SCTO Validation Platform

Business Processes Risk Assessment

Date: November 29, 2024

This document is an integral component of the SCTO Validation Platform

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ℹ Document development, review and version history

Development and Review

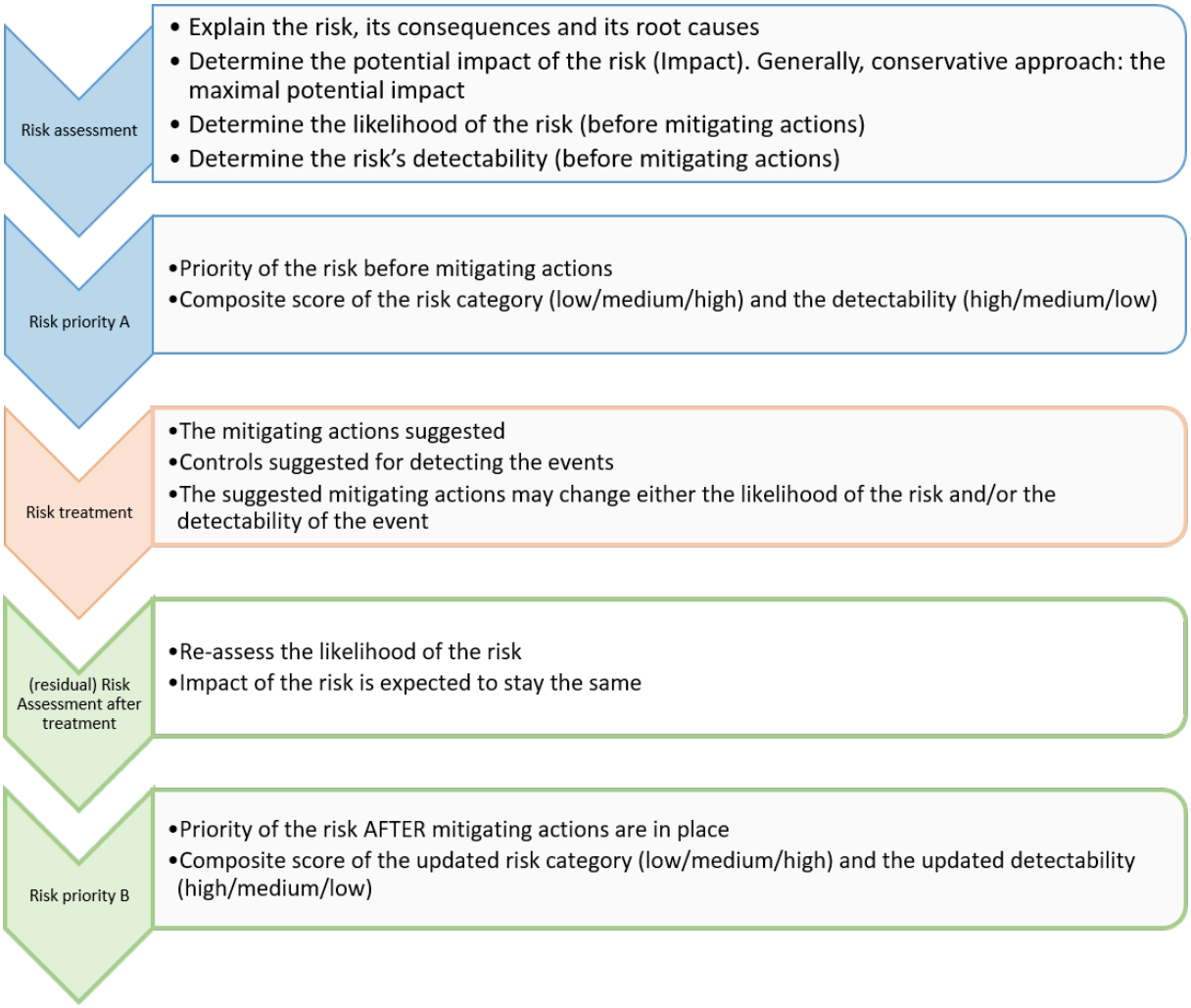
	Name	Date
Authored/Revised by	XXXXXXXXXX	xxxx-xx-xx
Reviewed by	YYYYYYYYYY	xxxx-xx-xx
Released by	ZZZZZZZZZZ	xxxx-xx-xx

Version History

Version	Date	Author	Summary of Changes
0.1	xxxx-xx-xx	XXXXXXXXXX	Initial draft

This is an explanation and 'dictionary' for the High Level Risk Assessment tool of the platform.

The file is structured as a process following the steps below:



The variables of decision are:

- Risk area:

- Risk Subarea
- Impact of risk (A):
  - Minor (1 point)
  - Major (3 points)
  - Critical (6 points)
- Likelihood (A): how likely is the event to take place (before mitigating actions are in place):
  - Unlikely (1 points)
  - Possible (2 points)
  - Likely (3 points)
- Risk A = multiplication of impact x likelihood
- Risk A category: categorization of Risk according to points received in Risk A
  - 1-2: Low (green)
  - 3-8: Medium (yellow)
  - ≥9 High (red)
- Detectability A: how fast and easily is the risk effect detected, potentially before consequences (before mitigating actions are in place):
  - High (easy to detect, 'jumps' to the eye immediately)
  - Medium (is detectable if one pays attention or examines this point specifically with a critical eye)
  - Low (hard to detect, only detectable if rigorously and specifically looking for problems)
- Priority A: The 'final' risk category and priority in need for handling (i.e., before mitigating actions). Is conditional on the Risk-A category and on the Detectability A according to the PharmaSUG suggestion (Figure 2) using for "risk class" the defined Risk Category A

- Risk treatment: the mitigating actions that can be implemented. Examples of possibilities are provided. Mitigating actions may:
- Reduce the likelihood of a risk to occur
- Increase the likelihood of detection of the risk occurring

- Risk analysis after treatment:
- Impact = the same as the impact in the risk assessment (does not change)
- Likelihood B: The likelihood of the risk to happen (Once mitigating actions are in place)
- Risk B: the calculated risk based on impact and the new likelihood
- Detectability B: the new detectability (Once mitigating actions are in place)
- Priority B: Final, residual, priority of the risk (once mitigating actions are in place)

- Risk monitoring: TO BE FILLED per CTU according to local SOPs and guidelines (local QM)

The high level risk assessment is available here .