Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

21 CFR Part 11 Considerations
November 14, 2002

Overview

- 21 CFR Part 11 Introduction
- Panel Discussion
- Questions

21 CFR Part 11 – What is it?

- Self Imposed
- Controls required to satisfy the FDA that electronic records and signatures and the legally binding equivalent to paper based records and signatures
- The regulation was published on **March 20, 1997** with an effective date of **August 20, 1997**
- Record requirements are mandatory
- Signature components are not currently mandatory
- File Cabinet Analogy

Requirements

Electronic Records:
- Validation
- Audit Trails
- Information Security
- Archiving
- Backup and Recovery
- Sequencing Controls
- Device Checks
- Ability to Export Data in Human Readable Form
- Training
- Document Control

Electronic Signatures (ID/Password/Reason)
- Password Controls
- Linking of Signatures to Records
- Legally Binding

21 CFR Part 11 Challenges

- Availability of Commercial Solutions that are Part 11 Capable
- Total compliance requires a combination of
  - Technical controls
  - Procedural controls
  - And, sometimes "Interim" controls
- "Baseline state" of the system needs to be identified
- Systematic approach to addressing gaps
- Timelines and the cost of remediation

Panel Discussion

- Compliance Costs and Timelines
  - How much should be spent to address remediation over what period of time?
  - Compliance Risk vs. Cost vs. Other Business Priorities
  - What timeframes are accepted by the FDA?
  - Convincing management of the risk and priority
  - Changing FDA GMP and Part 11 perspective
- Inspection/Audit Focus Areas
  - Individual systems
  - 21 CFR Part 11 program
  - IT Service Providers
  - Security
  - Disaster Recovery
  - Validation
  - Other

Panel Discussion

- Remediation Challenges:
  - Network Qualification
  - Consistent Validation Methodology/Approach
  - Security Program
  - Standard Operating Procedures
  - Coordination Across Business Units
  - Systems that are not "owned" by IT

Questions and Discussion