21 CFR Part 11
A Compliance Approach

Abbott Laboratories
Introductions

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Agenda

- 21 CFR Part 11 Compliance Challenges
- Abbott’s Compliance Approach
- Questions and Discussion
Compliance Challenges

- Management Support and Awareness
- A Common Perspective
- Breadth of Impact
- Information Security
- Project Management
Compliance Challenges

- Management Support and Awareness
- A Common Perspective
  - What is the organization’s view of risk?
  - What level of control is appropriate?
  - Who makes the decision?
  - How will the organization interpret the regulation?
- Breadth of Impact
  - Systems
    - Global perspective
  - Resources and funding
Breadth of Impact

- GLP
- GCP
- GMP

Data Acquisition
- Information
- (LIMS)

Centralized Laboratory
- and Reporting
- Entry
- Case Report

Execution (MES)
- Management (MMS)
- Calibration

Management Systems
- SOP Systems

Adverse Event Reporting
- Clinical Supply Systems
- Statistical Analysis Systems

Internet Applications
- EDI
- PLC Systems

SOP Systems
- cGxP Tracking
- cGxP Training
- SOP Systems

System Stability Systems
- Laboratory Robotics

Management (MMS)
- Laboratory Systems

Environmental Impact
- Calibration Management Systems

Internet Applications
- SCADA Systems

Planning (SCP)
- EDI
- PLC Systems
and Controls Framework

Security and Controls Vision and Strategy

- Business Initiatives and Processes
  - Technology Strategy and Usage
  - Threats and Vulnerabilities
- Policy
- Security and Controls Model
- Security and Controls Architecture and Technical Standards
  - Administrative and End-User Guidelines and Procedures
  - Enforcement Processes
  - Monitoring Processes
  - Recovery Processes
Project Management

- Consistent communication and training
- Aligning different functional perspectives and views of risk
- Consistent interpretation and approach
- Inventory and impact assessment
- Methods to track issues and progress
- Measurement
Agenda:

- Overview of the Abbott 21 CFR Part 11 program
- Policies, procedures, and processes
- Training programs
- Enabling software tools
Environment

- Human/animal drugs, biologicals, medical devices, diagnostic products, foods
- Employ third party manufacturers/manufacture for third parties
- Multiple divisions, multiple sites within divisions
- Full component of functions (e.g., IT, R&D, quality, manufacturing, etc.) within divisions
- U.S. and international operations
- Corporate “overview” functions including IT, quality/regulatory, purchasing, engineering, records
Objective

- Ensure the consistent worldwide interpretation and cost-effective implementation of the 21 CFR Part 11 regulation in time frames aligned with FDA expectations and technical capabilities existing in the marketplace.

- The program applies to all FDA regulated (e.g., GMP/QS reg/GLP/GCP/PDMA) electronic records and quality-related systems used by Abbott Laboratories worldwide.
Execution Strategy

- Corporate Chartered Teams
- Policies/Procedures
- Interpretation/Best Practices
- Tools
- Training/Awareness
- Inventory Evaluation Remediate
- Institutionalize Processes
Program Organization, Teams (Roles/Responsibilities)

Project Organization

Executive Committee

VP Information Technology

Corporate Executive Vice Presidents

Senior VP Specialty Products Division (Sponsor)

21 CFR Corporate Program Director

VP Corporate Regulatory and Quality Science

21 CFR Core Team

Division Teams

Special Teams

Support Teams
Program Organization, Teams (Roles/Responsibilities)

21 CFR 11 Core Team

Industry Assoc/Trade Group Communications

Stakeholder Communications

Product Evaluations

Business Interpretations

Best Practices, Examples, Standards

Suppliers

Training/Education

Special Teams
Program Organization, Teams (Roles/Responsibilities)

Support Teams

21 CFR 11 Core Team

- Corporate Legal
- Corporate Purchasing
- Corporate Records
- Finance and Accounting
- Tools/Processes
Sustaining Organization

Divisions
Implementation
Program Management/Control

HPD PPD ADD SPD RPD INT’L AHD CED AES

Corporate Panel
Change control (risk/impact analysis)
Continuous program process improvement
Subject area expertise (e.g., FDA, SEI, IEEE)
Compliance Program

21 CFR Part 11 Compliance Program

Overview Section (strategic)
- Background
- Program Objectives
- Scope
- Execution Strategy
- Critical Success Factors
- Organization/Reporting
- Life Cycle
- Milestones
- Funding/Accounting
- Audits/Assessments
- Status Reports

Teams Section
- Team Charters
- Scope
- Membership
- Deliverables

Divisions Sections (tactical)
- Background
- Program Objectives
- Scope
- Execution Strategy
- Organization/Reporting
- Roles/Responsibilities
- Plan Controls
- Training Plan
- Funding/Accounting
- Internal Quality Assessment
- Status Reporting
- Remediation Documentation
- Current Plan Year Project Goals

For existing systems as of 9/30/2000
- Inventory completed by:
- GAP analysis completed by:
- Systems remediated by:
- Process in place by 9/30/2000 to ensure new acquisitions/new development are 21 CFR Part 11 compliant or remediation plans exist

Project schedule by quarter
- Annual expense/capital budgets
Critical Success Factors

- Consistency in interpretation and implementation
- Coordination across divisional/functional boundaries
- Performance goals aligned with project deliverables/milestones
- Adequate resources to develop and execute the program
- Timely reporting and issues resolution
- Management commitment to timely reviews/decision making
- Independent assessment of the quality of work performed
- Project work takes precedent over other activities
Program Phases

**Corporate Level**
- Program planning/infrastructure development
- Develop/execute training programs
- Develop business interpretation/best practices (ongoing)
- Audit program implementation/execution (ongoing)

**Division Level**
- Planning/training for program implementation
- Inventory systems/policies/procedures
- Evaluate for 21 CFR Part 11 applicability/deficiencies
- Remediate deficiencies noted (fix/replace/retire)
- Test and validate
- Implement changes
- Audit program implementation/execution (ongoing)
- Program termination
Policies, Procedures, and Processes

- Electronic records, electronic signatures
- Review of capital and other expenditures
- Method for inventory, system evaluation, and remediation implementation
- Stakeholders communications
- Status reporting
Training

- General awareness
- Supplier implication/screenings
- Equipment/software acquisition
- Guide to 21 CFR Part 11
- Inventory tool
- GAP analysis tool
- Remediation tracking tool
Enabling Software Tools

- Guide to 21 CFR Part 11
- Inventory tool
- GAP analysis tool
- Remediation tracking tool
Guide to 21 CFR Part 11

Repository of Information:
- Single worldwide database
- 21 CFR Part 11 regulation
  - Abbott business interpretation of the regulation
  - Annotations/references
  - Best practices
  - Implementation examples
  - Standards
- Definitions
- Policies and procedures
Inventory Tool

- Single worldwide database
- Division/site oriented
- Descriptive system information/ownership
- Screen for regulated systems/21 CFR Part 11 implications
- Prioritization
- System owner/quality approvals
GAP Analysis Tool

- Linked to the inventory tool
- GAP evaluation criteria
- Documentation of objective evidence
- System owner/technical/quality approvals
- Compliance metrics
Remediation Tracking Tool

- Linked to the inventory tool
- Remediation tracking dates
- Implementation costs (plan/actual)
- Status (pending/active/completed)
- System owner/technical/quality approvals upon completion