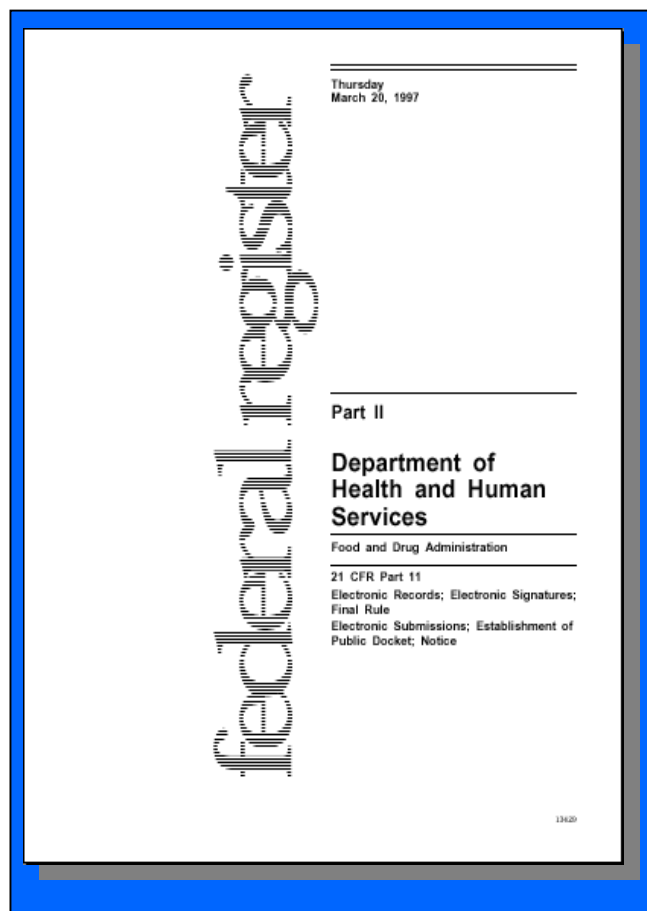


FDA Electronic Records and Signature Rule (21 CFR Part 11)

Is your company concerned about FDA audits? Are you particularly concerned about the FDA's new Rule 21 CFR Part 11 on Electronic Records and Electronic Signatures? What do you need to know to conform to these new directives?

What is the Electronic Records and Electronic Signature Rule?

The Electronic Records and Electronic Signature Rule (21 CFR Part 11) was established by the U.S. Food and Drug Administration and put into effect on August 20, 1997. (The rule may be accessed at: (www.fda.gov/ora/compliance_ref/Part11)). The rule defines the requirements for controlling electronic records, submitting documentation in electronic form and the criteria for approved electronic signatures. It is designed to assist laboratories in the areas of improved data management, simplified regulatory compliance, and increased data security and integrity. This Waters® Performance PerSPECTive provides an overview of the ruling and is designed to be used in conjunction with Waters Performance PerSPECTive WPP 52 entitled: "Using Millennium®³² Software to Help Comply with the FDA Electronic Records and Signature Rule (21 CFR Part 11)".



Scope of FDA Rule 21 CFR Part 11 Concerning Electronic Records and Electronic Signatures:

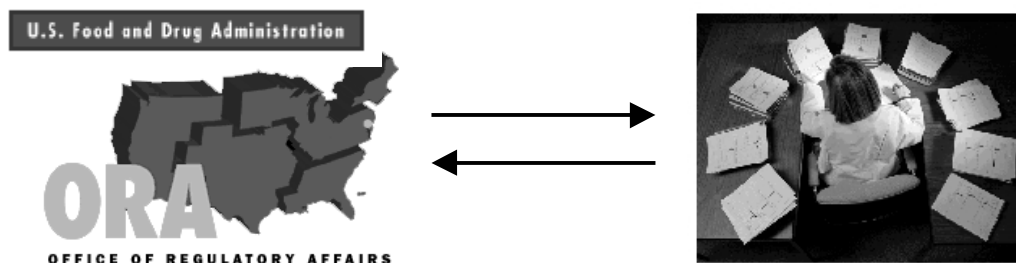
"The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper."

What are Electronic Records?

"Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system." **A printout of an electronic record is NOT the actual electronic record.** The ruling also indicates that electronic records for closed systems (i.e., where system access is controlled by persons responsible for the content) should be secure with computer-generated, time-stamped audit trails.

What are Electronic Signatures?

"A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature." At this time, **Electronic Signatures are NOT an FDA requirement for chromatography data systems.** If used, however, you must follow the rule, and the FDA must be informed in writing of this decision prior to implementation. From that point forward, any signatures made electronically will have the same legal ramifications as handwritten signatures.



Summary of Suggested Action Steps Concerning FDA Rule 21 CFR Part 11:

1. Visit the FDA Web site (www.fda.gov/ora/compliance_ref/Part11), to review the regulations and the compliance policy
2. Perform a gap analysis and determine any deficiencies with existing electronic data systems or implementation programs.
3. Create a plan for bringing existing systems and procedures into compliance. Refer to Waters Performance PerSPECTive WPP 52 and www.waters.com for the white paper "Using Millennium^{®32} software to Help Comply with the FDA Electronic Records and Signature Rule (21 CFR Part 11)."
4. Implement the plan.
5. Document the actions taken to help comply with FDA Rule 21 CFR Part 11.