GAMP®5
Quality Risk Management

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GAMP5 Key Concepts

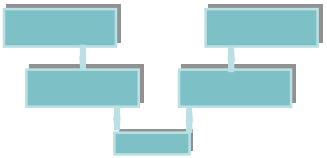
- Life Cycle Approach Within a QMS
- Scaleable Life Cycle Activities
- Process and Product Understanding
- Science-Based Quality Risk Management
- Leveraging Supplier Involvement

Quality Risk Management

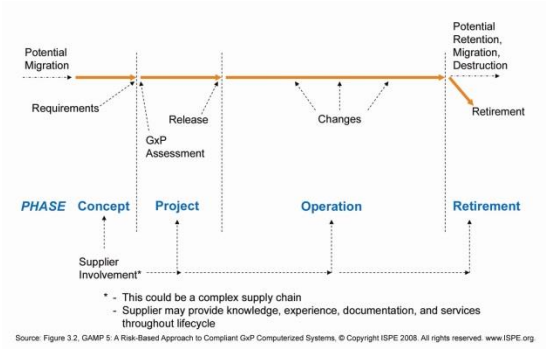
ICH Q9 definition:

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

Iterative…



Throughout life cycle



Concept to retirement

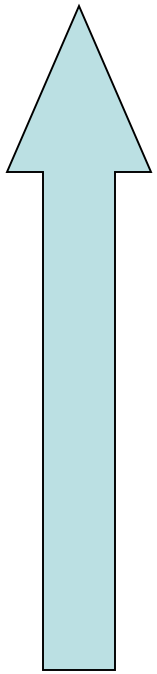
Business and Process Understanding

- 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…

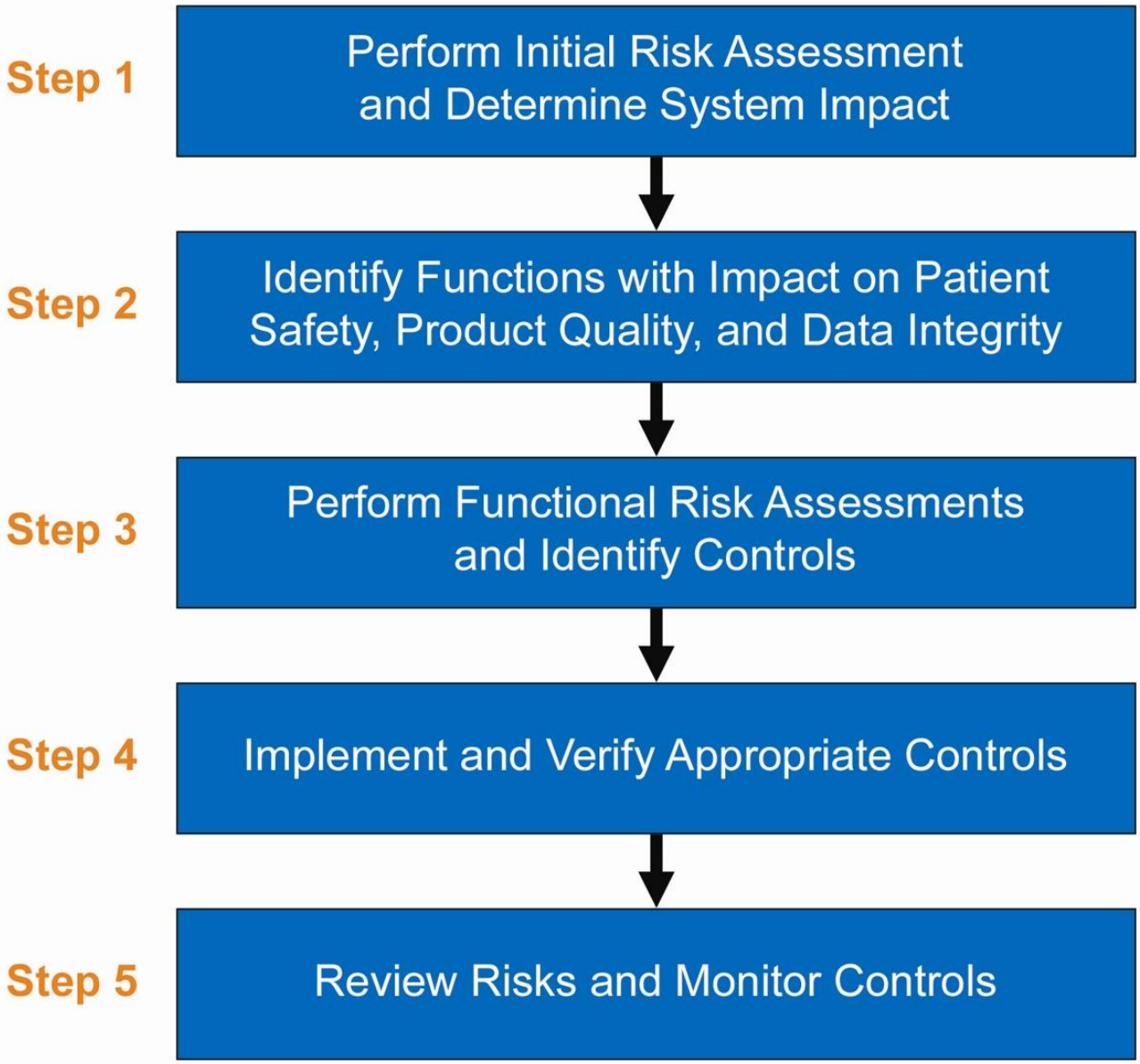
ICH Q9 Principles

"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.



Source: Figure 5.2, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems,

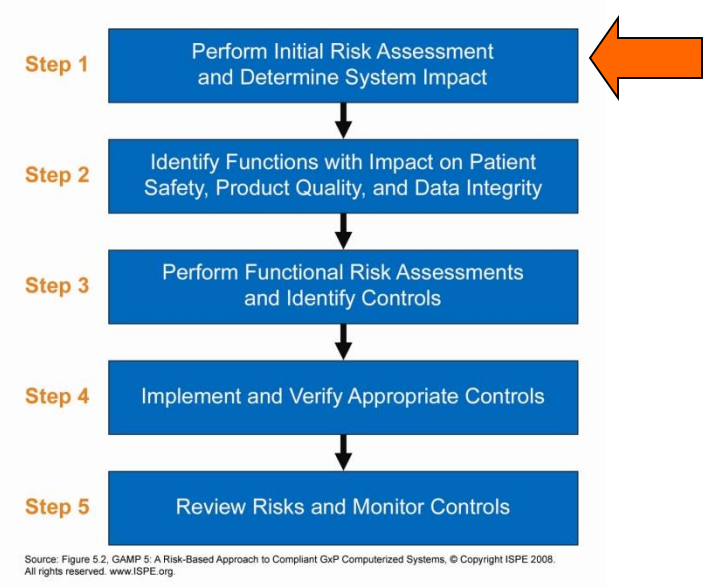
Step 1 – Initial Risk Assessment

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

Relevant previous assessments?

Don't repeat unnecessarily!

Is the system GxP regulated?



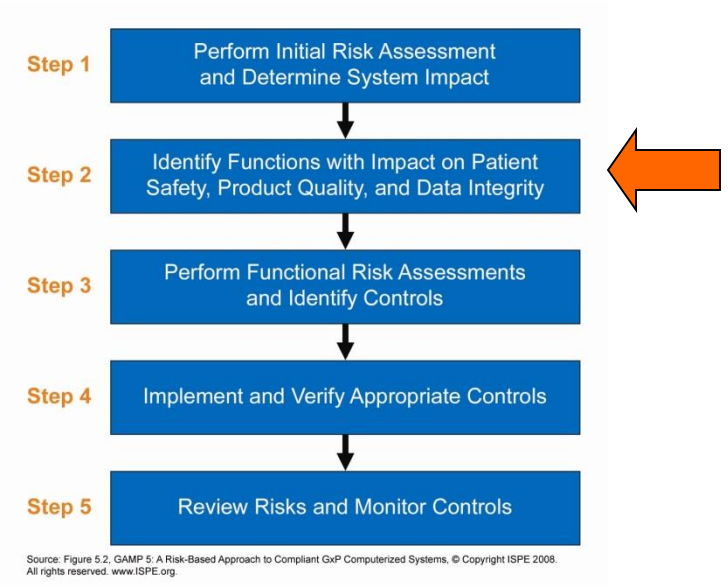
Step 2 – Identify Functions with GxP Impact

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

Refer to specifications,

system architecture,

categorisation of components

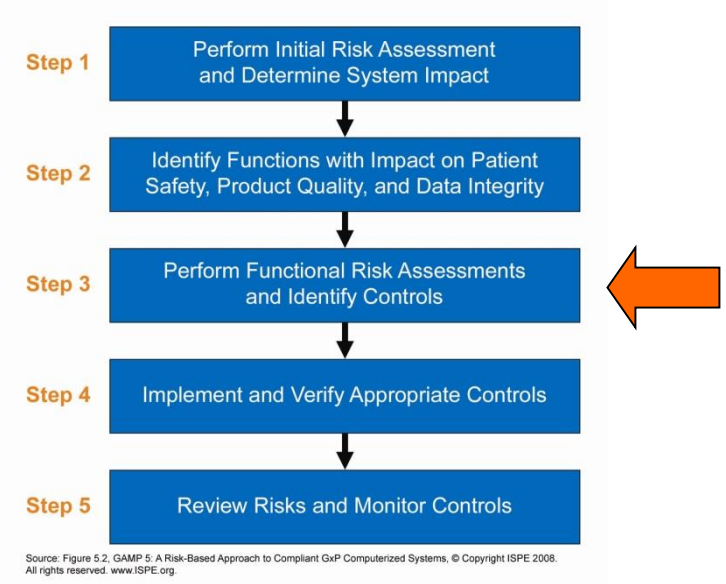


Step 3 – Perform Functional Risk Assessments & Identify Controls

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

For some functions a detailed assessment should be performed

Identify Appropriate Controls



Controlling the Risk

Change the process

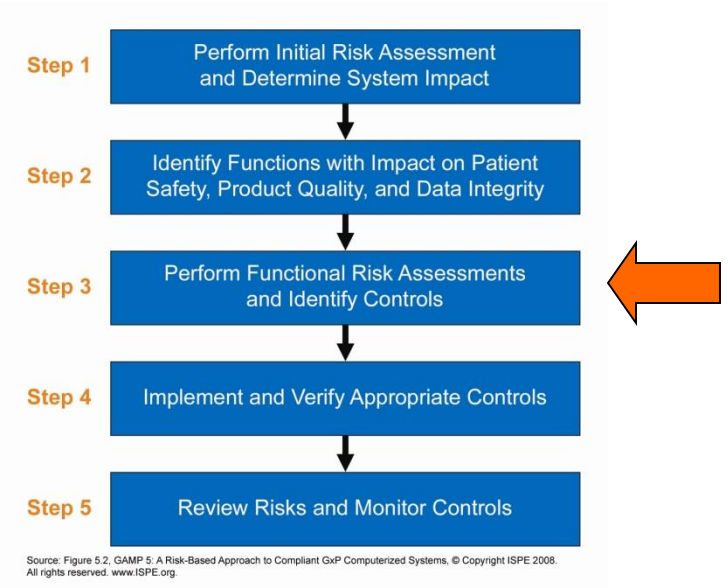
Change the design

Add new features

Apply external procedures

More detailed rigorous specification and verification

Eliminate the risk by Design if possible



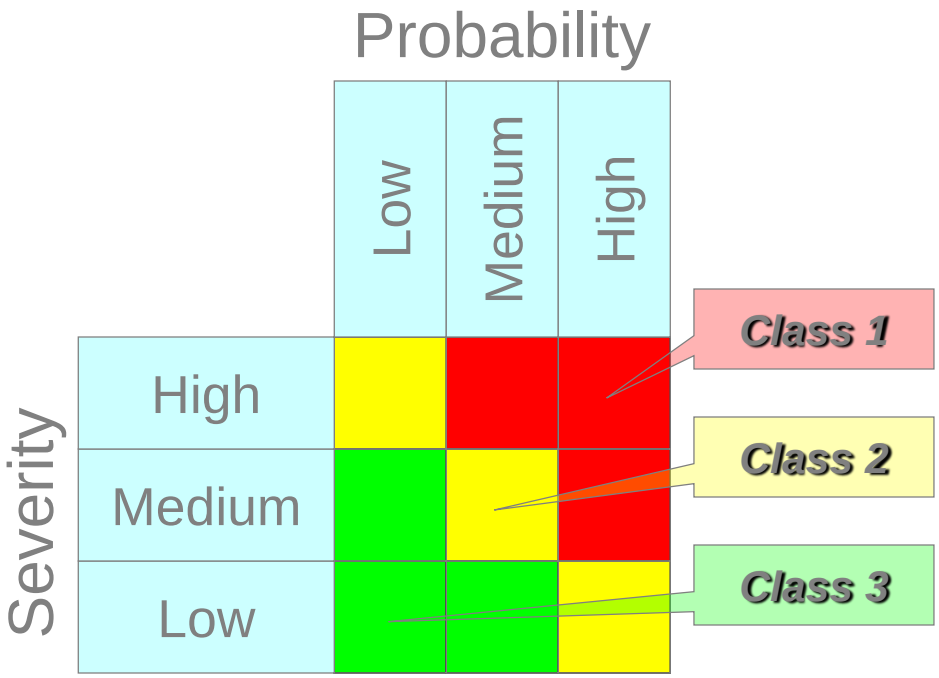
Functional Risk Assessment

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

Risk Assessment Tool

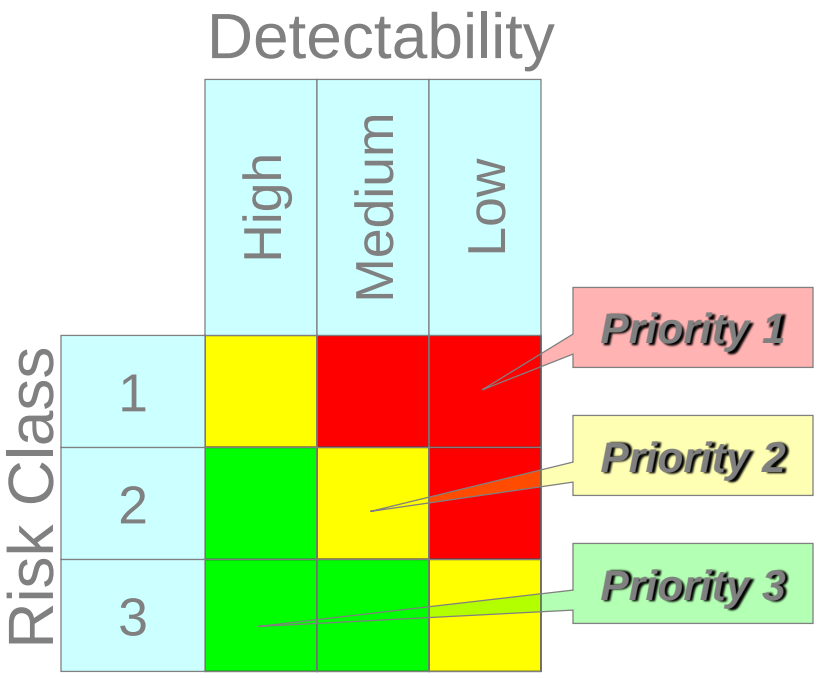
A simple two-step process:

❶ Plot **Severity** vs. **Probability** to obtain **Risk Class**



Risk Assessment Tool

❷ Plot **Risk Class** vs. **Detectability** to obtain ***Risk Priority***

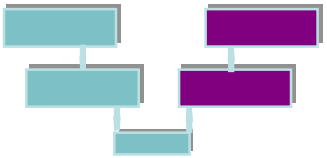


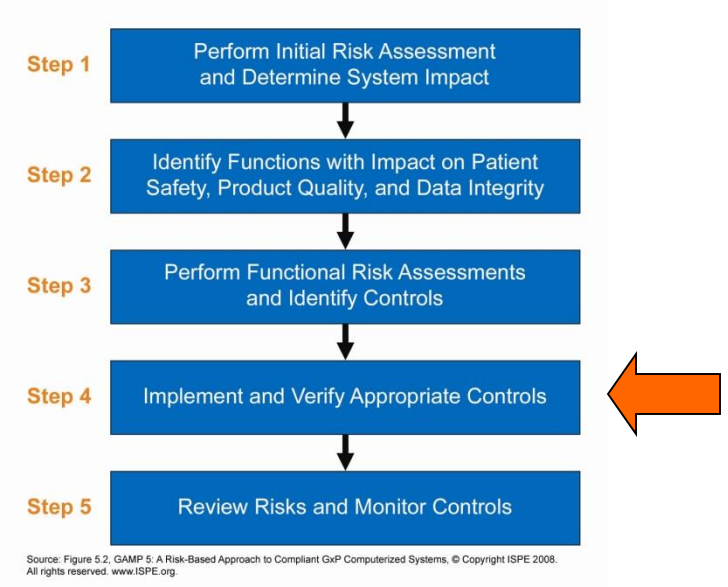
Example Risk Assessment Form

Project Title / Risk Assessment Overview								Project Number
Assessment Scope / Assumptions Made								
Function	**Sub-function**	**Assessment of Risk**						**Measures**
		Relevance (GxP / Business)	Risk Scenarios	Probability	Impact	Class	Detection	Priority
Risk Assessment Approved by:								

Step 4 – Implement & Verify Appropriate Controls

- Verification activity should demonstrate that the controls are effective in performing the required risk reduction.

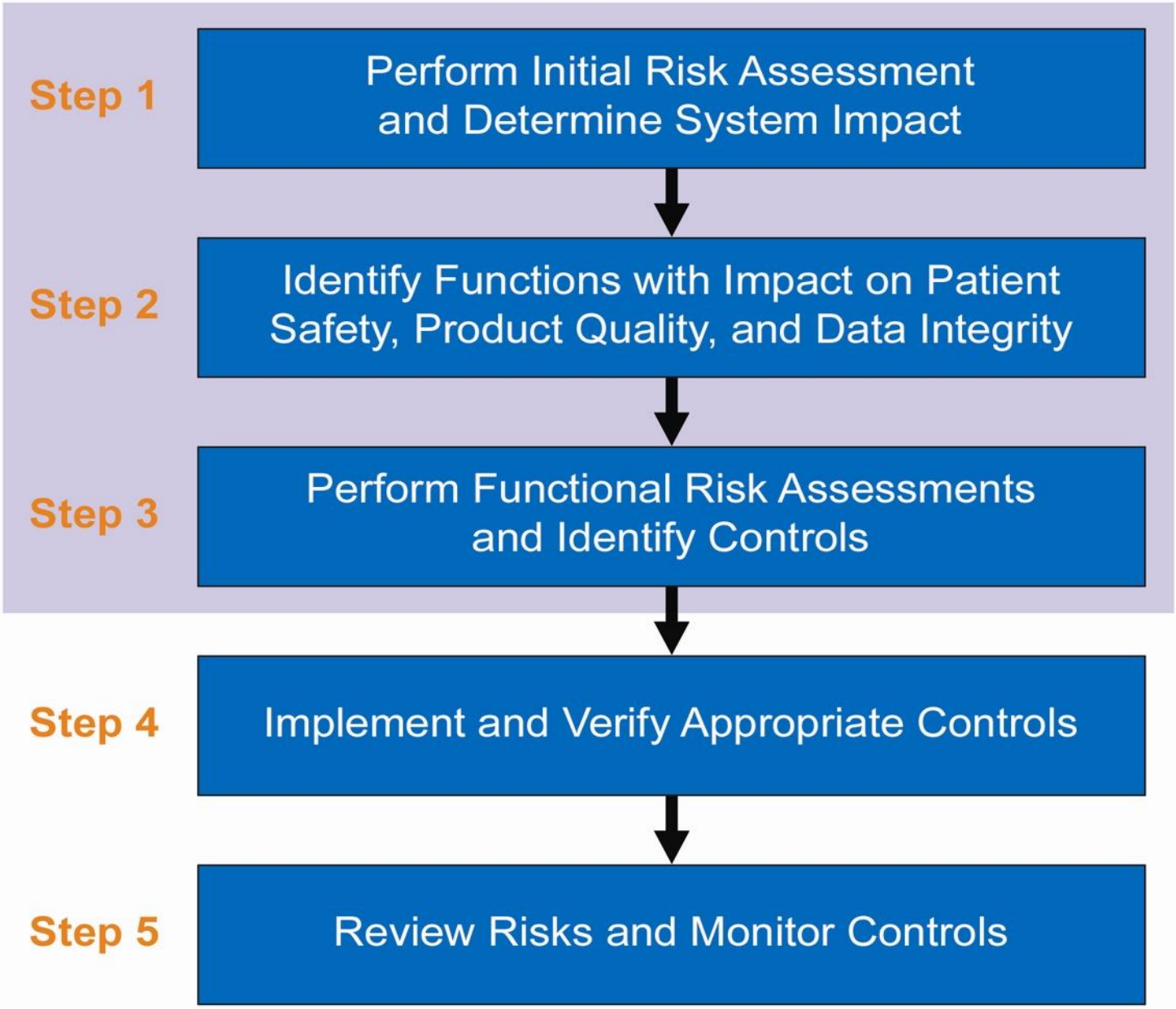




Step 5 – Review Risks & Monitor Controls

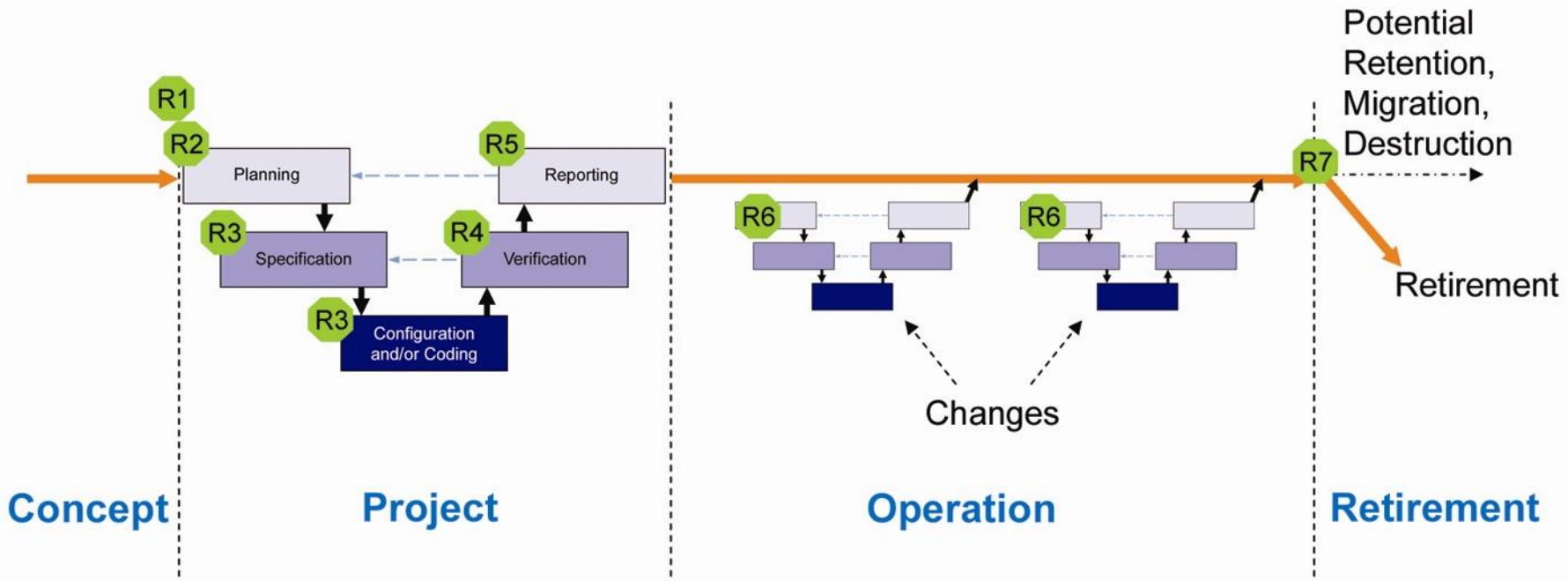
- Mechanism implemented.
- Monitor controls for effectiveness.
- Change management to apply risk management activities

Frequency and extent of any periodic review should be based on the level of risk



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

Decisions Through the Life Cycle



R1 Initial risk assessment

R2 Risk-based decisions during planning

R3 Functional risk assessments

R4 Risk-based decisions during test planning

R5 Risk-based decisions during planning of operational activities

R6 Functional risk assessments in change control

R7 Risk-based decisions when planning system retirement