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  - Issuance of Draft guidance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.
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- Draft guidance issued February, 2003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Withdrawal of Part 11 Compliance Policy Guide (CPG) and previous draft guidance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
Proposed Part 11 Approach

1. Determine Predicate Rule Requirements
2. Narrow Scope - Identify Electronic Records that Require Part 11 Compliance
   - Part 11 Records
   - Not Part 11 Records
3. Assess Risk - Evaluate Level of Controls Appropriate to Risk
4. Implement Appropriate Part 11 Controls
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)

 Validation

  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
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