conformity
keeping it compliant

# Data Integrity
## Through the Life Cycle
## Balancing Quality and Innovation

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# Theme

- Achieving harmony…
- Balancing **quality**, **safety,** and **compliance**…
- …with **technical innovation** and **progress**

# Overview

- What do we mean by Data Integrity?
- Regulatory Guidance and Citations
- Data Integrity Through the Life Cycle…and Beyond

# GAMP 5 Objectives

Patient safety

Product quality

Data integrity

# Data Integrity

*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**

# Data Integrity

- Maintaining and assuring the accuracy and consistency of data over its entire life-cycle
  - A critical aspect of the design, implementation and usage of any system that stores, processes or retrieves data.
  - Avoiding data corruption, which is a form of data loss.

# Data Integrity

- Overall intent:
  - ensure data is recorded as intended
  - upon later retrieval, ensure the data is the same in content and meaning as it was when it was originally recorded.
- Preventing unintentional  or unauthorized changes to information.

# MHRA GMP Data Integrity Definitions and Guidance for Industry

## March 2015

# MHRA Guidance

- Data Integrity:
  - "The extent to which all data are complete, consistent and accurate throughout the data lifecycle".
- Arrangements must ensure that the accuracy, completeness, content and meaning of data is retained throughout the data lifecycle.

# FDA Warning Letter Example (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.

# FDA Warning Letter Example (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.

# FDA Warning Letter Example (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.

# FDA Warning Letter Example (July 2013)

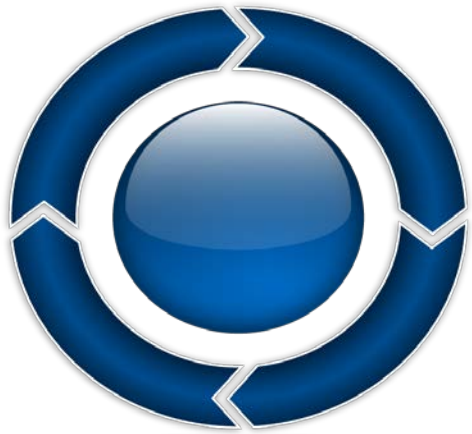
- This indicates that your current quality risk management approach, for identifying and controlling any potential risks to the quality of the drugs you manufacture, was not properly functioning.

# Built In

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

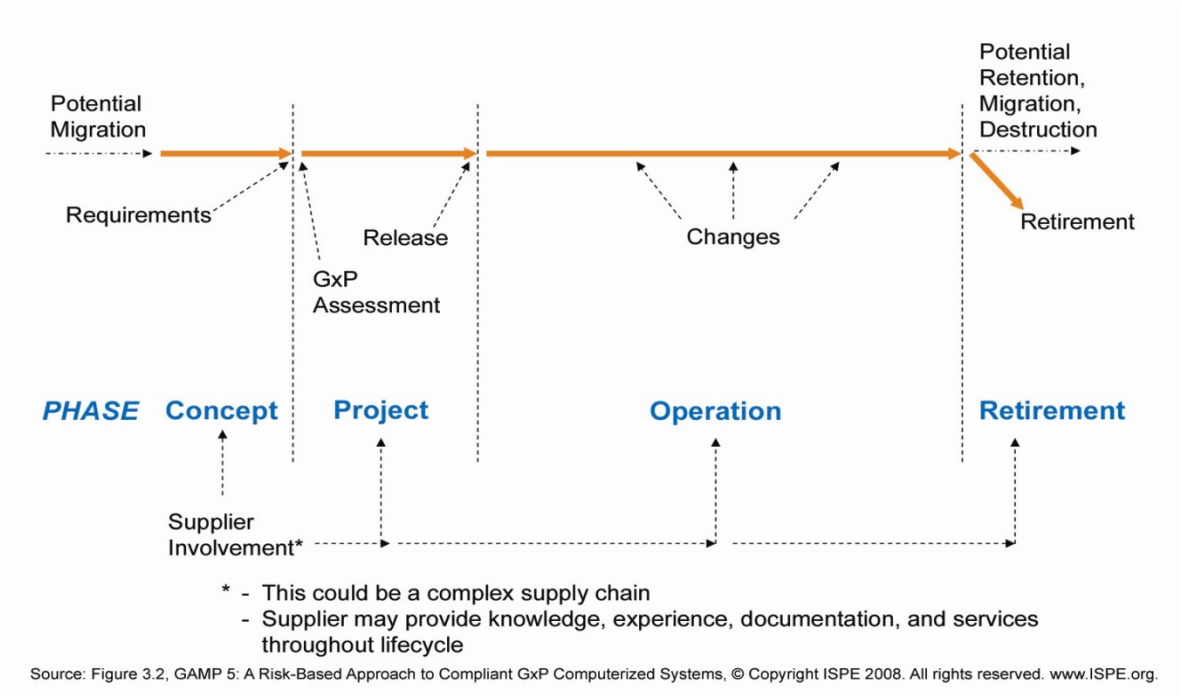
# Management of Data Integrity Risks

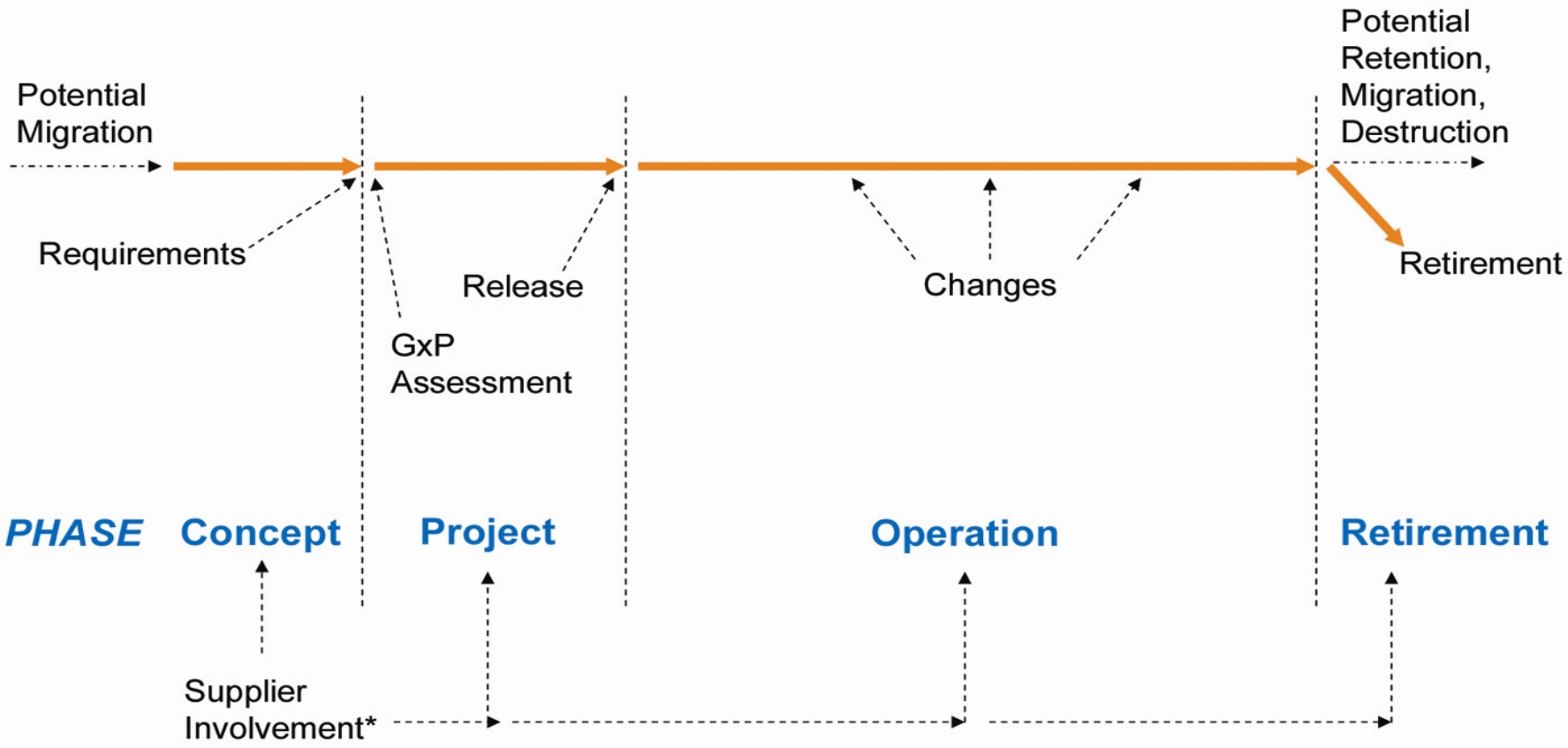
- A systematic process for the assessment, control, communication, and review of risks to data, as part of our QRM activities…
- …a continuous process throughout the entire computerized system life cycle from concept to retirement...and beyond



# GAMP Life Cycle

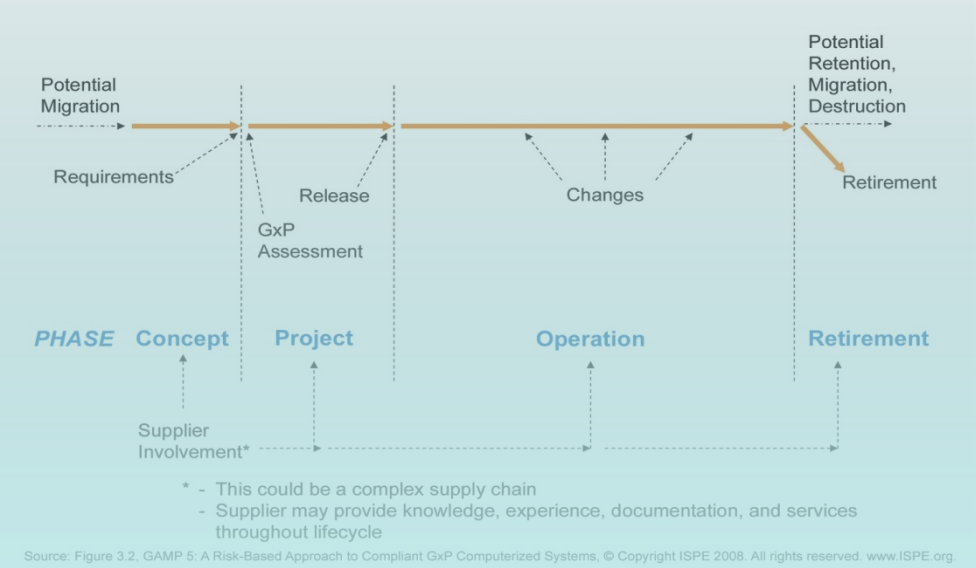
- Concept
- Project
- Operation
- Retirement






**…through the computerized system life cycle from concept to retirement...and beyond**

# Company Culture and Governance

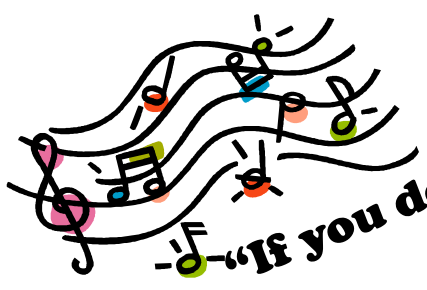


# Tone from the Top

- 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

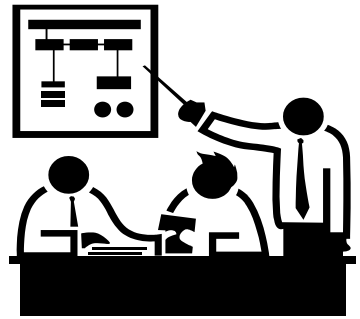
# Concept

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



"If you don't have a dream..."

# Project Phase



- Identify data-related requirements
- Define process data flows
- Identify critical records and data
- Anticipating retention, archiving, and migration needs

"Data integrity cannot be achieved without a complete understanding of the information flow"

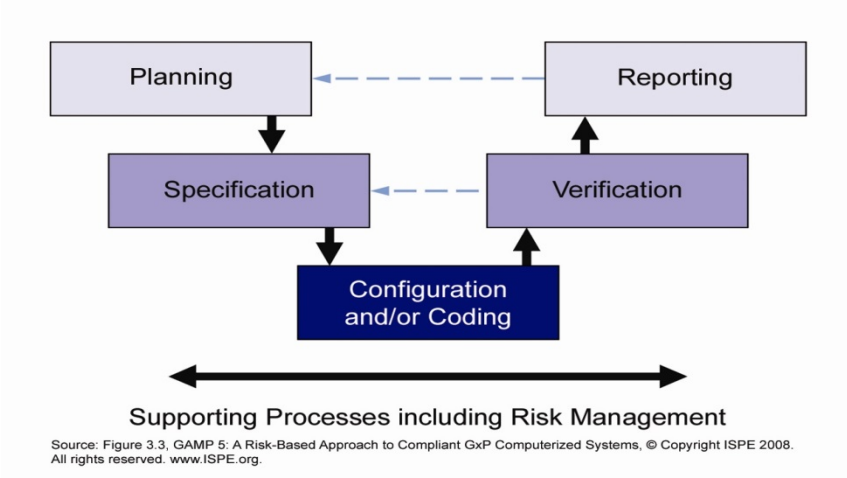
(GAMP *Laboratory Systems Good Practice Guide*)

# Project Phase

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

# Project Phase

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



Source: Figure 3.3, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.

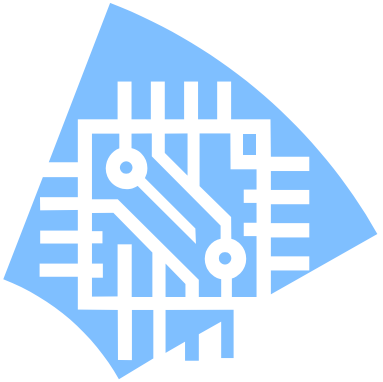
# Operation Phase

“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



# Operation Phase

If copying, archiving, or migrating…

*“Preserve content and meaning”*

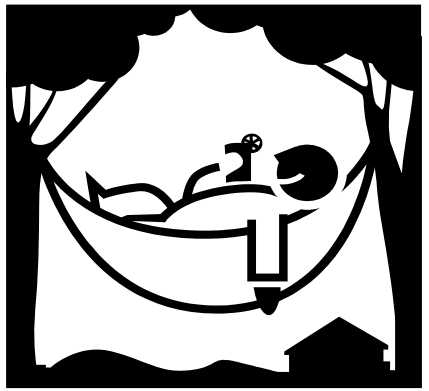
FDA Part 11 Guidance

# Operation Phase Activities

- Security, User and Access Management
- Incident and Problem Management
- Change and Configuration Management
- Backup and Restore
- Business Continuity Management & Disaster Recovery
- System Administration
- Archive, Retention, and Retrieval

# Retirement Phase

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



# Overall

- Data integrity must be built into every phase of the computerized system life cycle
- Especially in the operational phase, service providers may have a critical role to play in ensuring compliance and data integrity, e.g.
  - IT service providers
  - Infrastructure outsourcing
  - Cloud service providers

# Recap

- What do we mean by Data Integrity?
- Regulatory Guidance and Citations
- Data Integrity Through the Life Cycle…and Beyond

# Conclusions

- Data Integrity is a regulatory focus
- We can achieve it with appropriate culture, good governance,  suitable technical and procedural controls, and by applying GAMP good practice
- We must continue to strive for

**Balance** and **Harmony**

Balancing quality, safety, and compliance…

…with technical innovation and progress

# Thank You

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