Risk-Based Thinking

in

ISO 13485:2016

Risk Management / Analysis of Risk

Risk Management

Every version of the ISO 13485 standard has advocated risk management and risk avoidance.

The new ISO 13485:2016 standard continues to expect organizations to identify and address risks affecting compliance of products and services, resulting in improved customer satisfaction.

Besides identifying the risks, organizations should address opportunities for improvements and corrective actions based on the risk analysis.

Note, that while corrective action and preventive action are requirements of ISO 13485:2016, the concept of preventive action can be addressed through a risk-based approach where risks are determined and actions to address risks and opportunities, are taken.

At clause 7.1, the standard requires that one or more processes for the management of risks be documented. This risk analysis exercise is intended to outline several approaches / options for the management of risk at your company.

To prepare for the change, it is time to begin understanding Risk Based Thinking and begin looking at your processes in terms of risks.

As defined in clause 3.17, risk is the combination of the probability of occurrence of harm and the severity of that harm.

When evaluating risk, it is helpful to address it using two (2) metrics or parameters:

1. Severity (if harm happens, how serious is the event)
2. Likelihood (what is the probability of a harmful event occurring)

Because this topic is so important, it will have an impact on your QMS.

Exercise - Conduct Risk Analysis - Risk Management Worksheet – Basic Method

The first 6 columns of this form are used to list the Potential Risks and Assess the Significance of the Risks

The last 2 columns of this form are used to indicate whether or not the Process Step is at risk and requires attention.

*** Refer to the process flow diagram(s).**

**** Where both the Severity and the Likelihood are high, the risk is significant and the Process Step requires corrective action.**

* Step	What is present or could be introduced as a risk?	Description of Risk	Significance 1 = Severity 2 = Likelihood 3 = Significance **			Does a next step in process, eliminate the risk?	What controls exist to address the risk?	Is the Process Step at risk? Yes / No	** If YES, Issue the Corrective Action Request.
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Compiled by Management representative: _____, Date: _____

Quality Steering Team review: 1_____, Date: _____, 2_____, Date: _____

Exercise - Conduct Risk Analysis - Risk Management Worksheet

ACTION 1	ACTION 2	ACTION 3	ACTION 4			ACTION 5	ACTION 6	ACTION 7	ACTION 8
* Step	Input	Description of Risk	Significance 1 = Severity 2 = Likelihood 3 = Significance **			Does a next step in process, eliminate the risk?	What controls exist to address the risk?	Is the Process Step at risk? Yes / No	** If YES, Issue the Corrective Action Request.
---	---	----	1	2	3	Justifications			CAR #

Explanatory Notes for the Actions required at each Column, are provided in the next pages.

Medical Devices

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Product Realization and Risk Management In ISO 13485 Clause 7

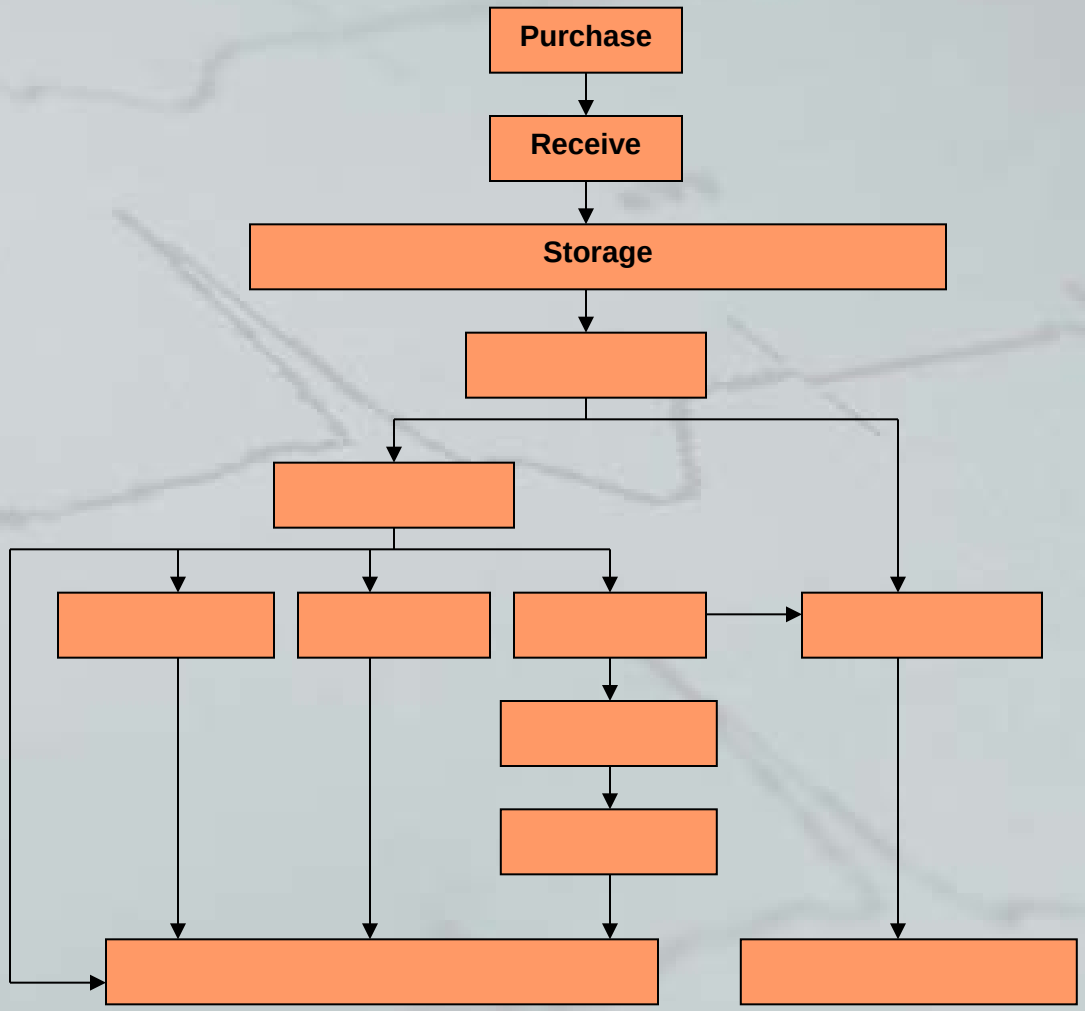
7.1 Planning of product realization

- Includes the planning and development of the processes needed for product realization with product objectives, relevant processes and resource, appropriate test & validation and records to provide the evidence that requirements are met.

- **Includes the documentation of one or more processes for Risk Management in the product realization process.**
- **Includes the maintenance of records of Risk Management activities.**

The question becomes–How can this be accomplished?

Draw the Process Flow Diagram(s) for your functions



Action 6 Conduct Risk Analysis - Risk Management Worksheet

ACTION 1	ACTION 2	ACTION 3	ACTION 4			ACTION 5	ACTION 6	ACTION 7	ACTION 8
* Step	Inputs	Description of Risk	Significance 1 = Severity 2 = Likelihood 3 = Significance **			Does a next step in process eliminate the risk?	What controls exist to address the risk?	Is the Process Step at risk? Yes / No	** If YES, Issue the Corrective Action Request
---	---	----	1	2	3		Justifications		CAR #

ACTION 6 What controls exist at the process step?

What measures need to be taken to prevent, reduce or eliminate the risk?

Controls will vary on the type of risk and obviously their significance. For example the controls may focus on sourcing components from approved suppliers, who produce them under controlled conditions.

In some cases, there will be more than one control for an identified risk, and conversely, more than one risk may be controlled by a specified control.

In certain instances, control measures may not be required due to the absence of any significant hazards at that step.

Risk Management Worksheet

Conduct Risk Analysis - Risk Management Worksheet

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1 2 3 4 5 6 7 8

Compiled by ISO management representative: _____, Date: _____

Quality Steering Team review: 1_____, Date: _____, 2_____, Date: _____