



**Medical Devices**

**Risk Management / Analysis of Risk**

**in**

**ISO 13485:2003**



# Product Realization and Risk Management In ISO 13485 Clause 7

## 7.1 Planning of product realization

- Includes product objectives, relevant processes and resource, appropriate test and validation.
- **Includes the application of Risk Management throughout the product realization process.**

The question becomes—How can this be accomplished?



## Conduct Risk Analysis for product realization steps required for your medical device products.

### Instructions:

- Prepare process flow diagrams to describe your activities / steps .. *in next slides* ..  
Consider the production steps and the activities/steps for all functions.
- Make use of the 8-column Risk Management Worksheet to systematically conduct a risk analysis for each of the steps identified in each process flow diagram .. *next slides* ..



## Task 15 Exercise G – Action 3 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
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### **ACTION 3** What type of risk is presented by the introduction of these inputs?

Describe the risks when non-complying product characteristics result in areas of:

**DIMENSIONAL** (item too big, too small, too wide, too narrow, etc)

**MATERIAL** (too hard, too soft, etc)

**APPEARANCE** (too dark, too light, too rough, too smooth, etc)

**FUNCTION ..**

**Others ..**



# Task 15 Exercise G - Risk Management worksheet

## Task 15 Exercise G Conduct Risk Analysis - Risk Management Worksheet

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

The last 2 column 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			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 = Severity	2 = Likelihood	3 = Significance				
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Compiled by ISO management representative: \_\_\_\_\_, Date: \_\_\_\_\_

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