

# Complying with New Industry Guidance on Computerized Systems Used in Clinical Trials

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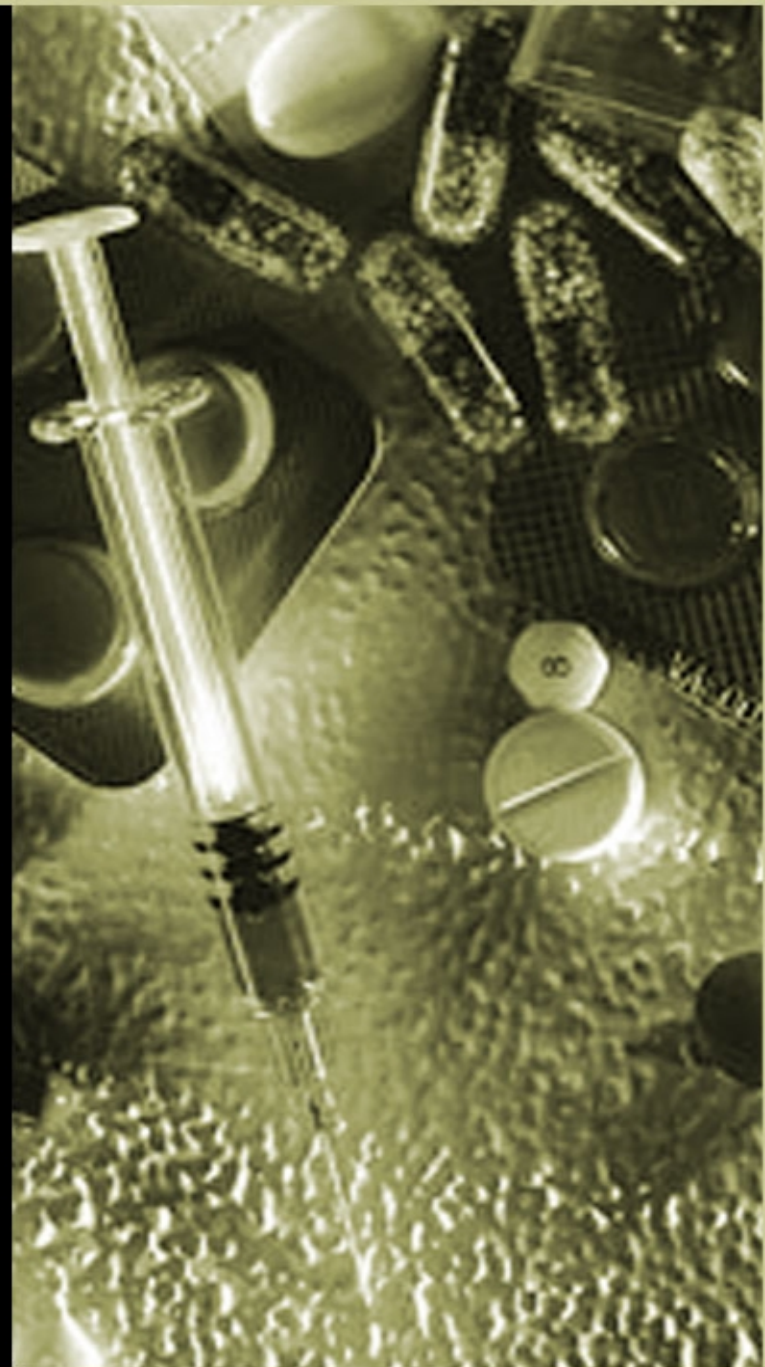
# Overview

- Regulatory Guidance
- System Development Life Cycle
- Specific Data Management Issues



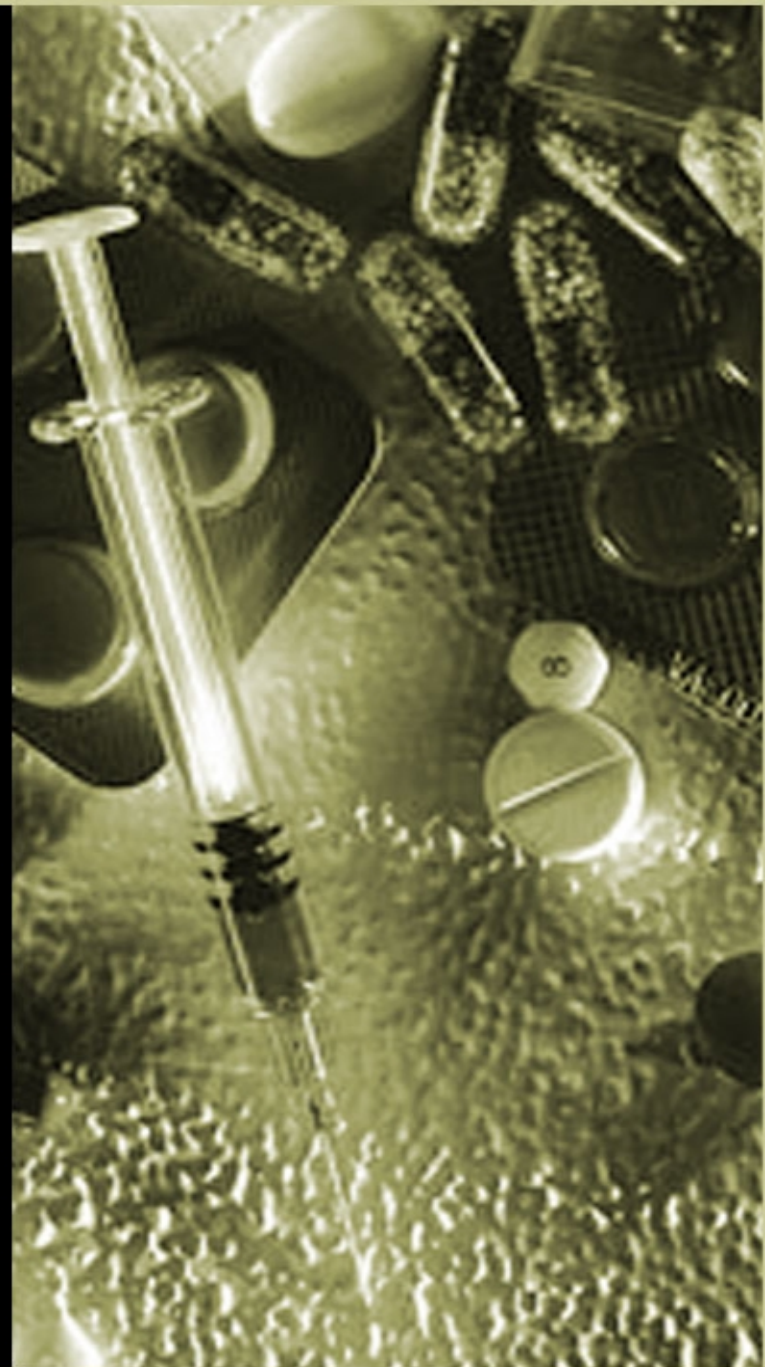
# Regulations

- 21 CFR Part 11
- Guidance for Industry: Use of Computerized Systems in Clinical Trials
- ICH Guidelines



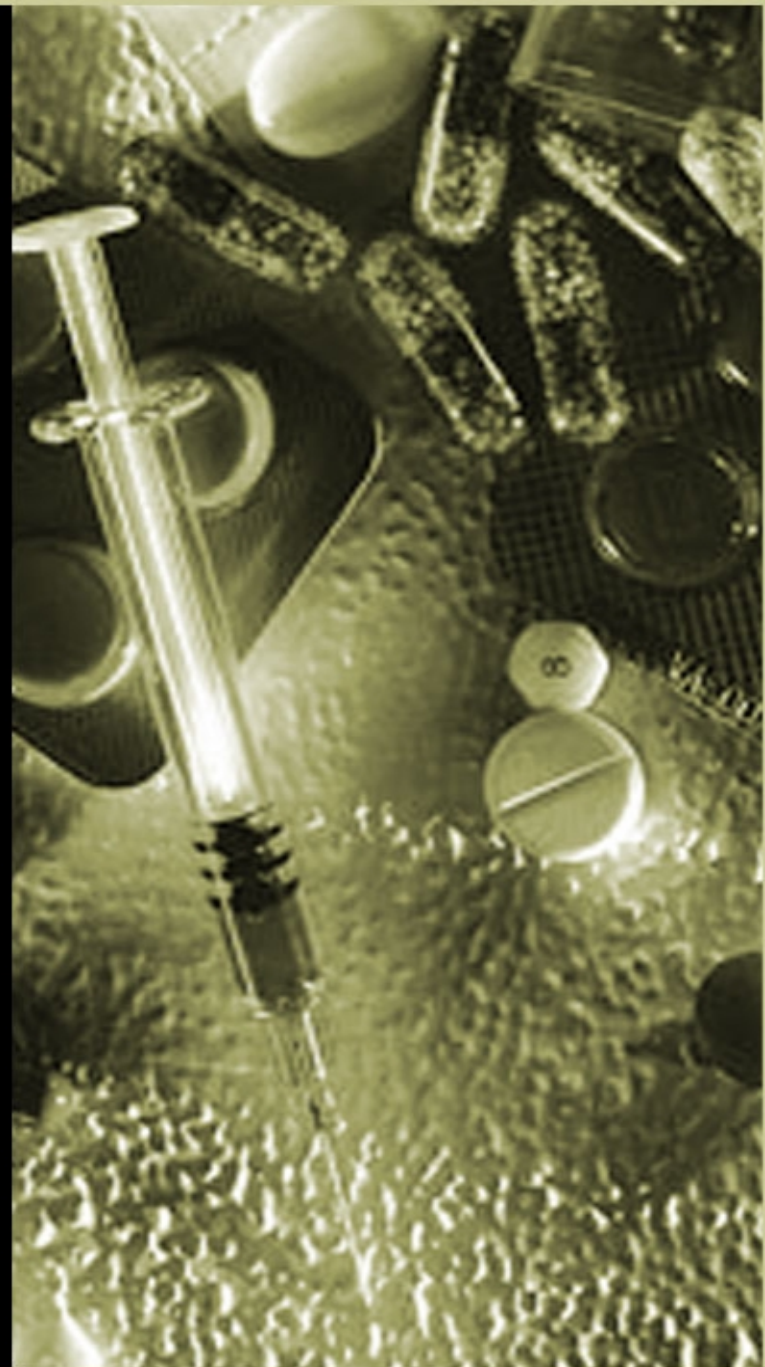
# 21 CFR Part 11

- Effective March 20, 1997
- Scope
- Open and Closed Systems
- Electronic Signatures
- Regulatory Actions for Non-Compliance



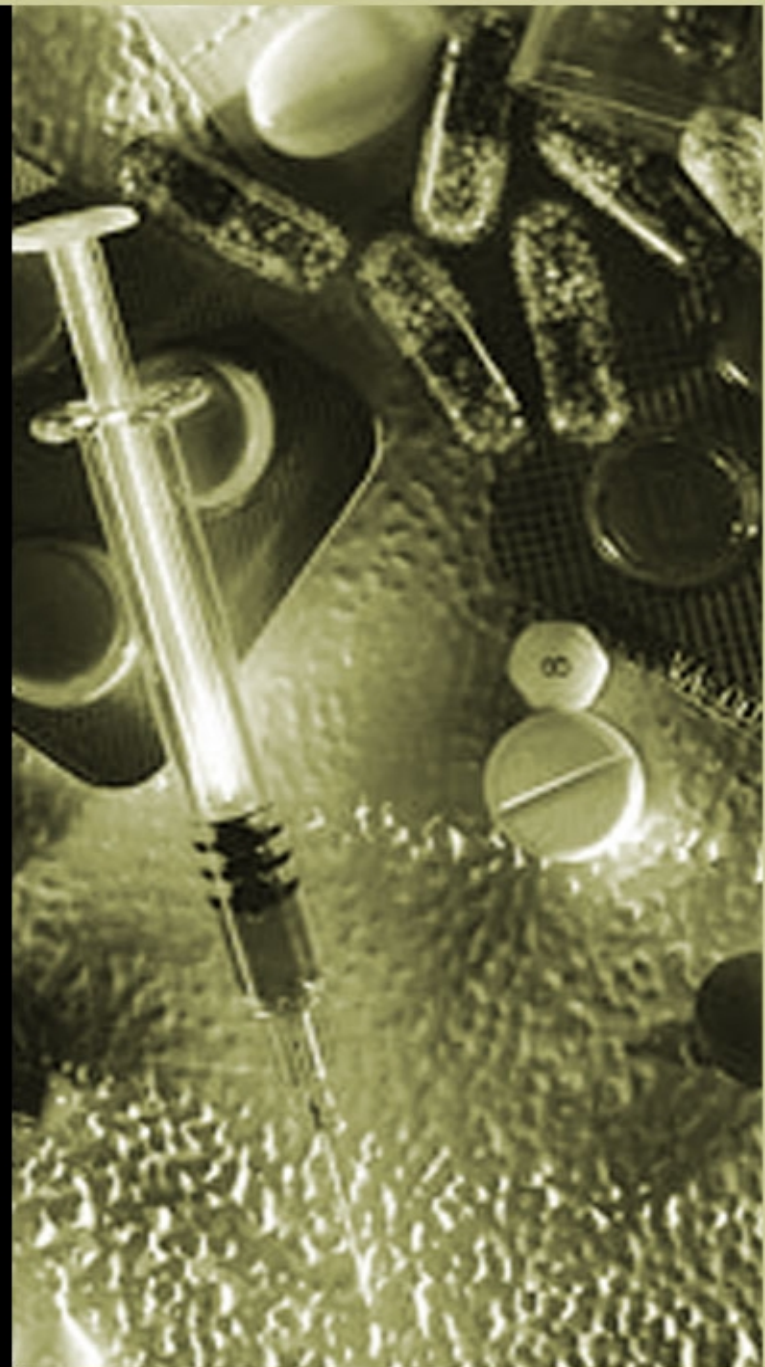
# Guidance for Industry

- Finalized April 1999
- FDA's 'Current Thinking'
- 'Fundamental Elements of Quality Should Be Met'



# ICH Guidelines

- Good Clinical Practice: Consolidated Guidelines (E6)
- General Considerations for Clinical Trials (E8)
- Statistical Principles for Clinical Trials (E9)



# System Development Life Cycle

- Concept and Purpose
- Methodologies
- Commercial Off-the-Shelf (COTS) Systems
- System Dependability
- System Controls



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graph TD; A[Concept for System] --> B[System Requirements]; B --> C[System Design]; C --> D[Design Testing]; D --> E[End User (Acceptance) Testing]; E --> F[Roll Out]; F --> G[Long Term Maintenance];
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Concept for System

System Requirements

System Design

Design Testing

End User (Acceptance) Testing

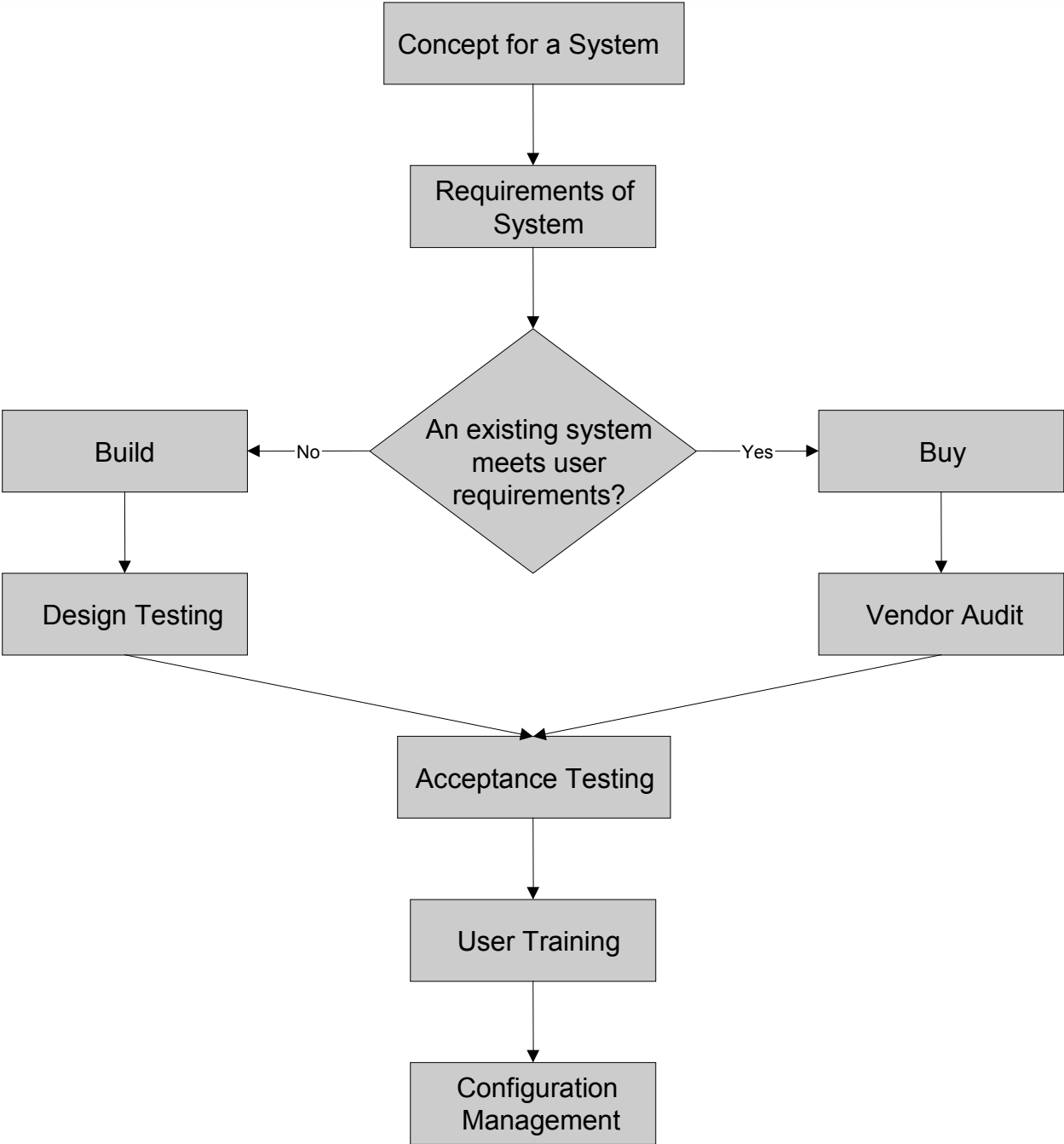
Roll Out

Long Term Maintenance

# COTS Systems

- Vendor Responsibility
- Sponsor Responsibility
- Functional Testing
- Special Cases





# System Dependability

- Documentation
  - Written Design Specification
  - Written Test Plan
  - Test Results
- Change Control
  - Written Procedures
  - Evaluation of Impact
  - Documentation of Changes



# System Controls

- Software Version Control
- Contingency Plans
- Backup and Recovery



# Specific Data Management Issues

- SOPs
- Data Entry
- System Features
- Security
- Training of Personnel



# Standard Operating Procedures

- System Setup/Installation
- Data Collection and Handling
- System Maintenance
- Data Backup, Recovery, and Contingency Plans
- Security
- Change Control



# Data Entry

- Electronic Signatures
- Audit Trails
- Date/Time Stamps



# Security

- Virus Protection
- Unauthorized Access
- Password Aging
- Unattended Workstations
- Entry Operator Identification
- Password Sharing



# Training

- System Security Issues
- Appropriate Qualifications
- Training in Specific Functions
- Ongoing Training
- Training Documentation



# Summary

- Significance of Regulations
- System Development Life Cycle
- Action Items
- Additional Information



# References

- [www.fda.gov](http://www.fda.gov)
  - [www.fda.gov/cder/guidance/index.htm](http://www.fda.gov/cder/guidance/index.htm)
  - [www.fda.gov/cder/esig/index.htm](http://www.fda.gov/cder/esig/index.htm)
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