

Electronic John Hancocks: E-signatures, e-records replace paper

E-cards, e-mail, e-verify, e-z pass all have one thing in common – the e stands for electronic. Add two more to the lexicon, e-records and e-signatures, courtesy of FDA.

The Agency's Part 11 regulations, officially known as Title 21 of the Code of Federal Regulations, Part 11, define how electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records and handwritten signatures. It applies to records electronically created, modified, maintained, archived, retrieved, or transmitted under any records requirements by FDA.

Part 11 regulations help:

- Ensure system validation and the protection of records
- Ensure operational consistency across all departments
- Improve productivity and efficiency of existing staff
- Minimize and possibly eliminate the maintenance and retention of paper documentation
- Meet study timelines
- Perform faster study-related searches and establish trends
- Provide study-related submission information in formats acceptable to FDA

Computerized systems should meet all regulatory requirements with the same degree of confidence provided by paper systems. The regulations require drug makers, medical device manufacturers, and other FDA-regulated industries to:

- Utilize appropriate controls to ensure that e- records/data and e-signatures are trustworthy, accurate, and complete.
- Use appropriate controls to ensure that clinical data are protected so that study related activities can be reconstructed.
- Use a risk-based approach for designing/utilizing computerized systems for clinical dataflexible regulations that support a risk based approach.

(For more information about how electronic signatures and records apply to clinical trials, tune in Monday, January 23, 2012 at 11am (ET), to CDER's webinar entitled ***CDER Small Business Electronic Documentation.***)