Data Integrity

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Data Integrity throughout the Computerized System Lifecycle
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Connecting a World of Pharmaceutical Knowledge

Introduction

"Patient safety is affected by the integrity of critical records, data, and decisions, as well as those aspects affecting physical attributes of the product. The phrase 'patient safety, product quality, and data integrity' is used throughout this document to underline this point."

(GAMP 5)

Overview

- Importance of Data Integrity
- Management responsibility…and the culture
- Data Integrity in the GAMP 5 Life Cycle

Key Message

- Data integrity must be built into every phase of the computerized system life cycle – and into the regulated company culture…

GAMP 5 Objectives

Patient safety

Product quality

Data integrity

FDA Warning Letter (July 2013)

- Unacceptable practices in the management of electronic data were also noted.
- The management of electronic data permitted unauthorized changes, as digital computer folders and files could be easily altered or deleted.

6

FDA Warning Letter (July 2013)

- Your inability to detect and prevent poor data integrity practices raises serious concerns about the lack of quality system effectiveness.
- It is imperative that the data generated and used to make manufacturing and quality decisions at your firm is trustworthy and reliable.

7

FDA Warning Letter (July 2013)

- This responsibility starts with designing computerized systems with appropriate security features and data audit trails, as well as many other elements that assure proper governance of your computerized systems.

8

FDA Warning Letter (July 2013)

- This indicates that your current quality risk management approach, for identifying and controlling any potential risks to the quality of the drugs you manufacture, was not properly functioning.

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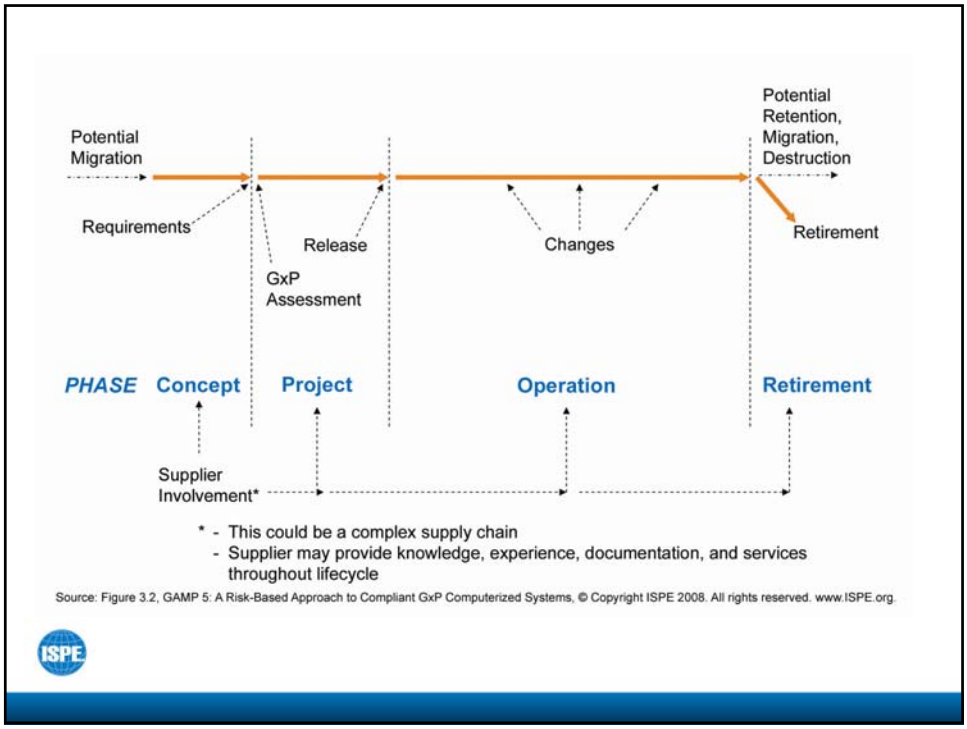
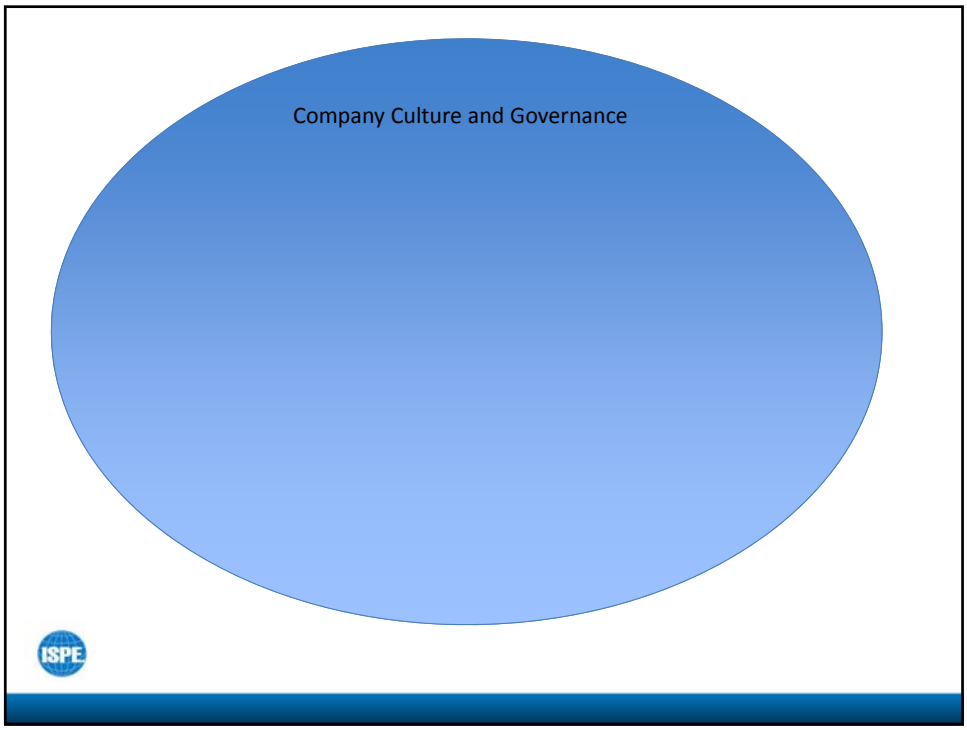
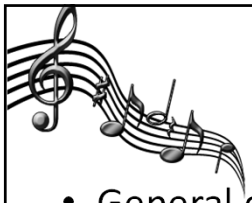
Analogous to Quality Risk Management…

- We require a systematic process for the assessment, control, communication, and review of risks to Data Integrity.
- This should be a continuous process throughout the entire computerized system life cycle from concept to retirement...and beyond


Potential Migration
Requirements
Release
GxP Assessment
Changes
Potential Retention, Migration, Destruction
Retirement
PHASE
Concept
Project
Operation
Retirement
Supplier Involvement*
* - This could be a complex supply chain
- Supplier may provide knowledge, experience, documentation, and services throughout lifecycle
Source: Figure 3.2, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.


Company Culture and Governance

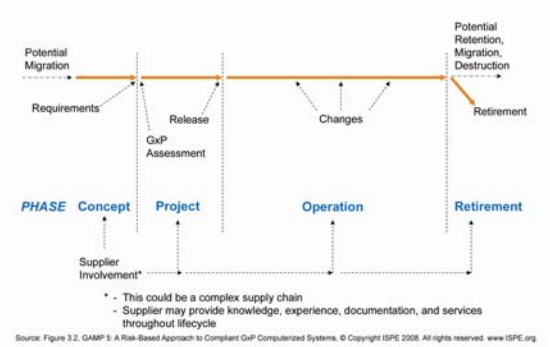


Tone from the Top

- General ethical climate, as established by the Board of Directors, and senior management
- Culture of data integrity
- Roles and responsibilities and close cooperation
  - Process Owners
  - System Owners
  - Quality Assurance

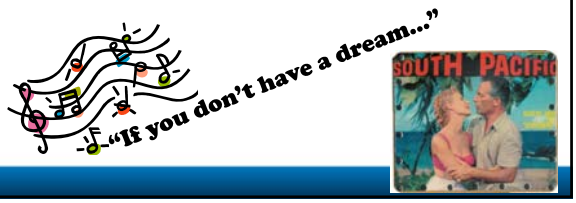
GAMP Life Cycle

- Concept
- Project
- Operation
- Retirement



Concept

- Clear data integrity goals and objectives
  - Begin with the end in mind
- Process understanding
- Process risk assessment
  - Identify process level data integrity risks



Project

- Data-related predicate requirements
- Process Data Flows
- Identify critical records and data
- Anticipating archiving and migration needs
  - As discussed in GAMP 5 Section 8.8

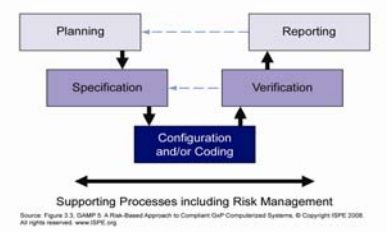
"Data integrity cannot be achieved without a complete understanding of the information flow" (*Laboratory Systems Good Practice Guide*).

Project

- Quality Risk Management
  - Initial and detailed risk assessments
- Supplier and product assessment
- Solution architecture
- The data life cycle

Project

- Translating requirements into controls
  - To manage identified risks
- Configuration and design of controls
- Testing for integrity



Operation

Protect and Preserve

"Data should be secured by both physical and electronic means against damage. Stored data should be checked for accessibility, readability and accuracy. Access to data should be ensured throughout the retention period."

EU GMP Annex 11

S.H.I.E.L.D.

Operation

"Preserve content and meaning"

FDA Part 11 Guidance

Preserve your ability to meet statutory and regulatory obligations

Operation

- Backup and restore
- Business continuity measures
- Change management
- Periodic review

Retirement

- System Retirement Planning (GAMP 5 Appendix M10)
- Data
  - Disposal
  - Migration
  - Archive
- Continue to meet regulatory and statutory obligations

Recap

- Importance of Data Integrity
- Management responsibility…and the culture
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Key Message

- Data integrity must be built into every phase of the computerized system life cycle – and into the regulated company culture…

Thank You!

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