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
---	---	----	1	2	3	Justifications			CAR #

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 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 #

1 2 3 4 5 6 7 8

Compiled by ISO management representative: _____, Date: _____

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