



NIST REPORT SUPPORTS BIOMETRICS TECHNOLOGY TO BOOST SECURITY

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A new Commerce Department study advocating biometrics to help secure U.S. borders against terrorists may also serve to boost the technology among FDA-regulated firms working toward Part 11 compliance.

Biometrics -- identity verification by measuring a physical feature or repeatable action, such as a vocal pattern, fingerprint or retinal scan -- has received a mixed reception from drug- and devicemakers for several reasons, including cost concerns and wariness about the effectiveness of the technology (PCR, Dec. 11, 2002, Page 5).

Positive reports like the one from Commerce's National Institute of Standards and Technology (NIST), in addition to legislation and standards, are important factors in increasing industry acceptance of biometrics in the Part 11 arena, said Daon Chief Executive Officer Oliver Tattan.

Last November, Daon rolled out its biometrics-based DaonSign digital signature software for testing with five drug firms to see how the system performs in a number of different scenarios (PCR, Nov. 27, 2002, Page 4). So far, DaonSign has not had a single failure where anyone broke into the system or was incorrectly rejected, Tattan said.

"We can completely solve the signing issues in Part 11 compliance for firms," Tattan said. That leaves them to focus on other areas of compliance.

But part of the problem facing biometrics, Tattan noted, is that the field barely existed when Part 11 was written in 1997. And what was available was so basic and insecure that it did not inspire confidence. "You had scanners where you logged yourself in; there was no security," he said.

The NIST study evaluated the ability of mature biometric technologies to enhance border security. It looked at two applications: positively identifying visa applicants, and verifying that the holder of a visa is the person to whom the document was issued. Based on the evaluations, NIST recommended use of at least two fingerprints to positively identify visa applicants, and a dual system of face and fingerprints to verify the identities of visa holders at points of entry into the U.S.

Tattan said fingerprint technology was far more advanced and useful for FDA-regulated companies working on security issues as part of Part 11 compliance programs. "Face technology is for catching the bad guys," he said.