21 CGR Part 11

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21 CFR Part 11

Overview

- The meaning of 21 CFR part 11 is as follows. 21 CFR — concerns the protection of privacy, Part 11 refers to electronic records and signatures. We are concerned with the GAMP interpretation of 21 CFR part 11

- ISPE's GAMP Forum and the PDA have operated two separate initiatives, but with close cooperation, to deliver industry guidance relative to electronic information. Both initiatives produced work products from different perspectives; however, the approaches are complementary and collectively, they cover the broad issues that are associated with electronic records and signatures

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Overview

- The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international agreements between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP

- PIC/S 21.5 - Pg 27 states: ‘When regulated users elect to use electronic records for GxP applications then it will be necessary for the companies to identify the particular regulations being applied and whether they are to be considered legally binding and equivalent to their paper-based counterparts’

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Overview

Paper 	Paper Only – No compliance issues with Respect to ERES
Transient 	No compliance issues with Respect to ERES
Hybrid – Electronic and Paper 	Requires careful analysis against ERES Requirements
Electronic only 	Needs to fully comply with all ERES Requirements

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Overview

- The Food and Drug Administration (FDA) in 1997 issued regulations that provide criteria for acceptance by FDA, under certain circumstances, electronic records and electronic signatures, recorded electronically, to be equivalent to paper records and hand written signatures executed on paper
- This is known as 21 CFR part 11
- So what's new in the rule?

Electronic Records = Paper Records

Electronic Signatures = Hand Written Signatures

- These are referred to as ER/ES systems

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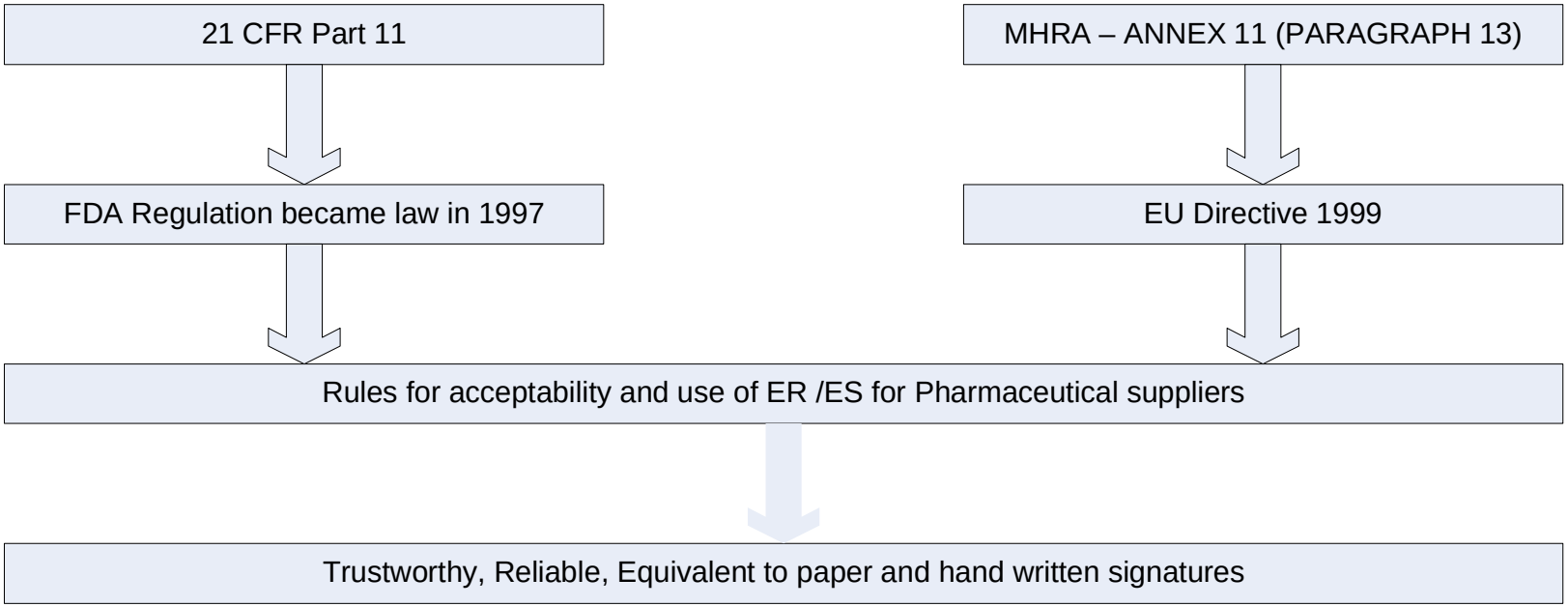

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Rules

- Can a supplier guarantee compliant system for Part 11? It is not possible for any supplier to offer a 'Part 11 compliant system?'
- Anyone who makes such a claim is incorrect. Part 11 requires both procedural controls (training, SOPs, administration) and administrative controls to be put in place by the user in addition to the technical controls that the supplier can offer
- At best, the supplier can offer an application containing the technical requirements of a compliant system
- The concerns are:

  Data Security – paper can be locked away

  Data Integrity – paper can be seen to have been altered

  Audit Trail Integrity – modifications to paper can be tracked

  Signature Repudiation – physical signatures are used universally in industry

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Rules

- Audit trails of electronic records record - WHO, WHAT, WHEN and WHY was a change made to a record
- However please note that Part 11 itself does not require the audit trail to record the reason WHY a record was changed, although another control usually requires recording this information

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Rules

- Closed systems - Access control by the company or group, Communication via secure network
- Validation of systems, protection of records, limiting system access, checks of devices, operations and authorities and Change control
- Open systems - Company delegates control, Communication control by the on-line service
- As closed systems, plus using open systems to create, modify, maintain, or transmit electronic records must employ procedures and controls to ensure the authenticity, integrity and the confidentiality of electronic records from the point of their creation to the point of their receipt
- All systems we discuss can be considered to be CLOSED

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Rules

- The controls for password/user ID usage apply across the board for ERES systems. They apply to the proper management of electronic records in addition to executing compliant electronic signatures
- In previous control systems the access method for controlling the system has been via a simple key-switch system. This however does not force any security regarding the operator making the changes and his proven ability to make these changes. Therefore a more sophisticated system is required. Within 21 CFR this is permitted in three ways:
- Token systems
- Biometrics
- Two part passwords

- Most companies have concentrated on method three

Thank you for your attention.

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