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Part 11 (21 CFR Part 11) applies to any paper records required by statute or agency regulations and supersedes any existing paper record requirements by providing that electronic records may be used in lieu of paper records. Electronic signatures which meet the requirements of the rule will be considered to be equivalent to

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Implementing CitectSCADA to meet the requirements of FDA 21 CFR Part 11 7 (e) Use of secure, computer-generated, time- stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information.

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Electronic Code of Federal Regulations (e-CFR) Title 21. Food and Drugs; Chapter I. FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; Subchapter A. GENERAL; Part 11. ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

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## ~~21 CFR Part 11 – ELECTRONIC RECORDS; ELECTRONIC SIGNATURES ...~~

§ 11.1 - Scope. § 11.2 - Implementation. § 11.3 - Definitions. Subpart B - Electronic Records § 11.10 - Controls for closed systems. § 11.30 - Controls for open systems. § 11.50 - Signature manifestations. § 11.70 - Signature/record linking. Subpart C - Electronic Signatures § 11.100 - General requirements.

## ~~CFR – Code of Federal Regulations Title 21~~

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21 CFR Part 11 applies to any electronic records or signatures which are created, maintained, or otherwise processed under any records requirements as defined by the FDA. Any records that are stored, signed, or processed digitally in the course of business for a biotech, life science, or other FDA regulated company fall under the regulation.

## ~~What is 21 CFR Part 11 and Why Does Compliance Matter?~~

This guidance is intended to describe the Food and Drug Administration's (FDA's) current thinking regarding the scope and application of part 11 of Title 21 of the Code of Federal Regulations ...

## ~~Part 11, Electronic Records; Electronic Signatures – Scope ...~~

For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR). Sec. 11.10 Controls for closed systems. Persons who use closed systems to create, modify,...

## ~~CFR – Code of Federal Regulations Title 21~~

CFR Title 21 Part 11 stabilisce i requisiti per garantire che i record elettronici e le firme siano sostituti affidabili, affidabili e equivalenti per i record cartacei e le firme manoscritte. CFR Title 21 Part 11 sets requirements to ensure that electronic records and signatures are trustworthy, reliable, and equivalent substitutes for paper records and handwritten signatures.

## ~~Food and Drug Administration CFR Titolo 21 parte 11 ...~~

CFR Title 21 Part 11 sets requirements to ensure that electronic records and signatures are trustworthy, reliable, and equivalent substitutes for paper records and handwritten signatures. It also offers guidelines to improve the security of computer systems in FDA-regulated industries.

## ~~Food and Drug Administration CFR Title 21 Part 11 ...~~

Part 11 of the 21 CFR (Title 21 – Food and Drugs of the Code of Federal Regulations) is a document issued by the United States Food and Drug Administration (FDA) that outlines the FDA criteria for accepting electronic records and signatures. The regulations in the final version of 21 CFR Part 11 became effective on August 20, 1997.

## ~~21 CFR Part 11 Compliance – Thermo Fisher Scientific~~

21 CFR part 11 and EU annex 11 both are guidance for the electronic records and electronic

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signature. The guidances are applied to the computerized systems that used to store the electronic data. FDA has made regulation 21CFR part 11 for the US-based pharmaceutical companies as well as the companies want to market the drug product into the US market.

### ~~Nothing Any Difference Between 21 CFR Part 11 And EU Annex ...~~

Title 21 CFR Part 11 is the part of Title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on electronic records and electronic signatures (ERES).

### ~~Title 21 CFR Part 11 - Wikipedia~~

21 CFR Part 11 defines the requirements for electronic document and signature submissions to the U.S. Food and Drug Administration (FDA).

### ~~Adobe Sign and 21 CFR Part 11~~

The 21 CFR Part 11 regulations from the Food and Drug Administration (FDA) sets forth the criteria under which the agency considers electronic records and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

### ~~Technical Note - FDA 21 CFR Part 11 Features~~

The 21 CFR Part 11 regulations from the Food and Drug Administration (FDA) sets forth the criteria under which the agency considers electronic records and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

### ~~Best Practices for meeting the FDA 21 CFR Part 11 ...~~

Electronic Code of Federal Regulations (e-CFR) Title 21. Food and Drugs; Chapter I. FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; Subchapter B. FOOD FOR HUMAN CONSUMPTION; Part 121. MITIGATION STRATEGIES TO PROTECT FOOD AGAINST INTENTIONAL ADULTERATION

### ~~21 CFR Part 121 - MITIGATION STRATEGIES TO PROTECT FOOD ...~~

Empower Software 21 CFR Part 11 Compliance Assessment Revision A, September 2002 1-2  
Waters Corporation Note: Information presented in this document assumes that the appropriate Empower System Policies have been configured for Electronic Record (ER) and Electronic Signature (ES) support. Overview Yes/No/NA

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