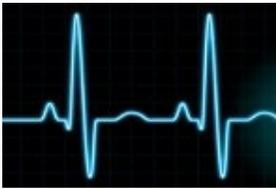


Note:

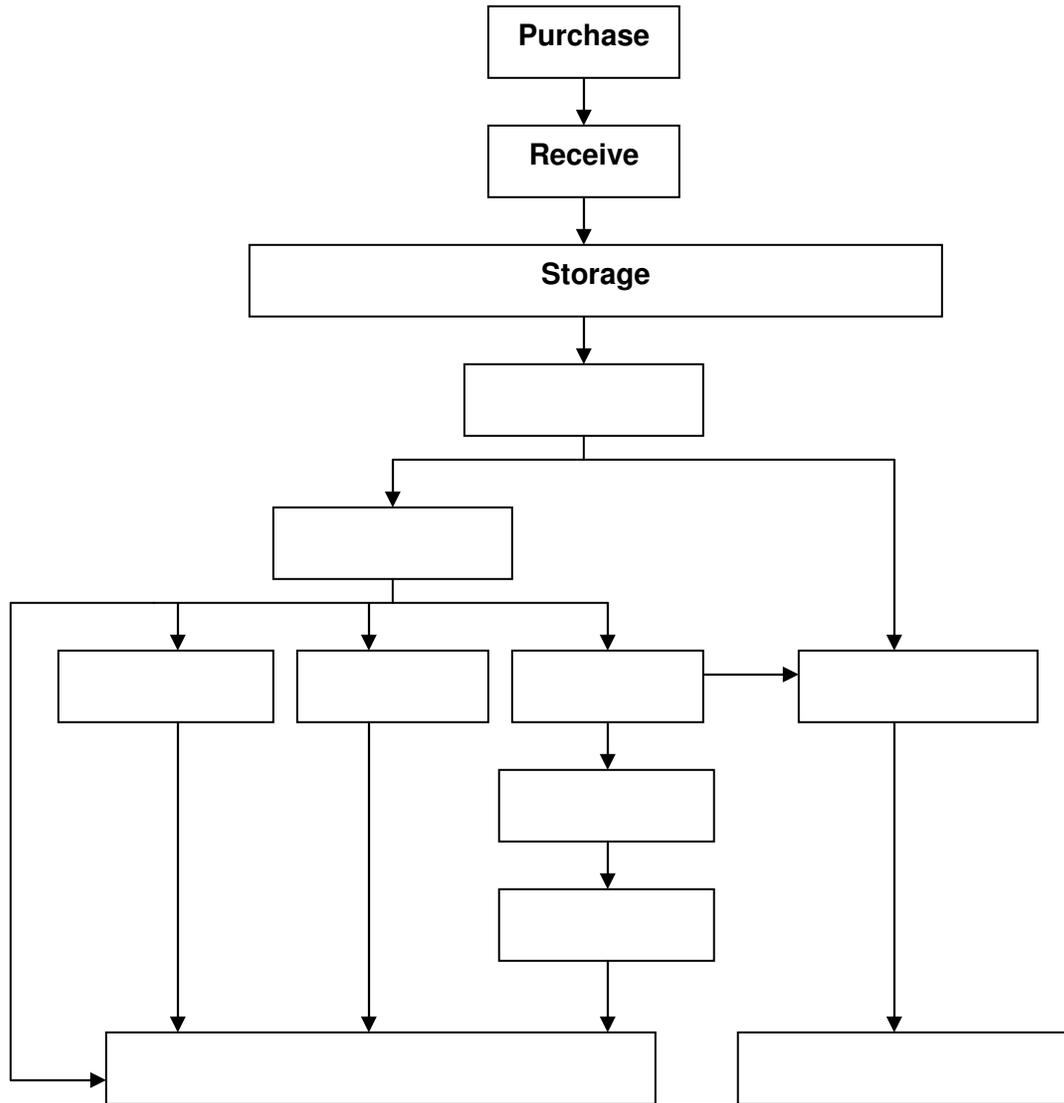
This Exercise deals with risk management and the analysis of risks throughout clause 7 for product realization.

The Task is from the [ISO 13485 Workbook](#) that details a series of tasks associated with the preparation, development, implementation and registration phases for the ISO project.

Visit www.13485store.com for additional information on the workbook Task 1 - Task 28.

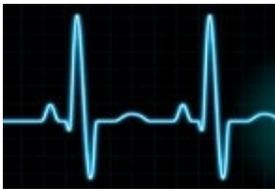


Draw the Process Flow Diagram(s) for your functions



Comments:

Prepared by; _____ Date: _____



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 ..