



# CFR Part 11 and CDER's Current Ongoing Part 11 Inspectional Assignments

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# Agenda

- Historic Review
- Past Events
- Current State
- Inspectional Assignments
  - Extent
  - Timeframes
  - Possible Outcomes of Re-evaluation
- Summary & Questions?

# History of Part 11

21 CFR 11 (Part 11) was promulgated in August, 1997

- Allowed for electronic records and signatures
- Required additional controls for computer systems that maintained electronic records – *INCLUDING VALIDATION of COMPUTER SYSTEMS*

# Part 11 Controls

- Accurate and complete copies of records
- Protection of records
- Limiting system access
- Operational system checks
- Authority checks
- Device checks
- Policies for accountability
- Systems documentation
- Integrity of electronic records
- Electronic signature controls
- Password controls
- Training

# Historical Issues

## Broadly interpreted

- All automated systems running in an FDA-regulated environment require Part 11 compliance, and therefore, validation

## Not risk-based

- All systems that require Part 11 compliance must be fully validated

# Historical Issues

Didn't grandfather legacy systems

- All automated systems that were operational prior to Part 11 must comply with Part 11 and be fully validated



***PHARMACEUTICAL CGMPS  
FOR THE 21ST CENTURY —  
A RISK-BASED APPROACH***

**Department of Health and Human Services  
U.S Food and Drug Administration  
September 2002**

# 21<sup>st</sup> Century Initiative

Objective: “...encourage implementation of risk-based approaches that focus both industry and Agency attention on critical areas...”

# Part 11 Reevaluation Effort

- Part 11 lead moved to CDER's Office of Compliance (OC)
- Creation of a Part 11 Working Group with representatives from all FDA Centers
- Guidance for Industry, "21 CFR Part 11 Scope and Application," final version issued in 2003

## 21 CFR Part 11 Scope and Application Guidance Events

FDA will use enforcement discretion to narrow the application of Part 11 to the following:

- electronic records required to be maintained to meet the requirements of, or essential to demonstrate compliance with, FDA predicate rules
- electronic records submitted to the FDA

# 21 CFR Part 11 Scope and Application Guidance Events

## Under the Narrow Scope:

- The *predicate rules* identify what records must be maintained
- *Part 11* addresses how those electronic records must be maintained

# 21 CFR Part 11 Scope and Application Guidance Events

FDA will apply enforcement discretion for the following areas:

- Validation
- Audit trails
- Copies of records
- Record retention
- All Part 11 requirements for legacy systems (pre-8/20/97)

# Current State

- Still in the Reevaluation Phase
- Part 11 did not go away
- Scope & Application guidance is still in effect, and will remain in effect for the foreseeable future
- Citations have been made to the Predicate Rules, not specifically to Part 11 (e.g. Validation)
- Posting of new Part 11 Q&A to FDA website, 8/3/2010

# Recent Part 11 Q&A Posting

- Question: “How do the Part 11 regulations and ‘predicate rule requirements’ (in 21 CFR Part 11) apply to the electronic records created by computerized laboratory systems and the associated printed chromatograms that are used in drug manufacturing and testing?”

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124787.htm>

# The “Short” Answer

“We recognize that there are cases where it could be appropriate for the printed chromatogram to be used within laboratories for the review of test results. Similarly, it also may be acceptable to provide the printed chromatogram during a regulatory inspection or for application review purposes. However, the electronic record must be maintained and readily available for review by, for example, QC/QA personnel or the FDA investigator.

In summary, decisions on how to maintain records for computerized systems should be based on predicate rule requirements. We recommend that these decisions be supported by a sound risk assessment.”

# Inspection Assignments

- ORA, under CDER direction, has began inspectional assignments of Part 11 requirements using enforcement discretion as described in the Part 11 Scope and Application guidance
- CDER intends to use the inspectional findings to help further assess how to proceed with regards to the possible modification of Part 11 regulation and/or guidance
- These inspectional assignments and their outcomes to evaluate industry's implementation of Part 11

# Inspection Assignments Objectives

- Evaluate the industry's current understanding of, and compliance with, 21 CFR Part 11
- Gather information to help determine the path forward with regard to Part 11 reevaluation

# Inspection Assignments Focus

- Human drug area (API, Finished DP and CTL facilities), domestic and international
- Areas of high risk if the appropriate Part 11 controls are not in place
- Where industry may not be complying with, or understand, the enforcement approach as explained in the guidance

# Inspection Assignments Approach

- Incorporate evaluation of specific Part 11 controls into FY2011 surveillance work plan
- Take appropriate action to enforce Part 11 requirements (specifically in significant violation of the predicate rules) for issues raised during these inspections

# Extent

- Start immediately
  - inspectional assignments issued December 2010
- Evaluate and make decisions when enough data is gathered
- Compliance policy and enforcement continue as explained in guidance
- Timeframes
  - Plan is to complete by the end of the year, including data analysis

# Reevaluation: Possible Outcomes

Outcomes may include, but are not limited to, the following:

- Status quo, plus publishing additional guidance focused on issues and concerns
- Amending the existing Part 11 regulation and/or preamble
- Proposing new wording/language to existing CPGs and CPMGs that contain outdated interpretations of Part 11 requirements
- Revoking the current ‘Part 11, Electronic Records; Electronic Signatures — Scope and Application’ guidance
- Amending the current ‘Part 11, Electronic Records; Electronic Signatures — Scope and Application’ guidance

# What does Part 11 do?

It helps to answer the following question: Do you have adequate **controls** in place to ensure that your regulated records (acquired or stored electronically) are trustworthy?

Part 11 is not an IT issue, but rather a way to manage the additional risks associated with electronic data.

# Part 11 Goals

- Part 11 Controls are aimed to:
  - Preserve content and meaning throughout the required record retention period
  - Ensure security and integrity to avoid unauthorized or unintended creation, modification or deletion
  - Limit access to authorized individuals and making sure that specific system functions are performed only by authorized individuals

# Acknowledgements

- CDER's members of FDA's Part 11 Working Group:
  - George Smith
  - Joseph Salewski
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# Thank You. Questions?

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