

CAPA Worksheet

1. Description.

Describe in detail the problem that has occurred.

2. Risk Assessment.

Determine if a CAPA is necessary by using a risk analysis approach. Using the diagram below, plot out the Likelihood (chance of occurring again) against the Impact (effect on patient safety, data integrity and /or compliance with regulations).

- **Green:** Problems plotted in the green area do not require a CAPA, but may require other interventions such as a protocol deviation. It is not necessary to complete this form beyond section 2. Print this form to document risk assessment.
- **Yellow:** Problems plotted in the yellow area require other considerations before deciding to use the CAPA process. Consider probability of other similar problems, how widespread the problem is, difficult to correct, etc.
- **Red:** Problems plotted in the red area require a CAPA. Complete the rest of this form in its entirety.

		Likelihood					
		Never	Unlikely	Possible	Likely	Frequent	Always
Impact	Severe						
	Moderate						
	Mild						
	Minimal						
	None						

Definitions

- Never: Will not occur at any time
 Unlikely: Roughly 1% likelihood
 Possible: Foreseeable to occur
 Likely: Will probably occur
 Frequent: Will occur multiple times

Always: Will occur every time

Severe: Extreme impact on patient safety, data integrity and/or compliance with regulations

Moderate: Serious impact on patient safety, data integrity and/or compliance with regulations

Mild: Some effect on patient safety, data integrity and/or compliance with regulations

Minimal: Very little effect on patient safety, data integrity, and/or compliance with regulations

None: No effect on patient safety, data integrity and/or compliance with regulations

3. Investigation

Describe in detail the investigation methods and outcomes. Include assessment of how widespread the problem is and what the root cause is.

4. Correction Methods

Describe in detail what measures will be taken to remedy the problem *which has already occurred*.

5. Preventive Methods

Describe in detail what measures will be taken to prevent this problem from occurring again.

6. Implementation Plan

Describe in detail how the preventive methods will be implemented. Include timelines, personnel responsible and personnel affected.

7. Verification of Effectiveness

Describe how the CAPA will be considered effective. Include plans for documentation, frequency of verification and total timeframe necessary.

CAPA Plan Approval:

Principal Investigator Signature: _____

Date: _____

CAPA Closure Approval:

I certify all elements of the plan outlined above have been successfully implemented. Evidence of CAPA effectiveness is enclosed and supports the closure of this CAPA.

Principal Investigator Signature: _____

Date: _____