

Risk Ranking and Filtering

1 Overview

Risk Ranking and Filtering is one of the most common facilitation methods used for Risk Management. This method is also known as “Relative Risk Ranking,” “Risk Indexing,” and “Risk Matrix and Filtering.” Its intent is to provide sharper focus to the critical risks within a system – typically, from a large and complex set of risk scenarios. Risk Ranking and Filtering works by breaking down overall risk into risk components and evaluating those components and their individual contributions to overall risk.

This document presents some guiding principles in the execution of Risk Ranking and Filtering. Successful application of any risk management model requires that tools are used in concert with the quality risk management process. This guide will present the principles of Risk Ranking and Filtering in the context of the accepted Quality Risk Management process consisting of Risk Assessment, Risk Control, Risk Review and Communication.

Definition: *SYSTEM is the subject of a risk assessment and generally includes a process, product, activity, facility or logical system.*

1.1 Usage

Risk Ranking and Filtering:

- ◆ Is most suited to compare and manage a “portfolio” of complex risks
- ◆ Is facilitated through careful breakdown of a risk into constituent risk scenarios with constituent components
- ◆ Requires agreed-upon sets of risk factors and evaluation criteria
- ◆ Provides a means to prioritize and filter individual risks by combining the evaluations of risk components against set criteria into a single risk “score”

<i>Advantages</i>	<i>Disadvantages</i>
+ Accepts a high degree of complexity	- May require significant effort in establishing risk factors and evaluation criteria*
+ Flexible for any type of risk	- May require significant effort in breaking down risk into many components*
+ Scalable to include multiple risk factors	- Results may be difficult to correlate directly with absolute risks
+ May be used with a variety of quantitative and qualitative evaluation criteria	

* Level of effort may or may not be significant and depends on the complexity of the issue under study and the expertise of the persons involved; in some cases the analysis may be relatively easy to accomplish.

1.2 Quality Risk Management Applications

Risk Ranking and Filtering is well-suited for a variety of applications, including:

- ◆ Prioritizing manufacturing sites for inspections / audits
- ◆ Filtering / prioritizing root causes to non-conformances or other systemic concerns

- ◆ Filtering / prioritizing portfolio risks (e.g., new products, technology transfers, engineering efforts, information system implementations).

2 Preliminary Tasks

2.1 Define Risk Question and Scope of System

The first step in any risk management effort is to define the overall risk question. Answering the risk question represents the ultimate goal of the risk assessment. Examples of risk questions include:

- ◆ How often should a manufacturing site be audited to assure GMP compliance?
- ◆ What root causes of non-conformances should we prioritize for remediation?
- ◆ What projects have the greatest probabilities of success?

2.2 Define Scope of System

It is also important that scope be carefully defined. Each of the examples above could gain clarity through definitions of boundaries (e.g., manufacturing sites in a given region, types of non-conformances, new product development projects).

Teams may also further narrow scope through qualitative filtering. For example, the list of new product development projects may be narrowed by filtering out low return-on-investment projects.

Tip: *It is worth the effort to reduce scope as early in the risk assessment as possible to avoid needless work.*

3 Risk Assessment

3.1 Define Head Topics and Subtopics

Once the risk question has been posed, a team of cross-functional experts should define the head topics and subtopics that relate to the risk question. Head topics are broad groupings of risk factors that relate directly to the risk question. Subtopics are factors that directly impact risk associated with a head topic. Figure 1 below depicts these relationships.

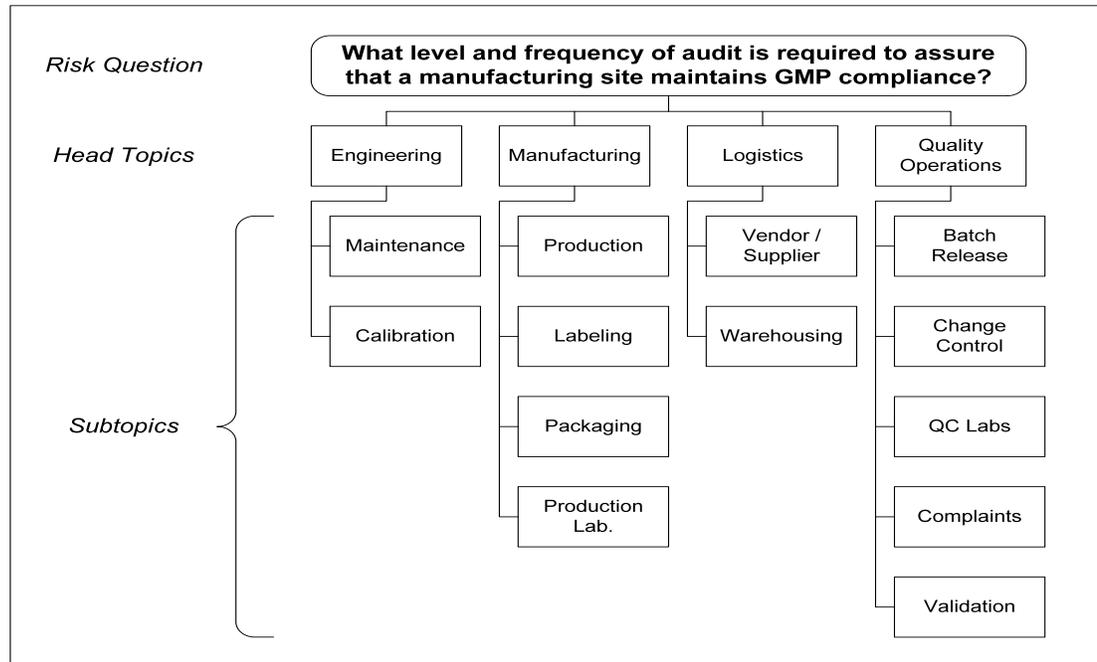


Figure 1 – Sample Risk Question, Head Topics and Subtopics

Head topics and subtopics are the sources of risk that will be evaluated and scored. As such, it is very important that teams gain input and consensus from all stakeholders who “own” the risk. Typical sources for head topics and subtopics for many quality operations are established procedures, regulatory publications, existing activity plans or company measures of performance. In the example of manufacturing site audits, many regulatory and industry publications exist to define structures for audits of regulated organizations. These same structures may be used to develop head topics and subtopics.

It is worth noting that, often, subtopics can be broken down into progressively more detailed risk components. Using the example from Figure 1, “Production” may be broken own further into workcenters, workcenters may be broken down into unit operations and unit operations may be broken down into process steps. While these additional levels provide greater accuracy, they also generally will require greater effort. Teams must make trade-offs between detail and accuracy versus time and resources. ***The appropriate level of detail is a matter of judgment dependent on the expertise and / or quantity of resources available for risk management and the nature of the situation to which it is applied.***

One approach to gauge the appropriate level of detail is to compare the effort required to asses risk at a given level of detail with the resources required to manage and mitigate the risk. Depending on the severity of risk, the effort required to assess risk should be one to many orders of magnitude less than the effort required to manage and mitigate the risk. This rule-of-thumb may help teams decide on an educated

Tip: A good starting point for defining Head Topics and Subtopics is the 7 “M’s”:

- ◆ Materials
- ◆ Manpower
- ◆ Methods
- ◆ Measures
- ◆ Machines
- ◆ Mother Nature
- ◆ Management

estimate of the target amount of time required to assess a given component. The target amount of time should clearly dictate the level of detail.

3.2 Establish Evaluation Criteria

Once the major components of overall risk have been categorized through head topics and subtopics, the evaluation criteria should be established. At a minimum, evaluation criteria should address the *Probability* and *Severity* of risk scenarios presented by the risk components. In effect, the evaluation criteria should bridge the gap between the risk components and the risk question by asking, “How can we gauge the individual contribution of a component to the overall risk?” As with all aspects of risk assessment, the level of detail of evaluation criteria must be balanced with the level of effort required to support evaluations.

3.2.1 Two-Criteria Evaluation

The simplest evaluation model uses probability or likelihood of a harm and the severity or impact of that harm. This typically lends itself to subjective and qualitative evaluations that sacrifice detail for speed and simplicity. The two-criteria model lends itself to a classical “Risk Matrix.” Figure 2 shows a Risk Matrix with evaluation levels for probability and severity as they relate to potential GMP failures at a manufacturing site.

Severity \ Probability	Low	Medium	High
High potential impact to product quality.	Medium Risk	High Risk	High Risk
Medium potential impact to product quality.	Medium Risk	Medium Risk	High Risk
Low potential impact to product quality.	Low Risk	Low Risk	Medium Risk

Figure 2 – Example Two-Factor Risk Matrix

3.2.2 Multi-Factor Evaluation

Depending on the level of detail and degree of objectivity required by the risk assessment, multiple factors may be employed to evaluate risks. Often, additional criteria are developed to clarify or justify overall probability or severity. Overall probability may include criteria that relate to the ability to detect a deviation or defect. The table below shows some clarifying criteria for the example of manufacturing site risk assessment.

<i>Probability</i>	<i>Severity</i>
<ul style="list-style-type: none"> ◆ Amount of time since Last Audit ◆ Occurrence of Non-conformances ◆ Ability to Detect Deviations / Defects ◆ Strength of Quality Controls / Support ◆ Adequacy of Staffing Levels 	<ul style="list-style-type: none"> ◆ Potential for Patient Harm (Unit Dose) ◆ Manufacturing / Distribution Volume ◆ Type of Patient Population ◆ Potential for Employee Harm

Other evaluation criteria may be added to capture needs from other stakeholders or to facilitate risk review. Examples include:

- ◆ Resources Required
- ◆ Costs
- ◆ Site Location
- ◆ Legal Risks
- ◆ Schedule Risks
- ◆ Patient Perception

3.3 Assemble Scoring Models

After evaluation criteria have been identified, a scoring model may be developed to incorporate all criteria to yield a single risk “score.” In general, scoring models use multiplicative or additive means to calculate risk. Very often, criteria are weighted based on the importance of a criteria to the overall risk. Several examples of scoring schemes are presented below.

3.3.1 Risk Matrix

The Risk Matrix presented in Figure 2 is a simple “scoring” model that requires no calculation. The matrix provides an excellent visual model that is easy to understand. This matrix is effective in models where only two criteria are involved.

3.3.2 +/- Scoring Scheme

The +/- scoring scheme provides a numerical range centered on zero for various criteria. The ranges are standardized to reflect that values on one side of zero always represent higher risk and values on the opposite side of zero represent lower risk. Scores assigned to each criterion are added together to yield overall risk. The table below shows a sample scoring model using the +/- scoring scheme.

<i>Criteria</i>	<i>Scoring Range</i>	<i>Actual Score</i>
Potential for Patient Harm	-10 to +10	+5
Level of Non-conformances	-3 to +3	-2
Ability to Detect Deviations	-5 to +5	+3
Adequacy of Staffing Levels	-3 to +3	-1
<i>TOTAL SCORE (Range: -21 to +21)</i>		+5

3.3.3 Multi-Factor Multiplicative Scheme

A multiplicative scheme provides numerical ranges for various criteria and multiplies or divides individual scores to obtain an overall risk score. The table below shows a sample scoring model using the multiplicative scheme.

<i>Criteria</i>	<i>Scoring Range</i>	<i>Actual Score</i>
Potential for Patient Harm	0 to 10	5
Level of Nonconformances	0 to 3	2
Ability to Detect Deviations	0 to 5	1
Adequacy of Staffing Levels	0 to 3	2
<i>TOTAL SCORE (Range: 0 to 450)</i>		20

3.3.4 Weighted Scheme

The weighted scoring scheme assigns a weighting to each criteria and uses a consistent numerical range for each criteria. The individual weighted scores are either averaged or added. Weighting may be defined as a percentage or as a value in a range. The table below shows a sample scoring model using the weighted scheme.

<i>Criteria</i>	<i>Actual Score</i>	<i>Weight</i>	<i>Weighted Score</i>
Potential for Patient Harm	5	60%	3
Level of Non-conformances	6	15%	0.9
Ability to Detect Deviations	2	25%	0.5
Adequacy of Staffing Levels	5	10%	0.5
<i>TOTAL SCORE (1 to 10)</i>			4.9

3.4 Score Risk Components

3.4.1 Scoring

Once a model or models have been agreed to by the team and, in concept, by risk “owners,” the process of scoring may commence. Often, a model will be piloted with a limited number of examples to validate the model and to facilitate review and buy-in from stakeholders. The extent to which the criteria reflect tracked data, the quicker and less subjective the scoring sessions will be. In cases where criteria are subjective in nature, team rules should be developed to standardize how consensus is reached.

Tip: Providing clarifying detail to your scores will help facilitate scoring and ensure that the model incorporates concerns from all team members

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3.4.2 Subtopic Filtering

In some cases, a simple Risk Matrix may be used to further narrow the focus of a study. For example, qualitative assessment of the subtopics in Figure 1 using a Risk Matrix might yield results as shown in Figure 3.

Severity \ Probability	Low	Medium	High
High potential impact to product quality.	Calibration	Production Labeling	Release QC Lab.
Medium potential impact to product quality.	Supplier	Product Lab. Change Ctrl.	Validation Complaints Packaging
Low potential impact to product quality.	Warehousing	Maintenance	-

Figure 3 – Example Risk Matrix used to Filter Subtopics

The qualitative assessment shows that Warehousing and Maintenance are two subtopics that pose low risk. The team may be able to use this preliminary assessment to rationalize reduction in scope by eliminating those risk subtopics from the assessment.

3.4.3 Ranking

Completed scores for all in-scope systems will yield a simple, numerical ranking. This allows ranking and filtering in a variety of ways. The table below provides some examples of the options to facilitate risk review through ranking.

Ranking Category	Example Use
◆ Systems under Study (Sites, Processes, Products, etc.)	◆ Overall Risk Scores to focus effort on high risk systems
◆ Head Topics	◆ Cumulative scores for Head Topics to focus on Departments or Workcenters
◆ Subtopics	◆ Scores for Subtopics across many systems to identify areas where competencies or controls are needed
◆ Evaluation Criteria	◆ Scores for evaluation criteria across many systems to prioritize systemic concerns

4 Risk Control

4.1 Filtering

Filtering involves focusing the scope of risk management by selectively reducing risk control for low-risk systems and increasing risk control for high-risk systems. Effectively filtering systems requires a consensus definition of action thresholds. Using the example of auditing manufacturing sites, a simple set of action thresholds might look as follows.

<i>Overall Site Risk Score</i>	<i>Action</i>
Greater than 7	Audit performed annually
3 – 7, inclusive	Audit performed once every two (2) years
Less than 3	Internal Audit not needed

Filtering can also result in reduced scope through elimination of low-risk criteria from risk control. Assessment of a portfolio of potential new products may be streamlined by eliminating products that are deemed to have higher risk than an established value.

4.2 Evaluate Alternatives

In addition to providing greater focus to high-risk areas, Risk Ranking and Filtering can also provide a means to evaluate mitigation options. By identifying possible risk mitigation options and re-evaluating the results through the scoring model, teams can identify the mitigation options that will have the most beneficial impact to overall risk.

5 Risk Review

5.1 Re-score

It is important to re-score systems as mitigation options are implemented and/or as factors change. It is also important to gather cross-system scores for subtopics and evaluation criteria to continuously assess whether or not the right criteria are being evaluated.

5.2 Operational Feedback

On a long-term basis, operational feedback should confirm that the assessment and control steps are adequately addressing the risk question. If this is not the case, it may be necessary to review all assumptions. Feedback should correspond to ensuring that assumptions made about the level of residual risks are still valid. Residual risks are risks that are expected to remain after risk control strategies have been exercised. It is also important to note that new risks may arise from risk control practices. Sometimes risks that were not originally identified or may have been filtered out during the initial risk assessment can become aggravating factors due to the implementation of risk control measures.

6 Risk Communication

Risk Ranking and Filtering is a powerful communication tool. The output of the tool should always be presented at a level of detail appropriate for the various stakeholders. This is important not just for presenting results, but also for obtaining early buy-in on the approach.

In cases where the Risk Ranking and Filtering approach is used as the basis for a “GxP” decision or some other regulated authorization, the approach should be documented in a Standard Operating Procedure. It may not be necessary to include detailed scoring steps or algorithms in the procedure, but they should be documented in a controlled report. Updates to the portfolio should also be controlled.