PRICEWATERHOUSECOOPERS

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

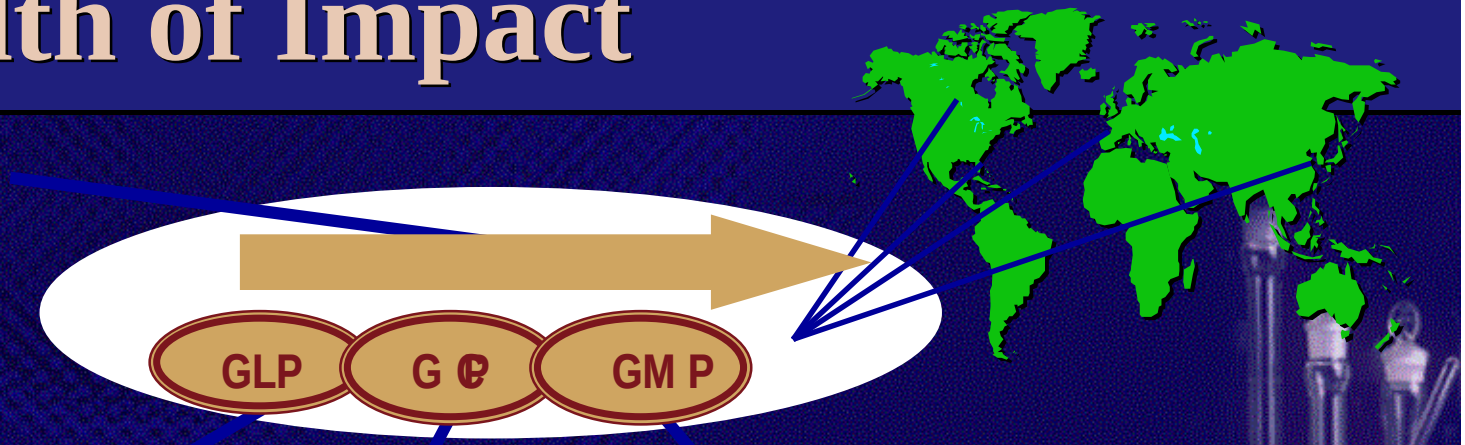
- Management Support and Awareness
- A Common Perspective
- Breadth of Impact
- Information Security
- Project Management

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

- cGxP Training
  cGxP Tracking
- SOP Systems

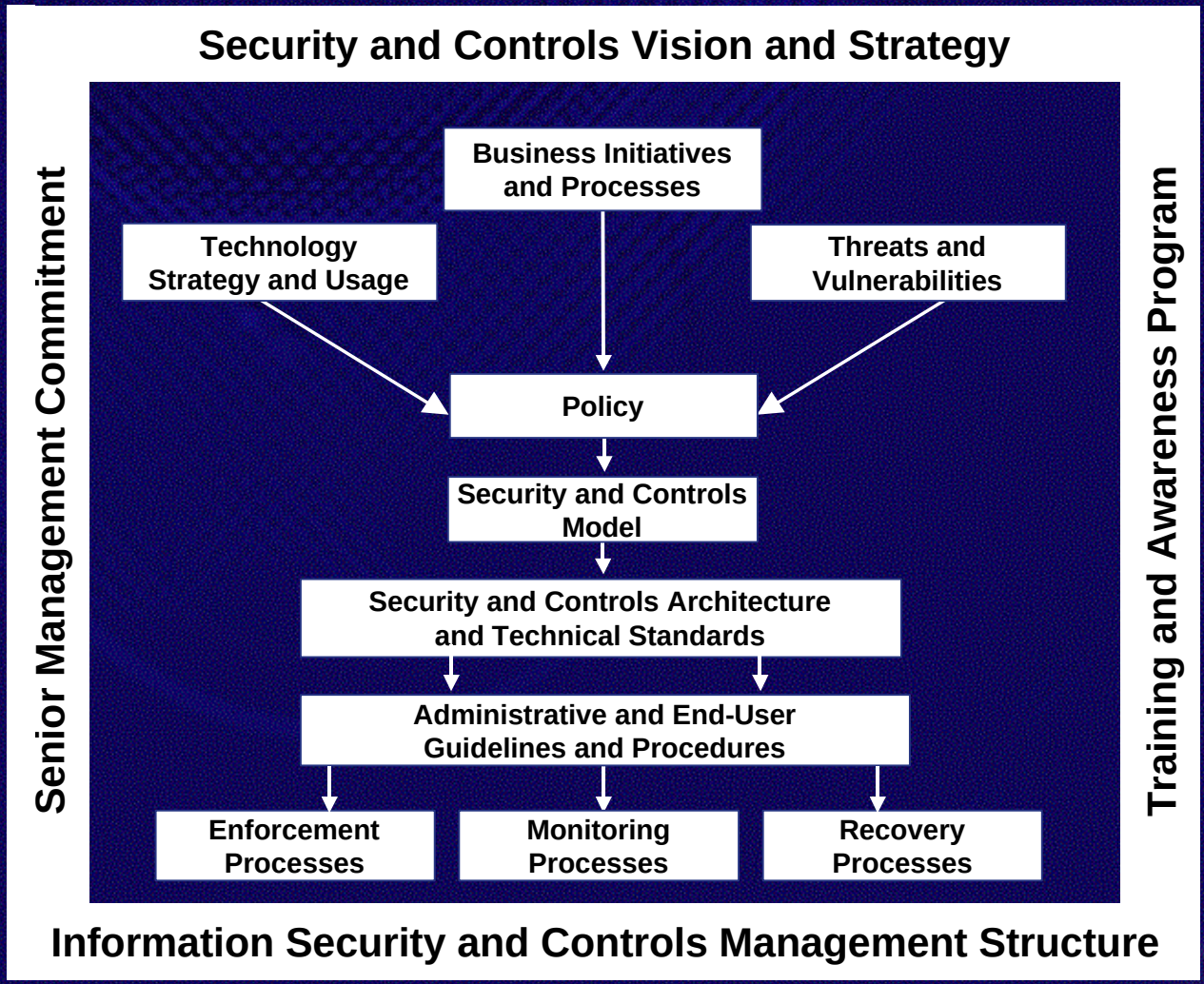


Data Acquisition
- Information
- (LIMS)
  Laboratory Robotics
  Toxicology Systems
  Stability Systems
  Environmental Impact

Centralized Laboratory
- and Reporting
- Entry
- Case Report
- Management
  Adverse Event Reporting
  Clinical Supply Systems
  Statistical Analysis Systems

- Execution (MES)
- Management (MMS)
  Calibration Management
  LIMS
- Systems
- Plan (ERP)
  SCADA Systems
- Planning (SCP)
  Internet Applications
- EDI
  PLC Systems

and Controls Framework



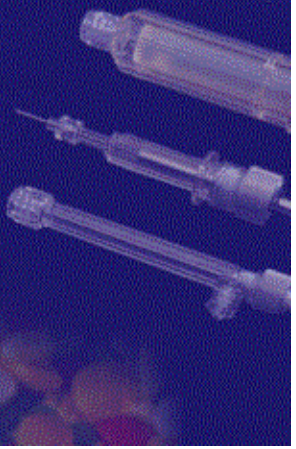
Project Management

- 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


SUPPLIERS
INDUSTRY
FDA

Agenda:

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



Environment

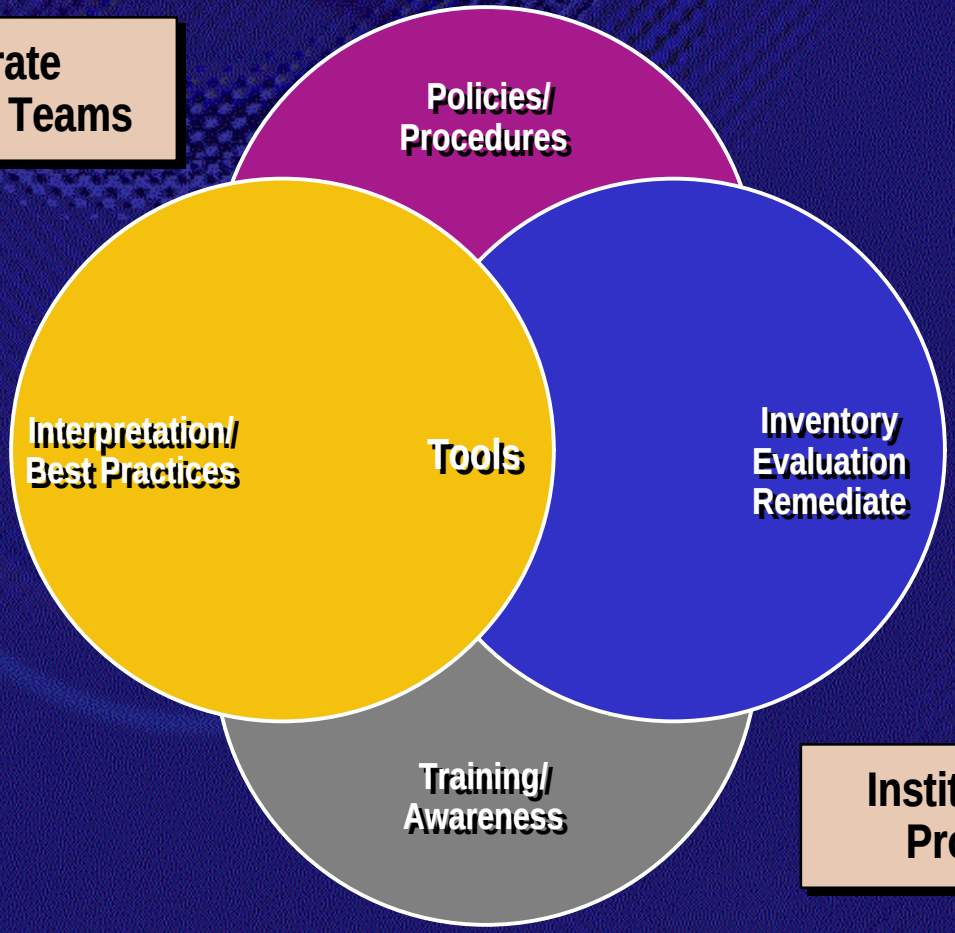
- Human/animal drugs, biologicals, medical devices, diagnostic products, foods
- Employ third party manufacturers/manufacture for third parties
- Multiple divisions, multiple sites within divisions
- Full component of functions (e.g., IT, R&D, quality, manufacturing, etc.) within divisions
- U.S. and 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



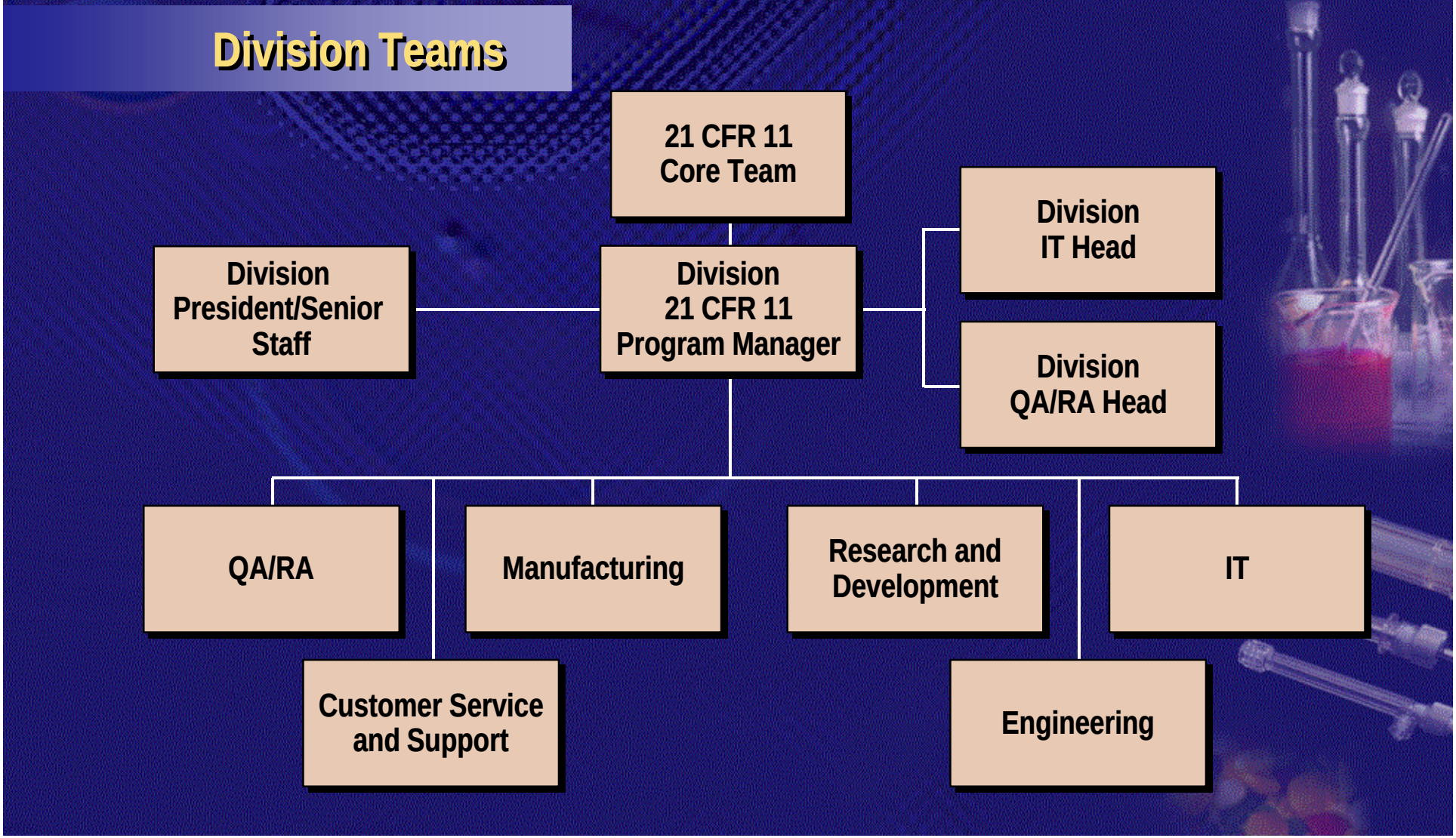
Institutionalize Processes

Program Organization, Teams (Roles/Responsibilities)

Project Organization

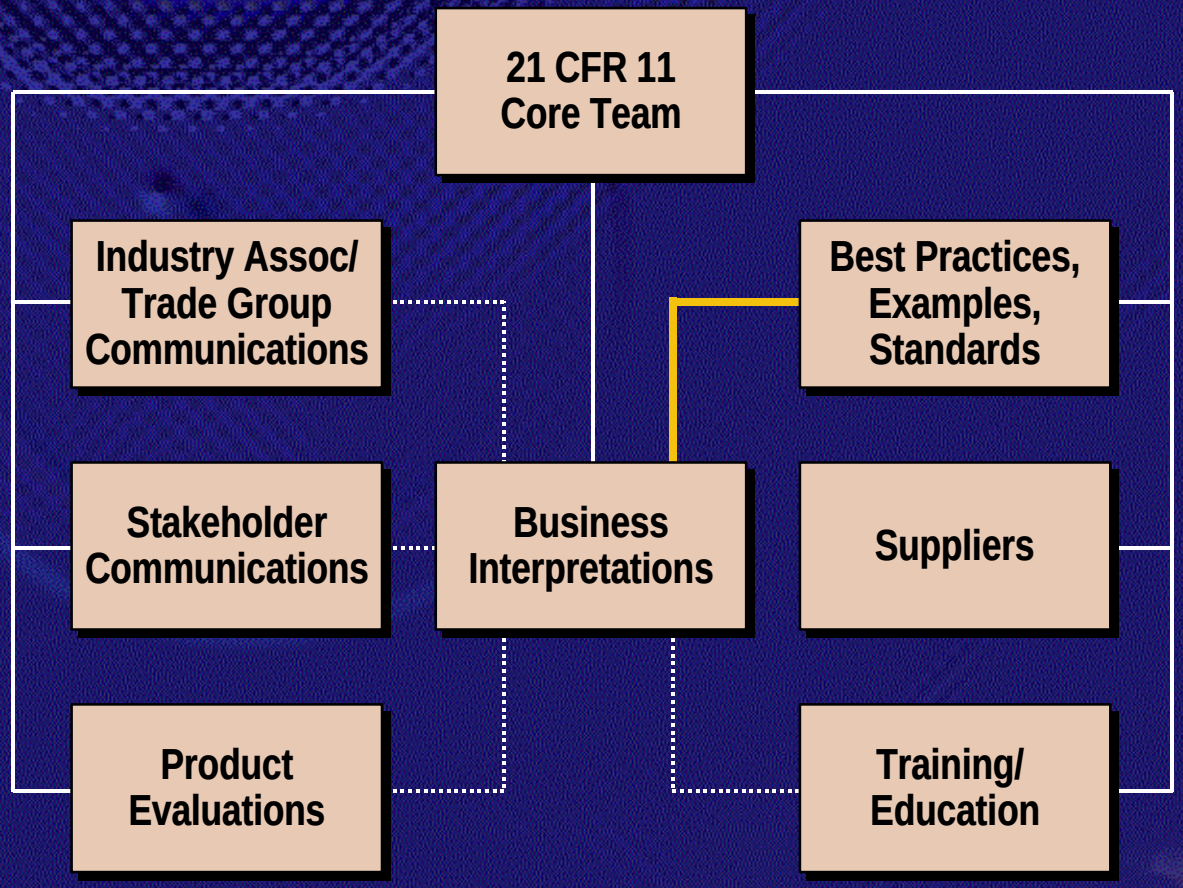
Program Organization, Teams (Roles/Responsibilities)

Division Teams



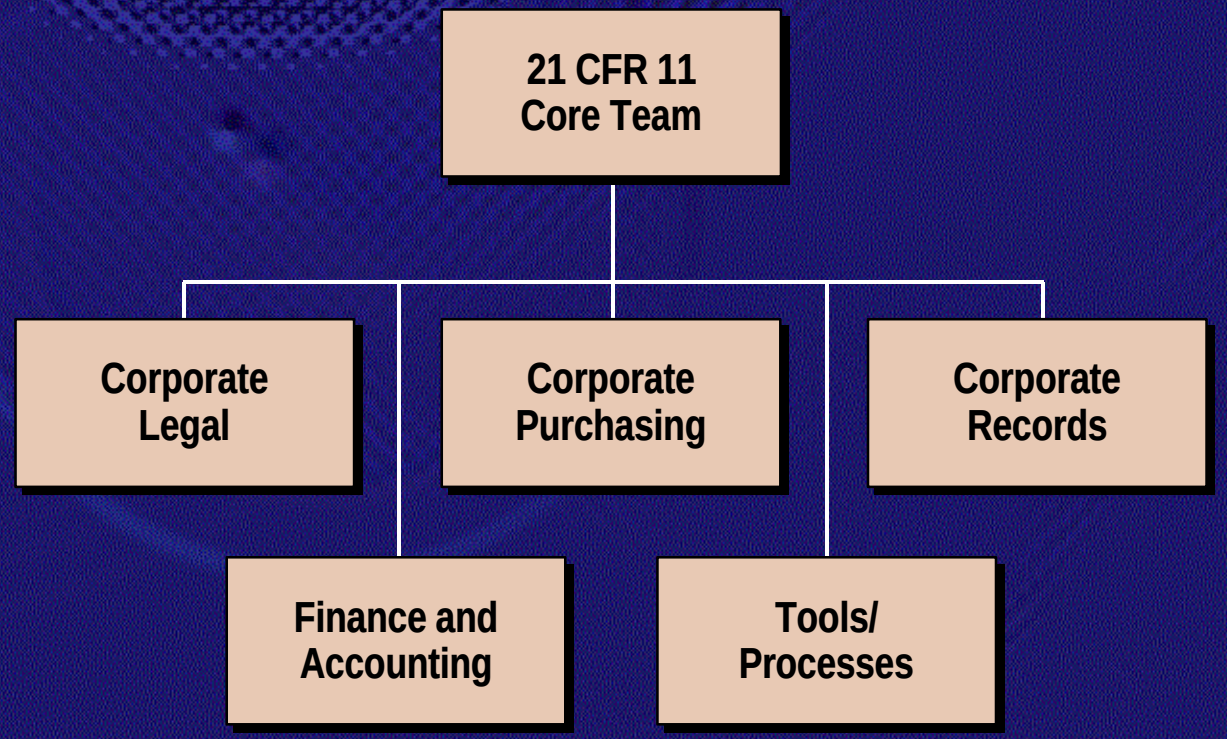
Program Organization, Teams (Roles/Responsibilities)

Special Teams



Program Organization, Teams (Roles/Responsibilities)

Support Teams

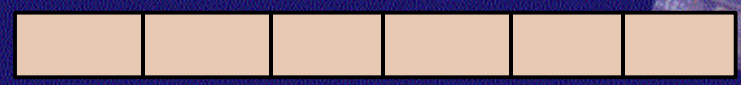


Sustaining Organization

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

→ 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

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

→ 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