

## **FDA NEWS PHARMA SOLUTION OF THE WEEK**

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It is believed that more than 40 percent of Department of Defense (DoD) suppliers were affected by the first phase of the DoD mandate on the use of radio-frequency identification (RFID) technology. That policy required suppliers to put RFID tags on the lowest possible piece of part case/pallet packaging by January 2005.

At the beginning of this year the requirement became effective for pharmaceutical companies. The DoD will require RFID tagging on individual items on Jan. 1, 2007. That requirement will affect a significant percentage of the Pharma and medical device industries, which are already heavily regulated by the FDA. The challenge for these companies will be how to reconcile their existing pre-defined and validated operating procedures with the additional process of applying RFID tags. The question facing many of these suppliers, as they decide how best to comply with the mandate, is whether they need to start from scratch and implement new packaging and labeling processes, or whether they should apply the RFID tags in a separate process.

An additional factor for pharmaceutical companies to consider is whether the applications and processes they use to meet this DoD requirement will past muster with the FDA when it comes to 21 CFR Part 11 requirements.

Any software system to be used for the production of labeling must provide a totally secure environment for label design, approval, automatic gathering of variable data and label printing. It should record critical activities and electronically link them to individual users, along with time and date stamping. The system also needs to store and protect those records in compliance with FDA regulations.

Some of the items that go into the creation of a secure system include:

- Controlling user permissions and passwords through the establishment of user profiles at the server level
- Automatic recording of all print actions in the audit log, including the writing of such details as to whom, what, when and why to a secure location on the server

- Retention of all label revisions and printing actions, along with any comments, in the audit log
- Encrypting and securely storing all version history user permissions and passwords
- Restricting access to users with correctly configured profiles specific to certain approved tasks
- Automatically requesting the addition of an acceptable electronic signature for each new record, before the record can be created
- Preventing editing or deletion of any electronic record within the application
- Automatically time-stamping and dating electronic records based on the server clock, with the process being proven as part of the validation of the labeling system
- Preventing changes to any label designs once they have been approved, forcing the creation of new versions to incorporate those changes and create a revision history
- Confining the creation of electronic signatures to a list of users with known user identifications and secret passwords
- Keeping all passwords secret through the use of encryption techniques, with each user creating his or her, own password.

To help meet this challenge, the latest version of PRISYM **Medica** from PRISYM<sup>LS</sup> can encode RFID tags as part of the flexible "Label Sets" feature that already exists within the product. This allows the printing of the product label, the case label and an RFID tag in one succinct operation and, most importantly, all from a system which is fully cGMP and 21 CFR Part 11 compliant. This feature will also be of particular interest to customers who must achieve compliance with mandated RFID procedures from retail organizations such as Wal-Mart and Tesco, to name two of the early adopters. Not only does PRISYM<sup>LS</sup> supply RFID-ready software, but the company can also supply and integrate a wide range of RFID infrastructure products such as encoders and readers from leading manufacturers, as well as supplying the tags themselves.

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