European regulatory requirements, are incorporated into the standard tablet coating, and a computer-controlled low-power CO₂ laser beam then exposes the required data onto the designated area on the tablet surface. The area undergoes a colour change when struck by the laser light, forming the

desired image or data on the tablet surface.

Colorcon has licensed certain patented DataLase additives to incorporate into film coatings for pharmaceutical or nutritional supplement tablets, so that the colour change that appears when laser strikes occurs in the film coating itself.

According to Colorcon, the technique offers manufacturers an alternative to the use of printing inks or debossing tablets to identify their products, resulting in fewer risks of cracked tablets as a result of contact marking. The system could also result in the removal of the need for some solvents during manufacture, a cleaner operation, fast change-over of product lines and potential cost-savings.

Contact: www.datalase.com

Global Forum 2008 – Call for Papers

The 4th Global Forum on Pharmaceutical AntiCounterfeiting takes place from June 4-6, 2008, Washington DC (the first time this event is being held in North America), and organisers Reconnaissance International have issued a Call for Papers.

The Global Forum brings together all the stakeholders involved in combating counterfeit pharmaceuticals, including manufacturers, health care professionals, drug regulators and anti-counterfeiting technology and service providers. It provides a unique interface between these stakeholders – all critical to the development and implementation of effective anti-counterfeiting strategies – and the focus will be on the latest initiatives that enable anti-counterfeiting policy to be translated into practice.

The programme committee, comprising experts in the field of regulation, production and distribution of pharmaceuticals as well as enforcement and patient/consumer issues, will be meeting shortly to draft the agenda. If you would like to be considered for inclusion in the programme, please send a 200-word abstract of your paper to Ian Lancaster or Ed Dietrich no later than the end of December.

The Forum will be accompanied by an exhibition of anti-counterfeiting services and technologies. Suppliers wishing to exhibit and/or become a sponsor of this agenda-defining event should also contact Reconnaissance.

Contact: ian.lancaster@reconnaissance-intl.com; edietrich@reconnaissance-intl.com; www.pharma-anticounterfeiting.info

