

# Risk Management in Quality Management Systems

## Module 8



# Contents

- Risk and opportunities
- Identifying and managing risks and opportunities in QMS



# Risk Based Approach

What is the risk-based approach in ISO?

- The ISO 9001 risk-based thinking approach has proven to be much more effective in allowing organizations to become stronger, fitter businesses. Taking a risk-based approach means: Determining the risks and opportunities. Planning actions to address them.



# Risk Management

The Quality System Risk management is a systematic process for identification, assessment, control, communication and review of risks to the quality system processes.

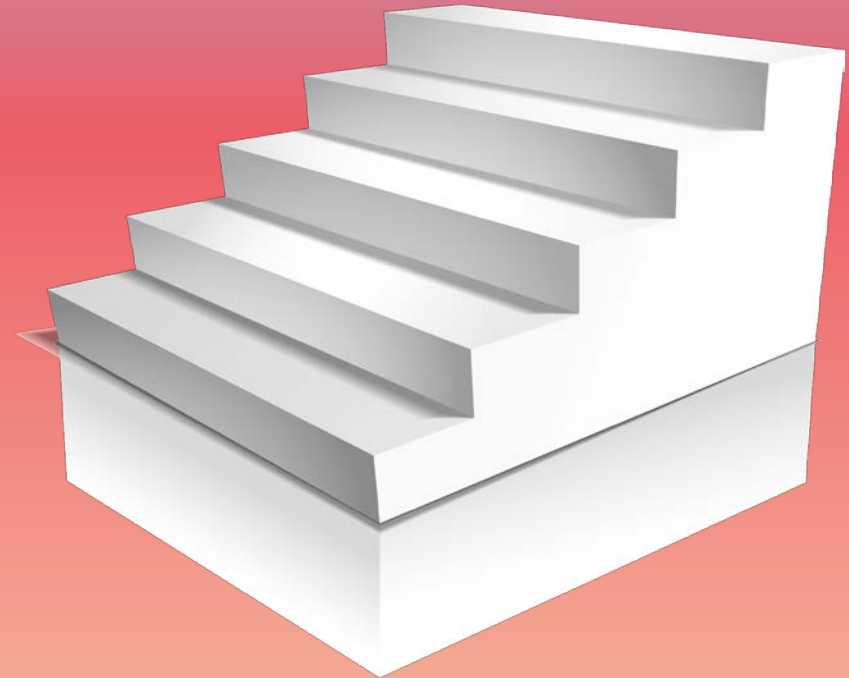
The risk assessment process involves:

- The identification of risks.
- Determination of their severity and likelihood of Occurrence.
- Selection of appropriate actions to mitigate them.



# Risks Management 5 Step Process

- **Identification**
- **Analysis**
- **Evaluate and Prioritise**
- **Treat**
- **Monitor**



# Identification

To identify the hazards,

- create a list the potential areas of concerns or foreseeable hazards
- based upon historical data, theoretical analysis, informed opinions, and the concerns of stakeholders.

Risk identification addresses the “What might go wrong?” question, including identifying the possible consequences.

This provides the basis for further steps in the quality system risk management process.



# Identification – Techniques

- Interviews. Choose key stakeholders, plan the interviews, formulate specific questions, and document the outcomes.
- Brainstorming.
- Checklists.
- Assumption Analysis.
- Cause and Effect Diagrams.
- Nominal Group Technique (NGT).
- Affinity Diagram.



# Identification – Example Types

Using PESTLE Analysis

**P** – Political

**E** – Economic

**S** – Social

**T** – Technological

**L** – Legal

**E** – Environment





# Analysis

- ❖ Risk analysis is the process of identifying and analyzing potential issues that could negatively impact key business initiatives or projects.
- ❖ It is essential for understanding the impact of risk on business goals and objectives, as well as how likely it is the risks could happen, and when.
- ❖ The goal of risk analysis is to help top management understand where to focus their most immediate attention



# Analysis – Methods

- Qualitative Risk Analysis
- Quantitative Risk Analysis
- Bow Tie Analysis
- SWIFT Analysis
- Decision Tree Analysis



# Evaluation & Prioritize

Risk evaluation compares the identified and analyzed risk against given risk criteria. The Risk evaluations consider the strength of evidence for the following fundamental questions.

01. What might go wrong?

02. What is the likelihood (probability) it will go wrong?

03. What are the consequences (severity)?



# Evaluation – Methods

## How a Risk Matrix Works

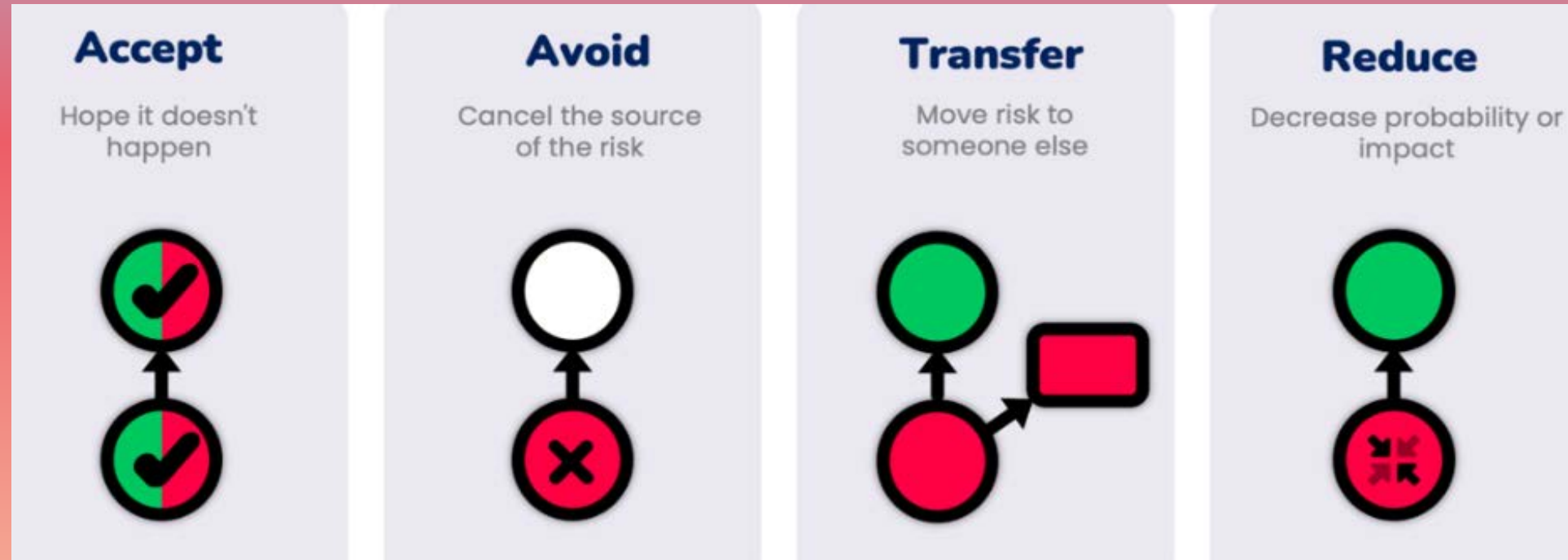
### IMPACT

		IMPACT				
		A	B	C	D	E
		Negligible	Minor	Moderate	Significant	Severe
PROBABILITY	E	Very Likely	Low Medium	Medium	Medium High	High
	D	Likely	Low	Low Medium	Medium	Medium High
	C	Possible	Low	Low Medium	Medium	Medium High
	B	Unlikely	Low	Low Medium	Low Medium	Medium
	A	Very Unlikely	Low	Low	Low Medium	Medium



# Treat

Risk treatment strategy is the way we deal with a particular risk. In other words, how we respond to the risk.



# Monitoring

Risk monitoring is the process of ensuring that an organization implements and evaluates measures to address risks and identifies any changes that may affect the organization's risk picture.



# Monitoring – Risk Register

- Identification ID
- Description
- Breakdown structure
- Categories
- Analysis
- Probability
- Priority
- Response
- Ownership



# SWOT Analysis

**S** – Strengths

**W** – Weakness

**O** – Opportunities

**T** – Threats





# Opportunities



# Opportunities

## Business or product development

- ❖ New-to-the-company,
- ❖ Improvement of existing product,
- ❖ Product line extension,
- ❖ New product-to-the-market

## Technology development

- ❖ Artificial intelligence
- ❖ The mobile phone
- ❖ Internet



# Q & A



thank you!

