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QSP 6.1 Subject: Risks

QSP 6.1 Actions to address risks and opportunities

01. **Purpose**

Make actions to address risks and opportunities a part of decision making on all levels of the Organization and one of the improvement mechanisms of processes and quality management system (QMS).

02. <u>Scope</u>

This procedure covers all processes of OMS and regulates the activity of the Organization's Leadership, Quality Manager, Risk Manager, Process Owners, Risk Owners, experts regarding risk management.

03. Responsibility and Authority

The responsibility and authority of the Organization's Leadership, Quality Manager, Risk Manager, Process Owners, Risk Owners, experts to ensure this procedure are given below, in the sec. 4.2.4.

04. Procedure

4.1 General

Inputs:

- Data of the processes operations, including criteria from QMS Processes; •
- Information flow about the internal and external context of the Organization (see sec. 4.2.1);
- Information on changes and Risk management tasks in QMS from the 'Management • Review' Process.

Outputs:

- Process control decisions to QMS Processes; ٠
- Data to evaluate effectiveness of the processes to QMS Processes;
- Suggestions for changes to the QMS, including resource needs to 'Management • Review' Process;
- Suggestions to initiate breakthrough projects to 'Management Review' Process;
- Data to evaluate effectiveness of the processes and the QMS as a whole to 'Management Review' Process.

Actions to address risks and opportunities (Fig. 1) consist of carrying out the 'PDCA' cycles related to risks on two levels:

- QMS level 'Actions to address risks and opportunities' Process (1st level process);
- Each Process Level 'Risk management processes' (2nd level processes).

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Quality System Procedure

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QSP	6.1
Subject:	Risks

'Risk management processes' are the constituent parts of the 'Actions to address risks and opportunities' Process.

'Actions to address risks and opportunities' Process is implemented in four phases:

- Planning actions to address risks and opportunities. Project of risk management framework.
- Integration and implementation of actions to address risks and opportunities into QMS processes.
- Evaluation of the effectiveness of actions to address risks and opportunities. Monitoring and analysis of risk management framework.
- Achieving improvement

Act

Achieving improvement

· Enhance desirable effects in

undesired effects in QMS;

efficiency of the 'Actions to

opportunities' Process and

the provision of resources,

· Conclude that the QMS can

2. Current QMS improvements.

3. Current improvements of

certain QMS Process.

1. Program QMS

QMS;

improvements, including:

· Prevent, or reduce,

Breakthrough projects;
Activities aimed at improving

address risks and

including budget;

result(s).

achieve its intended

Plan

Planning actions to address risks and opportunities. Project of risk management framework.

- Understanding the context of the organization
- Connection with the Policy
- Communication and reporting mechanism
- Responsibility and Authority (Leadership, Quality Manager, Risk Manager, Process Owner, Risk Owner, expert)
- Resources (people, budget, methods, procedures, training programs, organizational knowledge on risk management)

Control

Evaluation of the effectiveness of actions to address risks and opportunities. Monitoring and analysis of risk management framework.

- Analysis of the Risk Management Plan implementation effectiveness;
- Analysis of changes in QMS Processes as a result of actions to address risks and opportunities;
- Determination and analysis of changes of the 'Actions to address risks and opportunities' Process criteria;
- Analysis of the communication methods and reporting mechanisms effectiveness;
- Analysis of the adequacy and effectiveness of resource use.

Integration and implementation actions to address risks and opportunities into QMS Processes

Do

1. Implementation of risk management framework

- Raise personnel awareness of the importance of the actions to address risks and opportunities for decision making on all levels in the Organization, including adding this provision into the Quality Policy.
- Include in job description.
- Conduct systematic training on risk management at all levels of the company.

2. Implementation of risk management process:

- Communication and consultation
- Determination of situation (context, risk criteria)
- Risk assessment (identification: risk list, risk source; analysis: consequences, likelihood, level of risk; evaluation: level of risk and risk criteria comparison)
- Risk treatment (Avoiding the risk by deciding not to start or continue with the activity that gives rise to the risk. Accepting or increasing the risk in order to pursue an opportunity. Removing the risk source. Changing the likelihood. Changing the consequences. Sharing the risk with another party or parties. Retaining the risk by informed decision)
- Monitoring and review of risk management process

Fig. 1. Actions to Address Risks and Opportunities Diagram

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Quality	System	Procedure
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QSP 6.1 Subject: Risks

4.2 Planning actions to address risks and opportunities. Project of risk management framework.

4.2.1 <u>Understanding the Context of the Organization</u> It is a prerequisite for the risk management framework project, defining the levels of risk and risk criteria, as well as risk treatment.

Information flows on internal and external context include:

- Information on the applicable laws ('Control of documented information' Process);
- Standards ('Control of documented information' Process);
- Information on markets and market trends ('Marketing Activity' Process);
- Information on competitors including technology ('Marketing Activity' Process);
- Information about the policy, objectives, strategies, promising business opportunities ('Management Review' Process);
- Information about the organizational structure and resources ('Management Review' and 'Personnel Management' Processes);
- Information about the technologies and future developments ('Design and Development' Process);
- Information about the personnel qualification ('Personnel Management' Process);
- Other information, specific to the particular case.

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