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Compliance and consistency

Pharmaceutical, biotechnology, and medical-device companies that are regulated by the FDA and other industry environments are feeling heightened scrutiny to comply with 21 CFR Part 11.

Shannon Williams

The ICH processes and the shift to an electronic environment have converged to create the perfect storm.

In February, the Food and Drug Administration issued a draft guidance that withdrew all prior Part 11 draft guidances and indicated that it would narrow its scope when enforcing the rule.

Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any requirements set forth in agency regulations. Part 11 also applies to electronic records submitted to the agency under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations.

FDA officials explain that the agency intends to exercise enforcement discretion with respect to certain Part 11 requirements. In March 1997, FDA issued final Part 11 regulations that provided criteria for acceptance by the FDA, under certain circumstances, of electronic records, electronic signatures, and hand-written signatures attached to electronic records as equivalent to paper records and hand-written signatures executed on paper. These regulations, which apply to all FDA program areas, were intended to permit the widest possible use of electronic technology.

After Part 11 became effective in August 1997, significant discussions ensued between industry, contractors, and the agency concerning the interpretation and implementation of the rule.

Even as the FDA continues to accept industry comments regarding the draft, records still must be maintained or submitted in accordance with the underlying predicate rules.

And with the increasing number of 483s and warning letters, the cost of noncompliance will continue to be high.

According to industry sources, those organizations that the FDA has deemed out-of-compliance and have imposed consent decrees are spending millions of dollars in remediation and are experiencing plummeting company stock valuations. As inspections increase in 2003, FDA-regulated companies can expect compliance to continue to be a top priority and should be looked upon as an opportunity to improve business processes enterprisewide.

Compliance is just one of the benefits gained by implementing Part 11 requirements. Implementing electronic signatures and electronic records as specified by 21 CFR Part 11 yield many other benefits, including: improved efficiency, faster time to market, better quality, and better preparation for FDA inspections.

Compliance with 21 CFR Part 11 is just one piece of the puzzle. Companies must also begin to implement standards for submission documentation, better train every group involved in the submission process, and begin to embrace the necessary changes with regard to the common technical document (CTD) and eCTD.

"Pharmaceutical product development currently is experiencing a paradigm shift from a paper-based foundation to an electronic one," says Shannon Williams, manager, regulatory affairs, at PRA International. "Adding to the complexity of this transition, especially in the area of electronic publishing, is the concurrent emergence of the CTD format as the global standard for marketing applications. The ICH harmonization process and the shift to an electronic environment have converged to create the perfect storm. In addition, the myriad emerging regulations and efforts to standardize the language of pharmaceutical product development, such as the ICH process, European mandates for the use of the CTD as the standard format for submission, and CDISC only have served to increase its intensity."

Taren Grom
Editor