

Detailed Agenda: Prove FDA Compliance with Easy Records Management Techniques

1. FDA Rules and Expectations

- 1.1. Preclinical and design/development
- 1.2. Clinical
- 1.3. Supplier considerations
- 1.4. Bioterrorism considerations
- 1.5. Inspection considerations
- 1.6. Grassley and record integrity
- 1.7. Warning letter excerpts
- 1.8. Three suggested priorities from FDA directors

2. Records as Proof of Compliance

- 2.1. Intent versus activity
- 2.2. Costs – 3 aspects
- 2.3. Types of records
- 2.4. Types of records (simplified)
- 2.5. Retention schedules
- 2.6. Easy archiving
- 2.7. Privacy and security – defending intellectual property
- 2.8. Privacy and security – protecting clinical patients
- 2.9. Eight deadly (and costly) mistakes

3. Special Considerations for Electronic Records

- 3.1. FDA concerns about data quality
- 3.2. Understanding the 1:6 ratio
- 3.3. Role of your computer department
- 3.4. Basic electronic document management costs and tips
- 3.5. Revised 21 CFR Part 11 and Annex 11

4. Identifying and Mitigating Your Specific Challenges

- 4.1. Inventory – 4 techniques
- 4.2. Timetable experiences
- 4.3. Ownership versus stewardship
- 4.4. Archival – do's and don'ts
- 4.5. Litigation discovery – do's and don'ts

5. SmarterCompliance Strategy for Compliant Records

- 5.1. Policy framework (template)
- 5.2. Records matrix (template)
- 5.3. Organizational controls (checklist)
- 5.4. Technology controls (checklist)
- 5.5. Discovery and litigation – 5-step strategy
- 5.6. Systematic checks – 4 techniques
- 5.7. Benefits and cost savings

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