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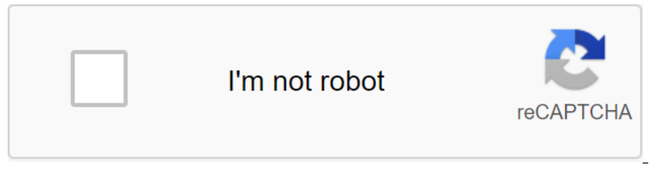

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Compliance with FDA rules on electronic records and electronic signatures (21 CFR Part 11) Section 21 CFR Part 11 is a U.S. federal regulation defining FDA guidelines for electronic records and electronic signatures. This requires most companies that deal with the FDA, such as pharmaceutical companies and medical device manufacturers, to exercise controls that ensure the integrity of their documents. Customers of Statgraphics regulated by the Food and Drug Administration (FDA) were asked about the 21 CFR portion of 11 compliance Statgraphics software products with FDA regulation of electronic records and electronic signatures (21 CFR Part 11). Starting with version 16.2, Statgraphics Centurion provides the ability to add passwords and user signatures to StatFolios, as well as automatic creation of an audit trail to record the date and time during which Statfolios are modified to work as FDA compliance software for 21 CFR Part 11. The degree to which the company's regulated 21 CFR part 11 is compliant not only depends on whether Statgraphics software is compliant, but also on how the regulated company uses Statgraphics in its research and data analysis. Regulated companies are responsible for reviewing their processes and systems that use Statgraphics, as well as for complying with guidelines for electronic record keeping and electronic signatures. The use of Statgraphics alone does not guarantee that users comply with this rule, only when used correctly can Statgraphics function as FDA compliance software. Safe accounting requires a system that satisfies all components described in Section 21 of the rules, and in particular the FDA Part 11 compliance guidelines. Statpoint recommends that customers contact the FDA for the most detailed information on compliance with 21 CFR Parts 11. The current 21 CFR Part 11 and Industry Guide To Part 11 documents or FDA compliance software are available on the www.fda.gov website. Other links to 21 CFR Part 11 Guides: CFR Title 21 Part 11 Guide to Industry Part 11, Electronic Reports; Electronic Signatures - The Scope Of Title 21 CFR Part 11 is part of Article 21 of the Federal Regulations Code, which establishes the United States Food and Drug Administration (FDA) rules on electronic documentation and electronic signatures (ERES). Part 11, as it is commonly called, defines the criteria by which electronic records and electronic signatures are considered reliable, reliable and equivalent to paper records (section 21 CFR Part 11.1 of Section 11.1 (a)). Coverage practically speaking, Part 11 refers to drug manufacturers, medical device manufacturers, biotech biologics, CROs, and other FDA-regulated industries, with some specific exceptions. This requires them to implement controls, including audits, system checks, systems, Trails, electronic signatures and documentation for software and systems involved in the processing of electronic data that FDA predicate rules require them to maintain. The predicate rule is any requirement set out in the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, or any FDA regulation other than Part 11. The rule also applies to materials submitted to the FDA electronically (e.g. new drug use), but not to paper representations by electronic methods (i.e. fax). Specifically, it does not require a 21 CFR Part 11 requirement for record retention for trackbacks by food manufacturers. Most food manufacturers are otherwise not explicitly required to keep detailed records, but electronic documentation is stored for HACCP and similar requirements must meet these requirements. Broad sections of the regulation have been challenged as very expensive and almost impractical for some applications, and the FDA said in a guide that it would exercise enforcement discretion on many parts of the rule. This has led to confusion as to what exactly is required and this rule is being revised. In practice, access control requirements are the only part that is usually met. The predicate rules that required organizations to keep records in the first place are still in force. If electronic records are unintelligible, unavailable, or corrupt, manufacturers are still subject to these requirements. If a regulated firm keeps hard copies of all required records, these paper documents may be considered an authoritative document for regulatory purposes, and the computer system is not in the area of electronic records requirements, although systems that monitor processes subject to predicate rules still require verification. Firms should be careful to make a statement that a solid copy of the required records is an authoritative document. In order for a hard copy from an electronic source to be an authoritative document, it must be a complete and accurate copy of the electronic source. The manufacturer must use a printed copy (rather than electronic versions stored in the system) records for regulated activities. The current technical architecture of computer systems is increasingly making Part 11, Electronic Reports; Electronic Signatures - The scope and application for a full and accurate copying requirement is extremely high. Content Subpart-A - General Provisions Of the Subpart-B Definition Implementation Area - Electronic Reports Office for Closed Systems Office for Open Signature Signature Systems Signature/Recording Links Subpart-C - Electronic Signatures General Signature Requirements and Identity Control / Passwords History FDA Title 21 CFR Part 11: Electronic Reports; Electronic signatures; Final Rule (1997) Various key speeches by FDA insiders at the beginning of the beginning The century (in addition to high-profile audit findings focusing on computer system compliance) has led many companies to try to establish protection against compliance with rules that they were procedurally and technologically unprepared. Many software and instrument vendors have released part 11 compatible updates that were either incomplete or insufficient to fully comply with the rule. Claims about the waste of critical resources unrelated to value-added aspects, in addition to confusion in the drug, medical device, biotechnology/biological and other industries about the true scope and law enforcement aspects of Part 11 led to the FDA release: FDA Guide to Industry Part 11, Electronic Reports: Electronic Signatures - Scope (2003) This document was intended to clarify how Part 11 should be implemented and implemented. But like all FDA recommendations, it was not intended to pass the full force of the law, but rather, it expressed the FDA's current thinking on Part 11 compliance. Many in the industry, while satisfied with the more limited coverage identified in the manual, complained that in some areas the 2003 guidance was contrary to the requirements of the 1997 Final Rule. A guide to industrial computerized systems used in clinical trials In May 2007, the FDA published the final version of its guide to computerized systems in clinical trials. This guide pushes out the leadership of the same name from April 1999; and complements the industry guide to Part 11, Electronic Reports; Electronic Signatures - Scope and International Harmonization Efforts by the Agency to apply these recommendations to baseline data generated locally in clinical trials. The FDA has previously announced that a new Part 11 will be released in late 2006. The Agency has since pushed back that release date. The FDA has not announced a revised release time. John Murray, a member of The Working Group on Part 11 (the FDA group developing the new Part 11), has publicly stated that the release schedule is flexible. See also the Electronic Laptop Lab Electronic Medical Record Secure Access for All (SAFE) Electronic Signatures in the Global and National Trade Act (ESIGN, USA) References to CFR - Code of Federal Rules Title 21. U.S. Food and Drug Administration. U.S. Food and Drug Administration. Received on September 15, 2016. The Food and Drug Administration CFR Title 21 Part 11. Microsoft. Microsoft. Received on September 15, 2016. Part 11, electronic records; Electronic signatures are the scope and application. Food Control Authority U.S. drugs. U.S. Food and Drug Administration. Received on September 15, 2016. 21 CFR Part 11 - Electronic records and electronic signatures. Compliance with the requirements of the laboratory. Compliance with the requirements of the laboratory. Received on September 15, 2016. The role of biometrics in corporate security (PDF). Dell. Dell. Extracted 15 15 2016 - Part 11, electronic records; Electronic signatures are the scope and application. U.S. Food and Drug Administration. U.S. Food and Drug Administration. Received on September 15, 2016. CFR - Federal Code of Rules Section 21. U.S. Food and Drug Administration. U.S. Food and Drug Administration. Received on September 15, 2016. Audit Trails: Patterns and Part 11 Compliance. SOLABS. SOLABS. Received on September 15, 2016. FDA External References: FDA Regulation 21 CFR Part 11 - Electronic Reports; Electronic Signature (1997) FDA Announcement 08-July-2010 (21 CFR Part 11) General Principles of Software Verification; The Final Guide for Industry and FDA Employees (2002) FDA Guide to Industry Part 11, Electronic Reports: Electronic Signatures - Scope (2003) obtained from Contains optional recommendations This guide presents the Food and Drug Administration (FDA) current thinking on this topic. It does not create or grant any rights to or on any person and does not work to link the FDA or the public. An alternative approach can be used if this approach meets the requirements of applicable legislation and regulations. If you want to discuss an alternative approach, contact the FDA in charge of implementing this guide. If you are unable to identify the appropriate FDA personnel, please call the appropriate number listed on the front page of this guide. I. INTRODUCTION This guide is intended to describe the current thinking of the Food and Drug Administration (FDA) regarding the scope and application of Section 11 of Article 21 of the Federal Rules Code; Electronic records; Electronic Signatures (21 CFR Part 11).2 This document contains recommendations for individuals who, as required by statute or other part of FDA rules to record or provide FDA3 information, choose to keep records or submit designated information electronically and, as a result, become the subject of Part 11. Part 11 applies to electronic records that are created, modified, maintained, archived, extracted or transmitted in accordance with any requirements for records set out in agency rules. Part 11 also applies to electronic documents submitted to the Agency under the Federal Food, Medicines and Cosmetics Act (Act) and the Public Health Service Act (PCG Act), even if such records are not specifically defined in Agency regulations (No. 11.1). The basic requirements set out in the Act, the PHS Act and the Rules (except Part 11), are referred to herein as predicate rules. As a result of its current Good Manufacturing Practices (CGMP) initiative for human and animal drugs and biologics,4 the FDA is re-examining Part 11 as it applies to all FDA-regulated products. We expect the initiation of rule-making Part 11 as a result of this re-examination. This guide explains that we will narrowly interpret the scope of Part 11. While Part 11 is currently being re-examined, we intend to exercise discretionary enforcement powers for certain requirements, in part 11. That is, we do not intend to take enforcement action to ensure compliance with verification, audit, record retention, and copying requirements for Part 11, as explained in this guide. However, reports must continue to be maintained or submitted in accordance with the basic predicate rules, and the Agency may take regulatory action for non-compliance with such predicate rules. In addition, we intend to exercise discretionary enforcement powers and do not intend to take (or recommend) measures to ensure compliance with any part of the 11 systems requirements that were put in place before 20 August 1997, the date of the introduction of Part 11 (commonly known as outdated systems) in the circumstances described in Section III. C.3 of this manual. Please note that Part 11 remains in force and that this exercise of discretionary enforcement powers applies only if defined in this guide. FDA guidelines, including this guidance, do not establish legally binding duties. Instead, the guidelines describe the Agency's current views on the topic and should only be considered as recommendations unless specific regulatory or regulatory requirements are made. The use of the word should be in the Agency's guidelines meaning that something is suggested or recommended, but is not required. Table Content II. BACKGROUND In March 1997, the FDA issued the final part of 11 rules that provide criteria for FDA adoption, under certain circumstances, electronic records, electronic signatures and handwritten signatures made in electronic records equivalent to paper records and handwritten signatures made on paper. These rules, which apply to all areas of the FDA program, were designed to ensure the widest possible use of electronic technologies compatible with the FDA's responsibility to protect public health. Since part 11 came into force in August 1997, significant discussions have begun between industry, contractors and the Agency on the interpretation and implementation of these provisions. The FDA (1) has talked about Part 11 at many conferences and has met many times with the industry coalition and other stakeholders in an attempt to hear more about a potential portion of 11 issues; (2) Published Compliance Policy Guide, CPG 7153.17: Enforcement Policy: 21 CFR Part 11; Entries Electronic signatures; and (3) published numerous draft guidelines, including: 21 CFR Part 11; Electronic records; Electronic Signatures, Check 21 CFR Part 11; Electronic records; Electronic Signatures, Glossary Of 21 CFR Part 11; Electronic records; Electronic Signatures, Time 21 CFR Mark Part 11; 11; Entries; Electronic Signatures, Electronic Records Service 21 CFR Part 11; Electronic records; Electronic signatures, electronic copies of electronic records throughout these messages, have been raised by concerns that some interpretations of Part 11 of the requirement (1) unnecessarily restrict the use of electronic technology in a way that is incompatible with the FDA's stated intention to issue a rule, (2) significantly increase compliance costs to the point that was not envisaged at the time of the rule's development, and (3) discourage innovation and advances in technological advances. without providing significant public health benefits. These concerns have been raised, in particular, regarding Part 11 requirements for verification, audit, record retention, copying of records and outdated systems. In response to these concerns, we have decided to consider some of the 11 documents and related issues, particularly in light of the CGMP initiative. In the Federal Register of February 4, 2003 (68 FR 5645) we announced the recall of the draft guidance for industry, 21 CFR Part 11; Electronic records; Electronic signatures, electronic copies of electronic records. We have decided that we want to minimize the time we want to review and comment on the draft guidance when this draft guidance may no longer represent our approach under the CGMP initiative. Then, in the Federal Registry of February 25, 2003 (68 FR 8775), we announced the withdrawal of part 11 draft review guidelines, a timeline glossary, a timeline, 5 electronic records maintenance, and CPG 7153.17. We have received valuable public comments on these draft guidelines and plan to use this information to assist in future decision-making regarding Part 11. We do not intend to reissue these draft guidelines or CNG. We are currently reviewing Part 11 and are awaiting the initiation of rule-making to revise the provisions of this provision. To avoid unnecessary resource costs under Part 11 requirements, we issue this guide to describe how we intend to exercise enforcement discretion regarding certain part 11 requirements during the re-examination of Part 11. As mentioned earlier, Part 11 remains in force during this re-examination period. Table Of Content III. THE GOOD approach to the requirements of Part 11, described in more detail below, the approach outlined in this guide is based on three main elements: Part 11 will be interpreted narrowly; we are currently clarifying that fewer entries will be considered in Part 11. With respect to those records that still fall under Part 11, we intend to exercise enforcement discretion regarding part 11 of the requirements for verification, audit trails, record retention and copying of records in described in this guide, as well as all parts of 11 requirements for that were put in place before the date of operation of Part 11 (also known as outdated systems). We will apply all predicate rules requirements, including requirements for predicate rules and accounting. It is important to note that the fda's exercise of discretionary enforcement powers, as described in this guide, is limited to this part 11 (the removal of outdated systems for which discretionary enforcement powers will be more broad under certain circumstances). We intend to ensure compliance with all other provisions of Part 11, including, but not limited to, certain controls for closed systems in No. 11.10. For example, we intend to ensure compliance with the following controls and requirements: limiting systemic access to authorized persons, using operational system checks of the use of authority checks, determining that those who develop, maintain or use electronic systems have the education, training and experience to meet their task of establishing and complying with written policies that hold individuals accountable for actions initiated under their electronic signatures. appropriate control over the system control of open documentation. Systems that meet the requirements of monitoring closed systems (No. 11.30) to electronic signatures (e.g., No. 11.50, 11.70, 11.100, 11.200 and 11,300) We expect further compliance with these provisions, and we will continue to enforce them. In addition, persons must abide by applicable predicate rules, and records that must be stored or submitted must remain secure and reliable in accordance with predicate rules. Details of the approach - Scope Part 11 Narrow interpretation of the scope We understand that there is some confusion in the area of Part 11. Some understand that part 11 is very broad. We believe that some of these broad interpretations can lead to unnecessary controls and costs and may hinder innovation and technological progress without providing additional public health benefits. As a result, we would like to clarify that the Agency intends to narrowly interpret the scope of Part 11. In accordance with the narrow interpretation of part 11, part 11 will apply to records to be conducted in accordance with predicate rules or submitted by the FDA, where persons choose to use electronic records instead of paper format. On the other hand, when individuals use computers to create paper printouts of electronic records, and these paper records meet all the requirements of applicable predicate rules, and individuals rely on paper records to In its regulated activities, the FDA generally does not consider individuals to use electronic records instead of paper records under Nos. 11.2 (a) and 11.2(b). In these cases, the use of computer systems will not call part 11. Determining Part 11 Reports In accordance with this narrow interpretation, the FDA considers that Part 11 will apply to the following records or signatures in electronic format (part 11 records or signatures): Records that must be retained in accordance with the requirements of the predicate rules and which are maintained electronically instead of paper format. On the other hand, records (and any related signatures) that should not be kept in accordance with predicate rules but which are nevertheless conducted electronically are not part of 11 records. We recommend that you determine, based on predicate rules, whether specific entries are part of 11 entries. We encourage you to document such solutions. Records that must be conducted in accordance with predicate rules, which are conducted electronically in addition to the paper format and which are relied upon to perform regulated activities. In some cases, actual business practice may dictate whether you use electronic records instead of paper records under No. 11.2(a). For example, if the record is to be conducted in accordance with the predicate rule and you use the computer to create a paper printout of electronic records, but you nevertheless rely on an electronic record to perform a regulated activity, the Agency may consider using an electronic record instead of a paper recording. That is, the Agency can take into account your business practices when determining whether Part 11 is applicable. Accordingly, we recommend that for every record required to comply with predicate rules, you will determine in advance whether you plan to rely on an electronic record or paper record to perform a regulated activity. We recommend that you document this solution (for example, in the Standard Operating Procedure (SOP) or in the document specification). Reports submitted by the FDA are in accordance with predicate rules (even if such records are not specifically defined in Agency regulations) in electronic format (assuming that the records were identified in list 92S-0251 as the types of representations that the Agency accepts electronically). However, a record that is not in itself present but is used to create a view is not part of 11 records unless it is otherwise required to be maintained in accordance with the predicate rule and is maintained electronically. Electronic signatures that are intended to be the equivalent of handwritten signatures, initials and other general signatures required by predicate rules. Part 11 of the signatures includes electronic signatures that are used, for example, to document the fact that certain events or actions occurred in accordance with the predicate rule (e.g., approved, reviewed verified). The Approach to a Specific Part 11 Claims Review Agency intends to exercise enforcement discretion regarding a specific part of 11 requirements for verifying computerized computerized (No 11.10 (a) and relevant requirements at No. 11.30). Although individuals still have to comply with all applicable predicate rule requirements for verification (e.g. 21 CFR 820.70 (i), this guide should not be read to introduce any additional verification requirements. We suggest that your decision to test computerized systems and the degree of verification take into account the impact of systems on your ability to comply with predicate rules. The impact of these systems on the accuracy, reliability, integrity, availability, and authenticity of the required records and signatures should also be taken into account. Even if there is no predicate requirement to verify the system, it may be important to check the system in some cases. We encourage you to base your approach on a valid and well-documented risk assessment and the potential of the system affecting product quality and safety, as well as the integrity of the record. For example, verification won't be important for a word processor used only to create SOPs. For further recommendations for checking computerized systems, see the FDA's guidance for industry and FDA employees general software review principles, as well as industry recommendations such as the GAMP 4 manual (see links). The Audit Trail Agency intends to exercise enforcement discretion regarding a specific part of 11 claims related to computer-stamped time audit trails (No. 11.10 (e), (k) (k) (2) and any relevant requirement at 11.30). Individuals must continue to comply with all applicable predicate requirements related to documentation, such as dates (e.g. 58.130 (e)), time or sequence of events, and any requirements to ensure that changes in records do not obscure previous entries. Even if there are no predicate rule requirements for documenting, such as date, time, or sequence of events in a particular case, it may be important to have audit trails or other physical, logical or procedural safety measures to ensure the reliability and reliability of records.6 We recommend that you base your decision on whether audit trails, or other appropriate measures, should be applied to the requirements of the predicate rule. , justified and documentary risk assessment, as well as determining the potential impact on product quality and the safety and integrity of the record. We propose that appropriate controls be applied on the basis of such an assessment. Audit trails may be especially appropriate when users need to create, modify, or delete adjustable records during normal operation. Legacy Systems7 intends to exercise discretionary enforcement powers in respect of all Part 11 requirements to systems that would otherwise be until 20 August 1997, the date of the introduction of Part 11, under the terms outlined below. This means that The Agency does not intend to take coercive measures to ensure compliance with any part of the 11 requirements if all the following criteria are met for a particular system: the system has been put in place before the date into effect. The system complied with all applicable predicate rules before the date in force. The system currently meets all applicable predicate requirements. You have documentary evidence and justifications for the system's appropriate use (including with an acceptable level of recording security and integrity, if applicable). If the system had been changed since 20 August 1997 and if the changes did not allow the system to comply with the requirements of the predicate rules, the controls 11 should apply to records and signatures based on Part 11, in accordance with the enforcement policy expressed in the manual. Copies of records the Agency intends to carry out as it sees fit for a specific part of the 11 requirements for the creation of copies of records (No. 11.10 (b) and any relevant requirement at 11.30am). You must give the investigator reasonable and useful access to the records during the check. All records you hold are subject to predicate rules (e.g. No. 211.180 (c), (d) and 108.35 (c) (3) (ii) We recommend that you supply copies of electronic records by: Producing copies of records held in general portable formats when records are supported in these formats Using established automated conversion or export methods where possible to make copies in a more general format (examples of such formats include, but are not limited to, PDF, XML, or SGML) In each case, we recommend that the copying process used produces copies that retain the content and meaning of the record. If you have the ability to search, sort, or trend part 11 entries, copies sent to the Agency should provide the same opportunity if it is reasonable and technically feasible. You must allow records to be verified, viewed and copied in human readable form on your website using your equipment and following established procedures and methods of accessing records. The Agency intends to exercise discretionary enforcement powers in respect of Part 11 requirements for record protection in order to ensure that they are accurate and ready to be searched for the duration of the records (No. 11.10 (c) and any relevant requirement of 11.30 euros). Individuals are still required to comply with all applicable predicate requirements for storage and records (e.g. No. 211.180 (c), d), 108.25 (g) and 108.35 (h)). We suggest that your decision on how to keep records is based on the requirements of the predicate rules and that you base your decision on a justified documented risk assessment and determination of the value of records over time. The FDA has no intention of objecting if you choose to archive the necessary records in the format for non-electronic media such as microfilm, microfiche and paper, or standard electronic file format (examples of such formats include, but are not limited to, PDF, XML or SGML). Individuals must continue to comply with all predicate rules, and records and any copies of the required records must retain their content and value. As long as the predicate requirements are fully satisfied and the content and meaning of the records are stored and archived, you can delete the electronic version of the records. In addition, the paper and electronic components of the record and signatures can coexist (i.e. hybrid 8 situation) as long as the requirements for the predicate rules are met and the content and meaning of these records are maintained. Table Of Content IV. HELP The Food and Drug Administration Links Glossary Computerized System and Software Development Terminology (Department of Field Investigations, Office of Regional Operations, Regulatory Authority, FDA 1995) General Principles of Software Verification; The final guide for industry and FDA employees (FDA, Center for Devices and Radiological Health, Center for Biologics Assessment and Research, 2002) Guide to Industry, FDA Reviewers, and Compliance on Off-The-Shelf Software Use in Medical Devices (FDA, Center for Devices and Radiological Health, 1999) Pharmaceutical CGMPs for the 21st Century: Risk-Approach; A scientific and risk-based approach to product quality regulation, including a comprehensive approach to quality systems (FDA 2002) Industry References to Good Automated Manufacturing Practices (GAMP) Guide to testing automated systems, GAMP 4 (ISPE/GAMP Forum, 2001) (ISO/IEC 17799:2000 (BS 7799:2000) Information Technology - Code of Information Security Management Practice (ISO/IEC, 2000) ISO 14971:2002 Medical Devices- Application of Risk Management for Medical Devices (ISO, 2001) Table Content 1 This guide was prepared by the Compliance Office at the Center for Drug And Research Assessment (CDER) in consultation with other Agency centers and the Office of Regulation in the Food and Drug Administration. 2 62 FR 13430 3 These requirements include, for example, some provisions of the current good practice regulations (21 CFR Part 211), quality system regulation (21 CFR Part 820) and logical laboratory practice for non-clinical laboratory research (21 CFR Part 58). 4 See Pharmaceutical CGMPs for the 21st Century: Risk-Based Approach; A scientific and risk-based approach to product quality regulation that includes a comprehensive approach to quality systems. 5 Although we have withdrawn the draft time-stamp guide, our current thinking is not in that when you use time stamps for systems that cover different time zones, we don't expect you to record local time. When using time stamps, they should be carried out with a clear understanding of the time zone link used. In such cases, the system documentation should explain the links of the time zone, as well as the acronyms of zones or other naming conventions. 6 There are various guidelines on information security (see References). 7 In this guide, we use the term legacy of the system to describe systems, already working until the date of the introduction of Part 11. 8 Examples of hybrid situations include combinations of paper records (or other non-electronic media) and electronic records, paper records and electronic signatures or handwritten signatures made for electronic records. Content table fda 21 cfr part 11 download

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