# Risk Management Plan

**Table of Contents**

1 Executive Summary.....
1.1 Purpose.....
2 Risk Management Strategy.....
2.1 Risk Identification.....
2.2 Risk Responsibilities.....
2.3 Risk Assessment .....
2.4 Risk Response.....
2.5 Risk Mitigation .....
2.6 Risk Contingency Planning.....
2.7 Tracking and Reporting .....
2.8 Processes to Address Immediate Unforeseen Risks .....

## 1 Executive Summary

Risk is defined as an event that has a probability of occurring, and could have either a positive or negative impact to a project should that risk occur. A risk may have one or more causes and, if it occurs, one or more impacts. For example, a cause may be requiring an environmental permit to do work, or having limited personnel assigned to design the project. The risk event is that the permitting agency may take longer than planned to issue a permit, or the assigned personnel available and assigned may not be adequate for the activity. If either of these uncertain events occurs, there may be an impact on the project cost, schedule or performance. All projects assume some element of risk, and it's through risk management where tools and techniques are applied to monitor and track those events that have the potential to impact the outcome of a project.

Risk management is an ongoing process that continues through the life of a project. It includes processes for risk management planning, identification, analysis, monitoring and control. Many of these processes are updated throughout the project lifecycle as new risks can be identified at any time. It's the objective of risk management to decrease the probability and impact of events adverse to the project. On the other hand, any event that could have a positive impact should be exploited.

The identification of risk normally starts before the project is initiated, and the number of risks increase as the project matures through the lifecycle. When a risk is identified, it's first assessed to ascertain the probability of occurring, the degree of impact to the schedule, scope, cost, and quality, and then prioritized. Risk events may impact only one or while others may impact the project in multiple impact categories. The probability of occurrence, number of categories impacted and the degree (high, medium, low) to which they impact the project will be the basis for assigning the risk priority. All identifiable risks should be entered into a risk register, and documented as a risk statement.

As part of documenting a risk, two other important items need to be addressed.
The first is mitigation steps that can be taken to lessen the probability of the event occurring. The second is a contingency plan, or a series of activities that should take place either prior to, or when the event occurs. Mitigation actions frequently have a cost. Sometimes the cost of mitigating the risk can exceed the cost of assuming the risk and incurring the consequences. It is important to evaluate the probability and impact of each risk against the mitigation strategy cost before deciding to implement a contingency plan. Contingency plans implemented prior to the risk occurring are pre-emptive actions intended to reduce the impact or remove the risk in its entirety. Contingency plans implemented after a risk occurs can usually only lessen the impact.

Identifying and documenting events that pose a risk to the outcome of a project is just the first step. It is equally important to monitor all risks on a scheduled basis by a risk management team, and reported on in the project status report.

### *1.1 Purpose*

This plan documents the processes, tools and procedures that will be used to manage and control those events that could have a negative impact on the *Insert Project Name Here* project. It's the controlling document for managing and controlling all project risks. This plan will address:

- Risk Identification

• Risk Assessment
• Risk Mitigation
• Risk Contingency Planning
• Risk Tracking and Reporting

Appendix A will present the risk impact assessment matrix and appendix B will present a sample of the risk register.

## 2 Risk Management Strategy

### *2.1 Risk Identification*

A risk is any event that could prevent the project from progressing as planned, or from successful completion. Risks can be identified from a number of different sources. Some may be quite obvious and will be identified prior to project kickoff.

Others will be identified during the project lifecycle, and a risk can be identified by anyone associated with the project. Some risk will be inherent to the project itself, while others will be the result of external influences that are completely outside the control of the project team.

The *Insert Project Name Here* Project Manager has overall responsibility for managing project risk. Project team members may be assigned specific areas of responsibility for reporting to the project manager.

Throughout all phases of the project, a specific topic of discussion will be risk identification. The intent is to instruct the project team in the need for risk awareness, identification, documentation and communication.

Risk awareness requires that every project team member be aware of what constitutes a risk to the project, and being sensitive to specific events or factors that could potentially impact the project in a positive or negative way.

Risk identification consists of determining which risks are likely to affect the project and documenting the characteristics of each.

Risk communication involves bringing risk factors or events to the attention of the project manager and project team.

The *Insert Project Name Here* project manager will identify and document known risk factors during creation of the Risk Register.

It is the *Insert Project Name Here* project manager's responsibility to assist the project team and other stakeholders with risk identification, and to document the known and potential risks in the Risk Register. Updates to the risk register will occur as risk factors change. Risk management will be a topic of discussion during the regularly scheduled project meetings.

The *Insert Project Name Here* project team will discuss any new risk factors or events, and these will be reviewed with the *Insert Project Name Here* project manager.

The project manager will determine if any of the newly identified risk factors or events warrant further evaluation. Those that do will undergo risk quantification and risk response development, as appropriate, and the action item will be closed.

At any time during the project, any risk factors or events should be brought to the attention of the *Insert Project Name Here* project manager using Email or some other form of written communication to document the item. The project manager is responsible for logging the risk to the Risk Register. Notification of a new risk should include the following Risk Register elements:

• Description of the risk factor or event, e.g. conflicting project or operational initiatives that place demands on project resources, unexpected study outcomes, delays, etc.
• Probability that the event will occur. For example, a 50% chance that the vendor will not have an animal colony that meets the criteria available.
• Schedule Impact. The number of hours, days, week, or months that a risk factor could impact the schedule. As an example, the animals require an additional 3 months to meet age requirements.
• Scope Impact. The impact the risk will have on the envisioned accomplishments of the project. Delayed animal delivery may result in a reduction in the number of studies that can be completed within the contract period of performance.
• Quality Impact. A risk event may result in a reduction in the quality of work or products that are developed. As an example, lack of funding caused by cost overruns may result in the reduction of the study size and impact statistical empowerment
• Cost Impact. The impact the risk event, if it occurs is likely to have onthe project budget.

### *2.2 Risk Responsibilities*

The responsibility for managing risk is shared amongst all the stakeholders of the project. However, decision authority for selecting whether to proceed with mitigation strategies and implement contingency actions, especially those that have an associated cost or resource requirement rest with the Project Manager who is responsible for informing the funding agency to determine the requirement for a contract modification. The following tables details specific responsibilities for the different aspects of risk management.

Risk Identification: All project stakeholders
Risk Registry: Project Manager
Risk Assessment: All project stakeholders
Risk Response Options Identification: All project stakeholders
Risk Response Approval: PM with concurrence from CO/PO/COTR
Risk Contingency Planning; Project Manager(s)
Risk Response Management; Project Managers
Risk Reporting; Project Manager

### *2.3 Risk Assessment*

Risk assessment is the act of determining the probability that a risk will occur and the impact that event would have, should it occur. This is basically a “cause and effect” analysis. The “cause” is the event that might occur, while the “effect” is the potential impact to a project, should the event occur.

Assessment of a risk involves two factors. First is the probability which is the measure of certainty that an event, or risk, will occur. This can be measured in a number of ways, but for the *Insert Project Name Here* project will be assigned a probability as defined in the table below.

| **Probability of Occurrences** | | |
|---|---|---|
| **Definition** | **Meaning** | **Value** |
| *Frequent* | • Occurs frequently<br>• Will be continuously experienced unless action is taken to change events | **5** |
| *Likely* | • Occur less frequently if process is corrected<br>• Issues identified with minimal audit activity<br>• Process performance failures evident to trained auditors or regulators | **4** |
| *Occasional* | • Occurs sporadically<br>• Potential issues discovered during focused review. | **3** |
| *Seldom* | • Unlikely to occur<br>• Minimal issue identification during focused review | **2** |
| *Improbable* | • Highly unlikely to occur | **1** |

The second factor is estimate of the impact on the project. This can be a somewhat subjective assessment, but should be quantified whenever possible. The estimated cost, the duration of the potential delay, the changes in scope and the reduction in quality are in most cases factors that can be estimated and documented in the risk statement and then measured using the standard project management tools (i.e. project plan, budget, statements of work). Rather than detailed impact estimates the Risk Register contains five ratings for impact;

**Catastrophic (A)**
Regulatory/Compliance violations/issues
Inability to validate data
Withdrawal of product manufacturer
Tainted product
Materials breech
Production delays
Technical miscommunications
Security/confidentiality breeches

**Critical (B)**
A non-compliance finding resulting in process, or operational degradation
A security finding requiring immediate corrective action prior to continued operation
Reoccurring violation of any safety regulation resulting in serious injury
Production errors containing regulatory violations that pose direct consequence to the operation

**Moderate (C)**

Security finding requiring a Corrective Action Plan
Production element errors that may pose indirect consequences to the operation

**Minor (D)**
No regulatory action anticipated
No compliance impact anticipated
No evident security threat affected
Minor errors in completed Company policy & procedures
Production errors containing quality system and / or opportunities for improvement

**Negligible (E)**
No regulatory/compliance violation
No security/confidentiality element affected
On time production
Validated experiments
"Clean" product
Properly executed communications

For each of the impact categories the impact assessment should include consideration of the following areas of impact also:
• Cost – This impact is usually estimated as a dollar amount that has a direct impact to the project. However, cost is sometimes estimated and reported as simply additional resources, equipment, etc. This is true whenever these additional resources will not result in a direct financial impact to the project due to the fact the resources are loaned or volunteer, the equipment is currently idle and there is no cost of use, or there are other types of donations that won't impact the project budget. Regardless of whether there is a direct cost, the additional resources should be documented in the risk statement as part of the mitigation cost.
• Scope – Whenever there is the potential that the final product will not be completed as originally envisioned there is a scope impact. Scope impact could be measured as a reduction of the number of studies completed, or not providing a deliverable such as an IND.
• Schedule – It is very important to estimate the schedule impact of a risk event as this often results is the basis for elevating the other impact categories. Schedule delays frequently result in cost increases and may result in a reduction of scope or quality. Schedule delays may or may not impact the critical path of the project and an associated push out of the final end date.
• Performance/Quality – Performance/Quality is frequently overlooked as an impact category and too often a reduction in quality is the preferred choice for mitigation of a risk. "Short cuts" and "low cost replacements" are ways of reducing cost impacts. If not documented appropriately and approved by the project sponsor, mitigation strategies that rely upon a reduction in quality can result in significant disappointment by the stakeholders.

Most risks will be assigned one category, but some might be assigned more than one, or all.

### *2.4 Risk Response*
For each identified risk, a response must be identified. It is the responsibility of the project team to select a risk response for each risk. The project team will need the best possible assessment of the risk and description of the response options in order to select the right response for each risk. The probability of the risk event occurring and the impacts will be the basis for determining the degree to which the actions to mitigate the risk should be taken. One way of evaluating mitigation strategies is to multiply the risk cost times the probability of occurrence. Mitigation

strategies that cost less than risk probability calculation should be given serious consideration. The possible response options are:
• Avoidance – Change the project to avoid the risk. Change scope, objectives, etc.
• Transference – Shift the impact of a risk to a third party (like a subcontractor). It does not eliminate it, it simply shifts responsibility.
• Mitigation – Take steps to reduce the probability and/or impact of a risk. Taking early action, close monitoring, more testing, etc.
• Acceptance – Simply accept that this is a risk. When choosing acceptance as a response the IMPD is stating that given the probability of occurring and the associated impact to the project that results, they are not going to take any actions and will accept the cost, schedule, scope, and quality impacts if the risk event occurs.
• Deferred – A determination of how to address this risk will be addressed at a later time. The results of the risk assessment process are documented in each Risk Statement and summarized in the Risk Register which will be reported on a monthly basis.

### *2.5 Risk Mitigation*

Risk mitigation involves two steps:
• Identifying the various activities, or steps, to reduce the probability and/or impact of an adverse risk.
• Creation of a Contingency Plan to deal with the risk should it occur.

Taking early steps to reduce the probability of an adverse risk occurring may be more effective and less costly than repairing the damage after a risk has occurred. However, some risk mitigation options may simply be too costly in time or money to consider.

Mitigation activities should be documented in the Risk Register, and reviewed on a regular basis. They include:
• Identification of potential failure points for each risk mitigation solution.
• For each failure point, document the event that would raise a “flag” indicating that the event or factor has occurred or reached a critical condition.
• For each failure point, provide alternatives for correcting the failure.

### *2.6 Risk Contingency Planning*

Contingency planning is the act of preparing a plan, or a series of activities, should an adverse risk occur. Having a contingency plan in place forces the project team to think in advance as to a course of action if a risk event takes place.
• Identify the contingency plan tasks (or steps) that can be performed to implement the mitigation strategy.
• Identify the necessary resources such as money, equipment and labor.
• Develop a contingency plan schedule. Since the date the plan will be implemented is unknown, this schedule will be in the format of day 1, day 2, day 3, etc., rather than containing specific start and end dates.
• Define emergency notification and escalation procedures, if appropriate.
• Develop contingency plan training materials, if appropriate.
• Review and update contingency plans if necessary.

• Publish the plan(s) and distribute the plan(s) to management and those directly involved in executing the plan(s).

Contingency may also be reflected in the project budget, as a line item to cover unexpected expenses. The amount to budget for contingency may be limited to just the high probability risks. This is normally determined by estimating the cost if a risk occurs, and multiplying it by the probability. For example, assume a risk is estimated to result in an additional cost of $50,000, and the probability of occurring is 80%. The amount that should be included in the budget for this one item is $40,000.

Associated with a contingency plan, are start triggers and stop triggers. A start trigger is an event that would activate the contingency plan, while a stop trigger is the criteria to resume normal operations. Both should be identified in the Risk Register and can be embedded, example; the stop trigger can be included in the contingency plan field.

### *2.7 Tracking and Reporting*

As project activities are conducted and completed, risk factors and events will be monitored to determine if in fact trigger events have occurred that would indicate the risk is now a reality.

Based on trigger events that have been documented during the risk analysis and mitigation processes, the project team or project managers will have the authority to enact contingency plans as deemed appropriate. Day to day risk mitigation activities will be enacted and directed by the project managers.

Contingency plans that once approved and initiated will be added to the project work plan and be tracked and reported along with all of the other project activities.

Risk management is an ongoing activity that will continue throughout the life of the project. This process includes continued activities of risk identification, risk assessment, planning for newly identified risks, monitoring trigger conditions and contingency plans, and risk reporting on a regular basis. Project status reporting contains a section on risk management, where new risks are presented along with any status changes of existing risks. Some risk attributes, such as probability and impact, could change during the life of a project and this should be reported as well.

### *2.8 Processes to Address Immediate Unforeseen Risks*

The individual identifying the risk will immediately notify the project managers. The individual notified will assess the risk situation.

If required, the project managers will identify a mitigating strategy, and assign resources as necessary.

The project risk manager will document the risk factor and the mitigating strategy.

Appendix A – Example Risk Assessment Matrix

| Probability of Occurrences | | | Catastrophic | Critical | Moderate | Minor | Negligible |
|---|---|---|---|---|---|---|---|
| **Definition** | **Meaning** | **Value** | **(A)** | **(B)** | **(C)** | **(D)** | **(E)** |
| *Frequent* | • Occurs frequently<br>• Will be continuously experienced unless action is taken to change events | **5** | **5A** | **5B** | **5C** | **5D** | **5E** |
| *Likely* | • Occur less frequently if process is corrected<br>• Issues identified with minimal audit activity<br>• Process performance failures evident to trained auditors or regulators | **4** | **4A** | **4B** | **4C** | **4D** | **4E** |
| *Occasional* | • Occurs sporadically<br>• Potential issues discovered during focused review. | **3** | **3A** | **3B** | **3C** | **3D** | **3E** |
| *Seldom* | • Unlikely to occur<br>• Minimal issue identification during focused review | **2** | **2A** | **2B** | **2C** | **2D** | **2E** |
| *Improbable* | • Highly unlikely to occur | **1** | **1A** | **1B** | **1C** | **1D** | **1E** |

Risk Levels:

- Risk is High for codes 5A, 5B, 5C, 4A, 4B, 3A
- Risk is Medium High for codes 5D, 5E, 4C, 3B, 3C, 2A, 2B
- Risk is Medium Low for codes 4D, 4E, 3D, 2C, 1A, 1B
- Risk is Low for codes 3E, 2D, 2E, 1C, 1D, 1E

Appendix B – Example Risk Register

| Risk Register for "Generic Vaccine" | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Gantt** | **WBS** | **Risk** | **Overall Impact** | **Mitigation** | **Contingency** | **CSP Impact** | **Timing / Option** |
| 30 | 1.3.2.4 | FDA does not agree with the characterization results (non-clinical and clinical studies planned, example if FDA requires NHP instead of used animal model) | Occasional + Moderate = 3C | Early and frequent meetings with the FDA prior to study execution. | Update program design with FDA input, modify SOW, obtain BARDA CO, PO, and Management Approval of new SOW, and provide budget request | Additional $400,000 for NHP Model Study<br><br>Addition of ~9 months | Q3, FY11 - BASE |
| | | Lab unable to produce an adequate amount of product to conduct all studies that are currently scheduled | | Subcontract negotiations with CMO to produce product for use in non-clinical studies. | 1. Slow the pace of the studies to accommodate the production availability<br>2. Use available lab product until CRO cGMP product is available | | |
| | | Contract negotiations failure | | Subcontract negotiations with CMO to produce non-GMP product for use in non-clinical studies. | 1. Use available lab product and schedule studies based on available product.<br>2. Transition financial resources from subcontract to expansion of lab for production.<br>3. Transition financial resources to expedite the execution of the cGMP subcontract. | | |
| | | Manufacturing failure | | Complete technical package and assistance available from lab. | 1. Second manufacturing attempt<br>2. Discontinue contract and use lab product<br>3. Discontinue contract and expedite the cGMP manufacturing contract. | | |
| | | Contract negotiations failure with cGMP facility | | Early RFP for evaluation of multiple CMO facilities | Alternate facility RFP | | |
| | | Tech Transfer failure (lack of detailed information) | | Completion of detailed manufacturing technical transfer package and SME provisions during pilot lot preparations | Manufacturing process development, testing, optimization and validation requirement | | |
| | | Study Task 2 (subtask studies task lines 37 and 38) could yield negative results, not meet success criteria | | Preliminary studies conducted with positive results | Alternate study design and potential product redesign | | |
| | | Study Task 1 (subtask studies task lines 45 and 46) could yield negative results, not meet success criteria | | Preliminary studies conducted with positive results | Alternate study design and potential product redesign | | |
| | | Study Task 3 (subtask studies task lines 52, 53, 54, and 55) could yield negative results, not meet success criteria | | Preliminary studies conducted with positive results | Alternate study design and potential product redesign | | |