

Executive Summary on New FDA Part 11 Guidance

On 20 February 2003 FDA published a new draft guidance document describing its current thinking regarding the scope and application of Part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures. The new guidance document explains that FDA intends to **re-examine Part 11**, and may propose revisions to that regulation, as part of the CGMP initiative Pharmaceutical [C]GMPs: A Risk-Based Approach. FDA is also withdrawing their previous draft guidance documents in this area, as well as the Compliance Policy Guide CPG 7153.17.

During the re-examining period of Part 11, FDA intends to interpret the scope of Part 11 narrowly, and intend to exercise enforcement discretion with respect to specific Part 11 provisions.

- FDA will not normally take regulatory action to enforce compliance with the **validation, audit trail, record retention, and record copying requirements** of Part 11.
- FDA also intends to exercise enforcement discretion with regard to systems that were operational **before the effective date of Part 11**.

Records must still be maintained or submitted in accordance with the underlying predicate rules. FDA will enforce predicate rule requirements for records that remain subject to Part 11, and intend to enforce all other provisions of Part 11. Regulated industry will continue to be responsible for maintaining and submitting secure and reliable records under predicate rules, and for meeting all other predicate rule requirements. Under the narrow interpretation, FDA considers Part 11 to be applicable to records that are required to be maintained by predicate rules, and the electronic format is used to perform regulated activities. Part 11 also applies to records submitted to FDA under the predicate rules, in electronic format; and to electronic signatures that are intended to be the equivalent of handwritten signatures, initials, and other general signings required by predicate rules.

The guidance draft underlines the importance of predicate rule requirements, and of documented and justified risk assessments.