

SCTO Validation Platform

Business Processes Risk Assessment

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This document is an integral component of the SCTO Validation Platform



i Document development, review and version history

Development and Review

	Name	Date
Authored/Revised by	XXXXXXXXX	xxxx-xx-xx
Reviewed by	YYYYYYYYY	xxxx-xx-xx
Released by	<u> </u>	xxxx-xx-xx

Version History

Version	Date	Author	Summary of Changes
0.1	XXXX-XX-XX	XXXXXXXXX	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:

Risk assessment

- Explain the risk, its consequences and its root causes
- Determine the potential impact of the risk (Impact). Generally, conservative approach: the maximal potential impact
- Determine the likelihood of the risk (before mitigating actions)
- Determine the risk's detectability (before mitigating actions)

Risk priority A

- Priority of the risk before mitigating actions
- •Composite score of the risk category (low/medium/high) and the detectability (high/medium/low)

- •The mitigating actions suggested
- •Controls suggested for detecting the events
- •The suggested mitigating actions may change either the likelihood of the risk and/or the detectability of the event

Risk treatment

- Re-assess the likelihood of the risk
 - •Impact of the risk is expected to stay the same

(residual) Risk Assessment after treatment

Risk priority B

- Priority of the risk AFTER mitigating actions are in place
- Composite score of the updated risk category (low/medium/high) and the updated detectability (high/medium/low)

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 .