

1 Purpose

The purpose of this document is to give guidance on a process for risk identification, assessment, control and review within the area of GxP regulated quality and compliance.

2 Scope and Applicability

This Guideline describes a framework for quality risk management and the responsibilities for ensuring that risks to quality and compliance are understood and managed appropriately. It does not describe specific risk management methodologies.

This Guideline is applicable to any site sites, functions and departments undertaking work, projects or providing support services, required to meet GxP throughout the life of a drug, from candidate drug acceptance until withdrawal of the marketed product. This includes new indications and line extensions.

The International Conference on Harmonization (ICH) guideline "Q9 Quality Risk Management" forms the basis of this document. It is compatible with the Integrated Risk Management Framework and supports risk management within the Project Management Framework.

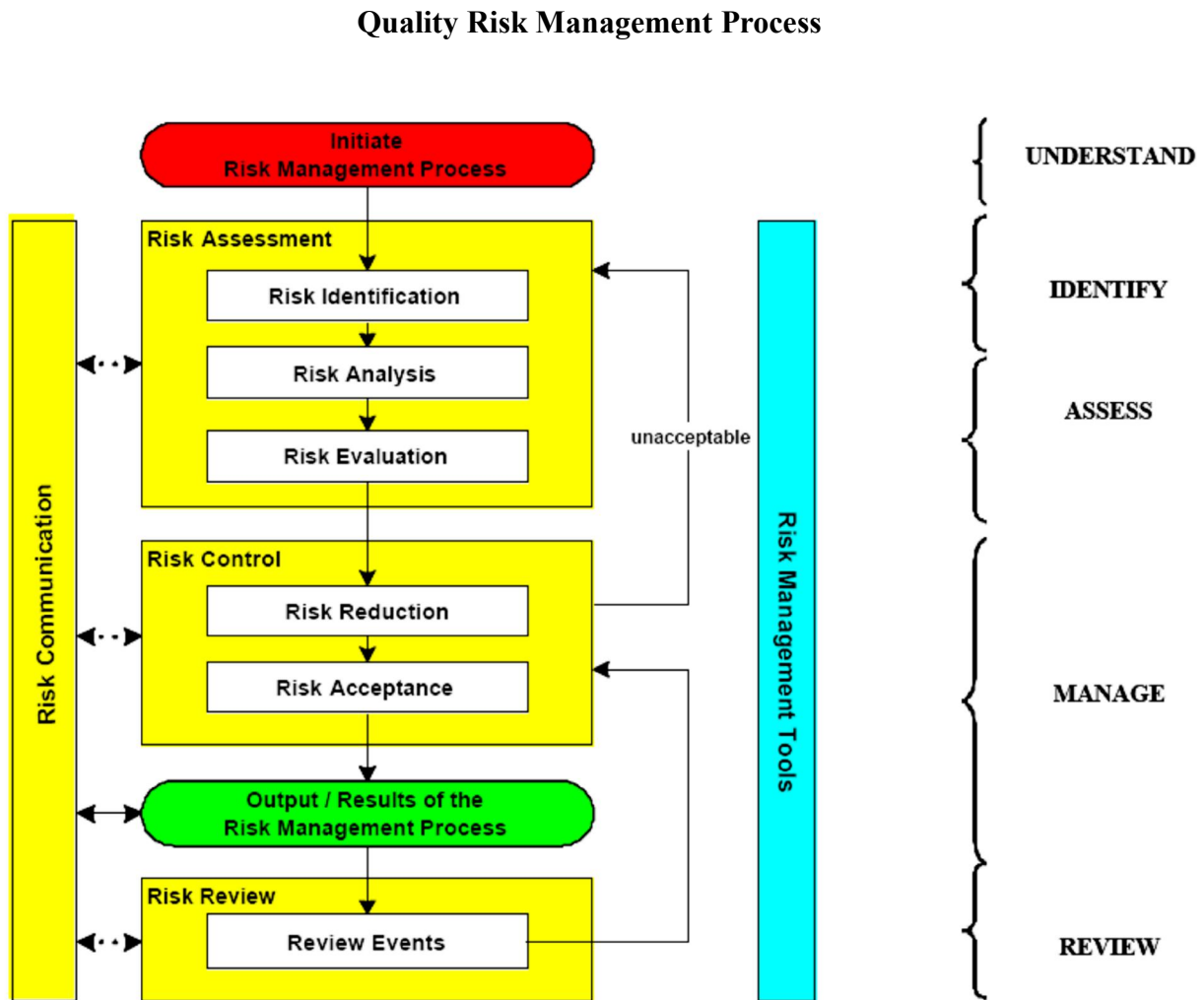
The Quality Risk Management framework is also applicable to computerized systems.

3 Definitions

- Harm ó damage to health, including the damage that can occur from loss of product quality or availability.
- Hazard - the potential source of harm.
- Quality risk management ó a systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product across the product lifecycle.
- Risk ó combination of the probability of occurrence of harm and the severity of that harm.
- Risk assessment ó a systematic process of organizing information to support a risk decision to be made within a risk management process. It consists of the identification of hazards and the analysis and evaluation of the risks associated with exposure to those hazards.
- Risk control - actions implementing risk management decisions.
- Risk review ó review or monitoring of the output/results of the risk management process considering (if appropriate) new knowledge and experience about the risk.
- Uncertainty ó the inability to determine, or the ambiguity in, the true state of a system caused by a combination of variability and incomplete knowledge.

The elements of the generic framework must be visible in any quality risk management process but need not be formalized.

Figure 1 Generic Framework for Quality Risk Management Process



5.2 Formal and Informal Quality Risk Management

The risks associated with processes, systems and projects that have the potential to impact product, safety, efficacy, quality or compliance must be managed effectively. However, the level of effort, formality and documentation associated with managing those risks should be appropriate to the level of risk to quality and be based on scientific knowledge. It is neither appropriate nor necessary to carry out formalized risk assessments for all quality risk decisions. Three broad areas can be defined that can help make an informed decision:

There are many tools and techniques that can be used to help identify hazards and assess the risks. No single tool or technique will meet all requirements.

5.3.3 Risk Control

Risk control describes the actions taken to deal with the identified quality risks and the acceptance of any residual quality risks. Risk control must address the following questions:

- Is the risk acceptable without further action?
- What can be done to reduce, control or eliminate risks.
- What is the appropriate balance among benefits, risks and resources?
- Are new risks introduced as a result of the identified risks being controlled?

Risks are controlled by either eliminating the hazard, reducing the consequences, reducing the likelihood of occurrence (or by some combination of these). Quality risk controls must be documented.

The acceptability of residual risks must be determined by making informed decisions on the criticality of the parameters involved. The acceptable level of risk is not an absolute but will depend upon, amongst other things, the potential benefit to be gained by accepting the risk weighed against the possible harm.

5.3.4 Output/Results of Quality Risk Management Process

The results of the quality risk management process must be communicated to the relevant stakeholders, including management and those operating the process or system who may be affected by those results. This requires that each step of the risk management process be documented at an appropriate level. The purpose of the output from the risk management process is :

- To share and communicate information about the risks and how they are controlled.
- To obtain the appropriate approval of the decisions taken.
- To demonstrate to stakeholders that there has been a properly conducted systematic approach.
- To provide a record of the risks that enables decisions to be reviewed and the process to be audited.
- To facilitate ongoing monitoring and review and to sustain the process.

The output from the risk assessment must specify a risk owner i.e. a person responsible for ensuring that any actions are implemented and that the risk is managed.

6 Appendix 1: Understanding the Level of Formality

