GAMP®5
Quality Risk Management

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GAMP5 Key Concepts

- Life Cycle Approach Within a QMS
- Scaleable Life Cycle Activities
- Process and Product Understanding
- Science-Based Quality Risk Management
- Leveraging Supplier Involvement
Quality Risk Management

ICH Q9 definition:

“A systematic process for the assessment, control, communication, and review of risks”

Iterative...

Throughout life cycle

Concept to retirement
Business and Process Understanding

- Focus on risk to *Patient Safety, Product Quality, and Data Integrity*
- Focus on systems that support *critical processes*
Critical Processes

• Generate, manipulate, or control data supporting regulatory safety and efficacy submissions
• Control critical parameters in preclinical, clinical, development, and manufacturing
• Control or provide information for product release
• Control information required in case of product recall
• Control adverse event or complaint recording or reporting
• Support pharmacovigilance
Managing the Risk

• Elimination by design
• Reduction to acceptable level
• Verification that risks are managed to an acceptable level

All activities scaled according to level of risk, complexity, novelty...
ICH Q9 Principles

“The evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient.”

“The level of effort, formality, and documentation of the quality risk management process should be commensurate with the level of risk.”
Definitions

- **Harm**: Damage to health, including the damage that can occur from loss of product quality or availability.

- **Hazard**: The potential source of harm.

- **Risk**: The combination of the probability of occurrence of harm and the severity of that harm.

- **Severity**: A measure of the possible consequences of a hazard.
Step 1: Perform Initial Risk Assessment and Determine System Impact

Step 2: Identify Functions with Impact on Patient Safety, Product Quality, and Data Integrity

Step 3: Perform Functional Risk Assessments and Identify Controls

Step 4: Implement and Verify Appropriate Controls

Step 5: Review Risks and Monitor Controls

Source: Figure 5.2, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.
Step 1 – Initial Risk Assessment

• Based on business processes, user requirements, regulatory requirements and known functional areas

Relevant previous assessments?

Don’t repeat unnecessarily!

Is the system GxP regulated?
Step 2 – Identify Functions with GxP Impact

- Functions with impact on patient safety, product quality, and data integrity

Refer to specifications, system architecture, categorisation of components
Step 3 – Perform Functional Risk Assessments & Identify Controls

- Assess GxP functions, considering
  - Possible hazards
  - How potential harm arising from these hazards may be controlled or mitigated

Identify Appropriate Controls
Controlling the Risk

- Change the process
- Change the design
- Add new features
- Apply external procedures
- More detailed rigorous specification and verification

Eliminate the risk by Design if possible
Functional Risk Assessment

• Described in Appendix M3
• Identify
  – Hazards and risk scenarios
  – Severity – impact on safety quality or other harm
  – Probability
  – Detectability
Risk Assessment Tool

A simple two-step process:

1. Plot **Severity** vs. **Probability** to obtain **Risk Class**
Risk Assessment Tool

2 Plot **Risk Class** vs. **Detectability** to obtain **Risk Priority**
# Example Risk Assessment Form

<table>
<thead>
<tr>
<th>Project Title / Risk Assessment Overview</th>
<th>Project Number</th>
</tr>
</thead>
</table>

**Assessment Scope / Assumptions Made**

<table>
<thead>
<tr>
<th>Function</th>
<th>Sub-function</th>
<th>Relevance (GxP / Business)</th>
<th>Risk Scenarios</th>
<th>Probability</th>
<th>Impact</th>
<th>Class</th>
<th>Detection</th>
<th>Priority</th>
</tr>
</thead>
</table>

**Risk Assessment Approved by:**

Module 6 – Quality Risk Mgmt.
Slide 17
Step 4 – Implement & Verify Appropriate Controls

- Verification activity should demonstrate that the controls are effective in performing the required risk reduction.
Step 5 – Review Risks & Monitor Controls

- Mechanism implemented.
- Monitor controls for effectiveness.
- Change management to apply risk management activities

Frequency and extent of any periodic review should be based on the level of risk
Step 1: Perform Initial Risk Assessment and Determine System Impact

Step 2: Identify Functions with Impact on Patient Safety, Product Quality, and Data Integrity

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Step 5: Review Risks and Monitor Controls

For typical Category 3 product these steps are combined in one assessment

Source: Figure M3.2, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.
Decisions Through the Life Cycle

Concept
- R1 Initial risk assessment
- R2 Risk-based decisions during planning
- R3 Functional risk assessments
- R4 Risk-based decisions during test planning

Project
- R5 Risk-based decisions during planning of operational activities
- R6 Functional risk assessments in change control

Operation
- R6

Retirement
- R7 Risk-based decisions when planning system retirement

Changes

Potential Retention, Migration, Destruction

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