21 CFR Part 11
Scope & Application

A Drug Quality System for the 21st Century

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Part 11 - Agenda

- The Past
  - Intentions
  - Interpretations
- The Present
  - Issuance of Draft guidance
    - Withdrawal of previous Guidance
    - Narrow scope
    - Enforcement discretion
    - Continued enforcement of all other elements of the rule

Part 11 - Agenda

- The Future
  - Finalize Guidance
  - Additional Guidance evaluation
  - Rule evaluation

Part 11 - The Past

- Effective August 20, 1997
- Original intention was:

To permit the widest use of electronic technology compatible with FDA's responsibility to promote and protect public health. The use of electronic records as well as their submission to FDA is voluntary

Part 11 - The Past (Continued)

- Problems and issues
  - Interpretation:
    - Can unnecessarily restrict the use of electronic technology
    - Significantly increase the costs of compliance to an extent not contemplated at the time the rule was drafted
    - Discourages innovation and technical advances without providing a significant public health benefit

Part 11 - The Present

- Draft guidance issued February, 2003

  Part 11 guidance: electronic records; electronic signatures - scope and application
- Part of the GMPs for the 21st century initiative
- Preliminary feedback is *Very Favorable*
- Comments are strongly requested to help us determine where additional clarification is needed

Part 11 - The Present (Continued)

- Withdrawal of Part 11 Compliance Policy Guide (CPG) and previous draft guidance
  - CPG 130.400 (7153.17) - enforcement policy
  - Electronic copies of electronic records
  - Maintenance of electronic records
  - Validation
  - Timestamps
  - Glossary of terms

Part 11 - The Present (Continued)

- **Concepts:**
  - **Predicate rule**

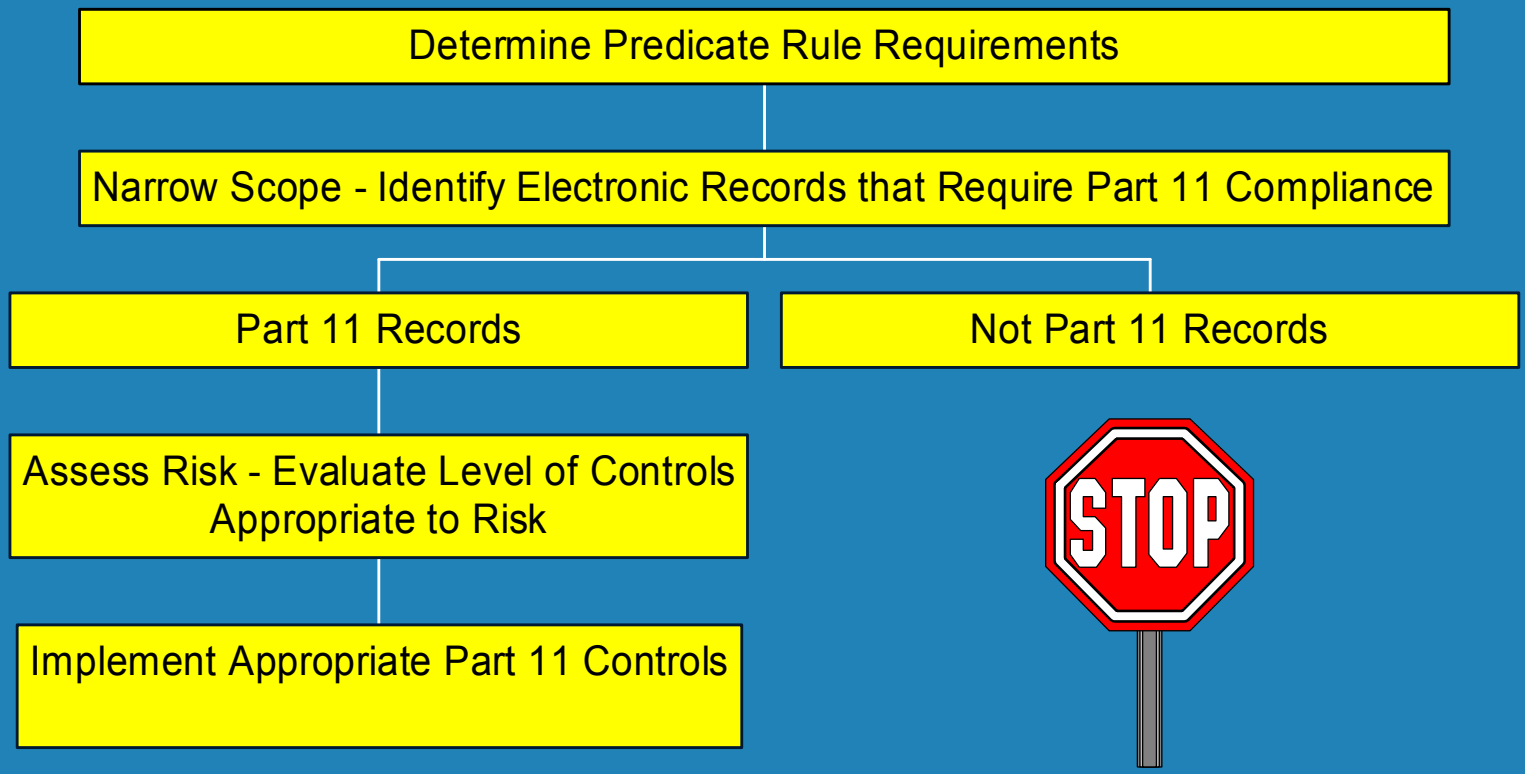
    Requirements set forth in the Act, the PHS Act, or any FDA regulation, with the exception of Part 11

  - **Enforcement discretion**

    FDA will not normally take regulatory action with certain requirements of Part 11

Part 11 - The Present (Continued)

Proposed Part 11 Approach



Part 11 - The Present (Continued)

- Narrow the scope of Part 11
  - Part 11 *ONLY* applies to :
    - Electronic records required by predicate rules
    - Electronic signatures that a company plans to use in lieu of paper-based signatures when those signatures are required by predicate rules
    - Electronic records submitted to the FDA
      e.g. NDAs & ANDAs

Part 11 - The Present (Continued)

- New approach - narrow the scope

If the computer system is merely incidental to creation of paper -

Part 11 does not apply

Part 11 - The Present (Continued)

- New approach - utilize a risk based approach
  - Determine ‘critical’ electronic data as per predicate rules
  - Implement appropriate controls (process and Part 11) necessary to mitigate risk and satisfy predicate rule requirements

Part 11 - The Present (Continued)

- High risk example
  - Data used to make quality decisions (e.g. critical control points; batch release data)
- Low risk example
  - Intermediate versions of SOPs

Part 11 - The Present (Continued)

- New approach - enforcement discretion

  Utilize enforcement discretion and not 'normally' take regulatory action to enforce of five Part 11 requirements

Part 11 - The Present (Continued)

- New approach - enforcement discretion (continued)

1. Validation
   - Must comply with predicate rule(s)
   - If none, the decision on and extent of validation be based on risk assessment/product quality/ safety/record integrity

Part 11 - The Present (Continued)

- New approach - enforcement discretion (continued)

2. Audit trails
   - Consider predicate rule(s)
   - Based on a risk assessment
   - Determine need or alternative controls

Part 11 - The Present (Continued)

- New approach - enforcement discretion (continued)

3. Legacy systems
   - Must comply with predicate rules(s)
   - For systems prior to 8/20/97 enforcement discretion for compliance with Part 11
   - For systems since 8/20/97 Part 11 applies per this guidance

Part 11 - The Present (Continued)

- New approach - enforcement discretion (continued)

4. Copies of records
   - Must comply with predicate rules(s)
   - Supply copies in reasonable form (e.g. PDF)
   - Supply copies to the Agency compatible with the firms (e.g. Same ability to search, sort, and trend)

Part 11 - The Present (Continued)

- New approach - regulatory discretion (continued)

5 Record retention

  - Must comply with predicate rules(s)
  - Justified and documented risk assessment (value of records over time)
  - Allows for the migration to non-electronic media

Part 11 - The Present (Continued)

- What remains of Part 11 that will be enforced?
  - E-signature requirements
    - Signature/record linking requirements
    - Written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures
  - Controls for identification codes and passwords
  - Educational requirements

Part 11 - The Present (Continued)

- What remains of Part 11 that will be enforced ? (continued)
  - Revision and change control procedures (including system documentation controls)
  - Authority and device check controls
  - Controls for the protection of records (including the ability to generate accurate and complete copies of records)

Part 11 - The Present (Continued)

- What remains of Part 11 that will be enforced ? (continued)
  - System access controls and operational system checks
  - Controls for authenticity, integrity, and confidentiality
  - Appropriate encryption and digital signature standards

Part 11 - The Present (Continued)

- FDA Internal ORA - Center Training April 9, 2003 Teleconference with Field offices and Centers
- May 16, 2003 DIA CDER - Live Drug Quality Regulation for the 21st Century

Part 11 - The Future

- Next steps
  - Finalize *Part 11 guidance: electronic records; electronic signatures - scope and application* based on feedback from comments and questions
  - Examine the need for additional guidance
  - Re-examine 21 CFR 11 based upon feedback received