Good Business Practices Can Satisfy Compliance Requirements

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Overview

- Good Practices = Compliance
- Foundation for Good Practices
- System Implementation Lifecycle
- Tie-in to Sarbanes-Oxley Controls
- Solutions2Projects Validation Principles
- FDA Validation Principles Correlation
- Summary

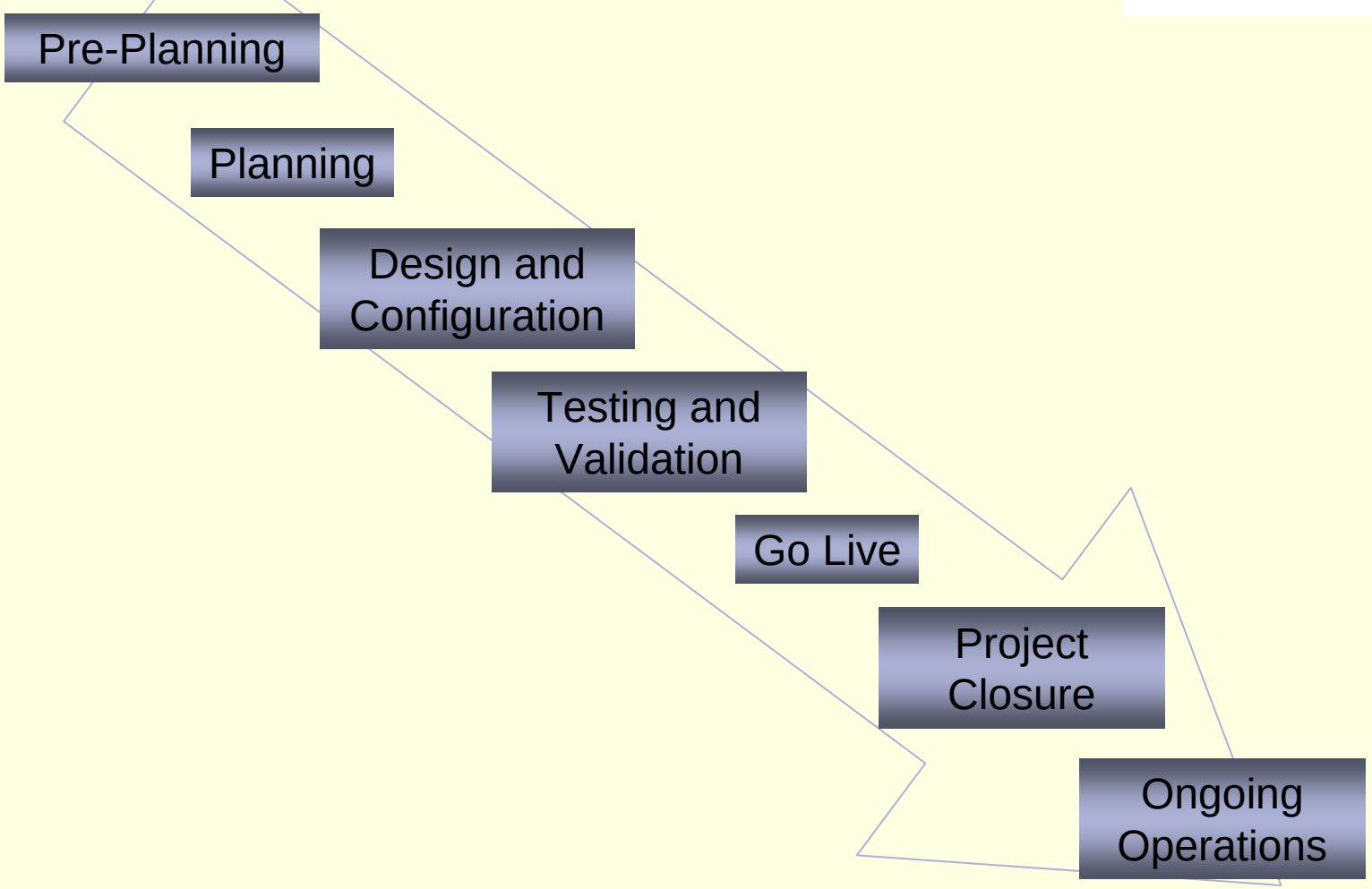
Good Practices = Compliance

- Compliance guidelines are logical
  - Define what you're going to do
  - Do it
  - Make sure you did it
  - Document it
  - Make sure you keep doing it until you are done
  - Monitor what you are doing

Foundation for Good Practices

- PMBOK
- GAMP 4
- 21 CFR Part 11
- Sarbanes-Oxley Controls (RoseRyan)
- *General Principles of Software Validation; Final Guidance for Industry and FDA Staff* (1/11/2002)
- Experience

System Implementation Lifecycle



Pre-Planning

- Get executive approval for project concept
- Define high-level user requirements and process flows
- Formalize vendor selection based on user/technical requirements including vendor audit
- Develop project charter and approve project
  - Scope, resources, business case, cost

Planning

- Project Management Document
  - Use as project guide
- Create detailed Project Plan
- Conduct team kick-off
- Provide team training
- Define other plans
  - Testing
  - Data migration/verification
  - Training
  - Validation Master Plan
  - Change Management
  - Go Live Support

Design and Configuration

- Define functional requirements
- Define system and application design
- Install hardware/software
- Conduct unit testing
- Begin traceability to requirements
- Identify impacted processes/procedures
- Ensure proper security
- Draft procedures and work instructions

Security Components

- Limit/control/monitor access to systems
  - Unique user IDs (including administration IDs)
  - Strong passwords & rules
  - Restrict physical access to systems
  - Limit administrative access
  - Audit trails
  - Violation of access/attempts to access
- Formal processes for user access
  - Access to system (role based)
  - Approvals
  - Termination of access
  - Outline segregation of duties
- Establish periodic, documented reviews

Procedures & Work Instructions

- Benefits
  - Assists in ensuring consistency of system use
  - Facilitates training and cross-training
  - Reduces ‘guess work’ and allows users to focus on items that require critical thinking
- Verify business processes against system
  - Provides additional ‘sanity check’

Testing and Validation

- Get users involved
- Train prior to test execution
- Develop integrated testing using business scenarios
- Execute validation testing (for GxP systems)
- Test data migration/verification process
- Refer to drafts of procedures/work instructions
- Test back up/restore/disaster recovery
- Define ongoing operations including maintenance, training, support

Go Live

- Final data migration and verification
- End user training
- Final release and training on new procedures
- Roll out to users
- Go Live Support

Project Close Out

SOLUTIONS2PROJECTS

- Debrief Project
  - Lessons learned
- Close out issues
  - Define resolution plans
- Close out contracts/POs
- Close out documentation
  - Hand-off to system owner
- Move system into operational mode
- Move support to ‘helpdesk’ or other support structure

Ongoing Operations

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- Preventive maintenance
- User support
- User training
- Deviation tracking
- Patch/upgrade management
- Issue and support Measurement
  - Use data for system improvements and training
- Retirement/Replacement
- Change control

Change Control

- Formalize the process
- Train the users on the process
- View as a helpful business tool and not a burden
- Capture
  - Change
  - Justification
  - Impact (system, processes, documentation)
  - Plan (change, testing, training, documentation)
  - Approvals prior to and after execution

Tie-In to Sarbanes-Oxley Controls

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Pre-Planning

- Formal business cases are developed to justify acquisition of new applications and are approved by Executive Management and included in the budget
- For large application system evaluations, a formal evaluation and system selection process is followed

Planning

- A formal project plan is created and maintained during the life of the project
- A formal implementation plan is created and approved by the Project Manager and IT Director

Source: *RoseRyan*

Sarbanes-Oxley Controls

SOLUTIONS2PROJECTS

Design and Configuration

- A conceptual solution design is approved by the Project Manager, business system owner and IT Director, signed off, and maintained with the project documentation

Source: *RoseRyan*

Sarbanes-Oxley Controls

SOLUTIONS2PROJECTS

Testing and Validation

- Throughout the implementation, the project team is responsible for performing integration testing within the development environment
- Data conversion testing, when required, is done in a development environment. Controlled sample test data is reconciled by the business users

Source: *RoseRyan*

Sarbanes-Oxley Controls

Project Closure

Ongoing Operations

- The project team (key business users, application vendor, and IT personnel) performs post implementation review and support. During this phase, the project team identifies and ensures the resolution of issues identified after implementation. All identified issues are reported through the helpdesk and monitored through conclusion

Source: *RoseRyan*

Sarbanes-Oxley Controls

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Ongoing Operations

- Requests for changes are reviewed and approved by the Business System Owner (BSO) and IT Director
- Changes are unit tested in a development environment by IT and/or the VAR
- On a quarterly basis, the BSO and IT Director review the system generated list of program object changes, and compare the baseline configurations and settings for each financial application against the email approvals from the BSO to provide reasonable assurance that no unauthorized changes have been made

Source: *RoseRyan*

Validation Principles

- Validation is a process that starts at the beginning and continues through the life of the system
- If it's not documented, it didn't happen
- Define what you want and need, then execute and document what you did
- Focus efforts based on risk assessment and document justification
  - Risk-based approach

FDA Validation Principles

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Planning

- *"Validation ensures accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records"*
- *"All [software] should have documented requirements that fully define its intended use, and information against which testing results and other evidence can be compared, to show that the software is validated for its intended use"*
- *"The software validation process is defined and controlled through the use of a plan."*

Source: *General Principles of Software Validation; Final Guidance for Industry and FDA Staff* (1/11/2002)

FDA Validation Principles

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Planning

- *"Preparation for software validation should begin early, i.e., during design and development planning and design input.."*
- *"Validation coverage should be based on the software's complexity and safety risk."*
- *"Design and development planning should culminate in a plan that identifies necessary tasks, procedures for anomaly reporting and resolution, necessary resources, and management review requirements, including formal design reviews."*
- *"Software validation takes place within the environment of an established software life cycle."*

Source: *General Principles of Software Validation; Final Guidance for Industry and FDA Staff* (1/11/2002)

FDA Validation Principles

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Ongoing Operations

- *"All problems discovered during maintenance of the software should be documented."*
- *"Documentation should be carefully reviewed to determine which documents have been impacted by a change."*
- *"All proposed modifications, enhancements, or additions should be assessed to determine the effect each change would have on the system."*

Source: *General Principles of Software Validation; Final Guidance for Industry and FDA Staff* (1/11/2002)

Summary

- Good business practices naturally lead to Sarbanes-Oxley and FDA compliance
  - Plan
  - Design
  - Document
  - Test & Validate
  - Execute
  - Close out
  - Support

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Credentials

- MBA, New Ventures/Small Business Management
- PMI Project Management Professional (PMP)
- Nine years system implementation experience
  - ERP, SAE, CTMS, HRIS, Payroll, Equipment Maintenance, Calibration, SFA, PLM, Promotional Ordering
- Seven years biotech/device system implementation experience including validation
- Diverse business background
  - Accounting, finance, manufacturing, distribution, HR