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## DataFax 4 Software Validation

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### Presentation Outline

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- 21 CFR Part 11; Electronic Signatures and applicability to DataFax 4
- Software validation
- Software validation of 21 CFR Part 11 systems

## 21 CFR Part 11 Final Rule

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- Federal regulation in the US effective March 1997
- "... objective of enabling electronic records and signatures to have standing equal to paper records and handwritten signatures."
- "However, this part does not apply to paper records that are, or have been, transmitted by electronic means."
- "The agency does not intend part 11 to apply to paper records even if such records are transmitted or received by fax."

## 21 CFR Part 11 and DataFax 4

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- Does not apply directly to DataFax 4 as the paper record is the source document
- Indirectly, parts of the regulation do apply, such as those dealing with user permissions and authentication, and audit trails
- "Validation of systems to ensure accuracy, reliability, consistent intended performance..."

## Software Validation

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- “Is DataFax 4 validated?”
- What is your definition of “validated”?
- What is the FDA’s definition of “validated”?
- A good starting point is:  
*“Documented evidence that a software system was developed from a pre-established set of requirements, following generally accepted practices in a controlled environment, and thoroughly tested to demonstrate that the requirements were met accurately, reliably, and consistently.”*

## FDA’s View of Software Validation

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- Documented in the following guidances:
  - General Principles of Software Validation; Final Guidance for Industry and FDA Staff
  - 21 CFR Part 11; Electronic Records; Electronic Signatures Validation (Draft Guidance for Industry)

## General Principles of Software Validation

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- Final guidance issued January 11, 2002
- “For FDA purposes, the guidance applies to any software related to a regulated medical device,…”
- “This document is based on generally recognized software validation principles and, therefore, can be applied to any software.”

## 21 CFR Part 11; Electronic Records; Electronic Signatures Validation

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- Draft guidance issued August 2001
- “... the FDA’s current thinking regarding considerations in meeting the validation requirements of Part 11...”
- “... is not intended to cover everything that computer systems validation should encompass in the context of electronic record/electronic signature systems.”
- In practice, this guidance **will be** widely applied to software systems in the pharmaceutical industry

## Developer: Key Principles 1

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- Documented end-user requirements
  - What are the user needs and intended uses?
  - How does one demonstrate that software meets needs without first documenting them?
  - Must be traceable to design, implementation, and testing
  - Requirements for DataFax 4 have been collected from DataFax 3, past DFUG meetings, new feature requests of support database, regulatory, and industry trends

## Developer: Key Principles 2

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- Documented validation
  - Begin with definition of validation
  - Extent of validation required, risk assessment
  - Validation plan
    - What is to be done, by whom, and when
  - Validation procedure
    - Detailed steps for conduct
    - System configuration, expected outcomes
    - Acceptance criteria
  - Validation report
    - Detailed, quantified test results
    - Approved by QA group

### Developer: Key Principles 3

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- Equipment installation
  - Installed following vendor guidelines
  - Inventoried
  - Manuals are readily available

### Developer: Key Principles 4

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- Testing
  - “normal” or “expected” values
  - Boundary values, error conditions, stress conditions
  - End-user environment under actual operating conditions
  - Quantifiable test results
  - Static verification including code inspections, technical reviews

## Developer: Key Principles 5

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- **Configuration Management**
  - Assessment of impact of change
  - Regression analysis
  - Appropriate revalidation

## End User: Key Principles 1

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- **End User Requirements**
  - Must be documented
  - May be different from developer's specifications
  - Compare with developers requirements: most vendors will be unwilling to share this information

## End User: Key Principles 2

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- **Software integrity**
  - Research the use of the software over its history
  - Perform a reliable audit of the software developer, either by the end user's organization or a trusted third party (more tomorrow...)
- *PDA Technical Report #32 and Audit Center Repository*
  - *CDSI plans to participate*

## End User: Key Principles 3

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- **Functional testing**
  - Based upon **own** requirements, test all of the functions that the end user will use
- *Should CDSI continue with the ATK?*
  - *Penetration is limited*
  - *Not sufficient to establish software adequacy or end user functional testing*

## Issues Not Addressed

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- Standardized procedures or guidance used by the developer
- Standardized procedures or guidance used by the end user

## You Can Help

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- Current comment period for the draft guidance has closed, however a 90 day extension period is being considered

Source: FDAnews, Part 11 Compliance Report, Jan 9 2002

## FDAnews, Part 11 Compliance Report

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- FDA has no plans to drop the requirement that investigative sites must maintain an original copy of data submitted to the agency
- Preferred solution at this time is to save case report forms on local hard drives in Adobe PDF (more tomorrow...)

## The Cobbler's Children Have Bare Feet

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- "We're starting a validation process and targeting external vendors first"
- Tendency is to over-scrutinize external entities while at the same time under-scrutinizing (or ignoring) internal entities
- I.e. vendor configuration management has little real meaning if installed in an environment where there is no configuration management
- Get your children some shoes!

## In Summary...

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- Computer software validation is a real concern for everyone
- Must be done
- Requires time and money (yours and ours)
- Support the initiative that Phil is presenting tomorrow

## References

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- 21 CFR Part 11; Electronic Records; Electronic Signatures; Final Rule  
[http://www.fda.gov/ora/compliance\\_ref/part11/FRs/background/pt11finr.pdf](http://www.fda.gov/ora/compliance_ref/part11/FRs/background/pt11finr.pdf)
- 21 CFR Part 11; Electronic Signatures Validation  
<http://www.fda.gov/cber/gdlns/esigvalid.html>
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