

Standard Operating Procedure

Title: Quality Risk Management Techniques

Department	Quality Management	Document no	QMS-135
Title	Quality Risk Management Techniques		
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1.0 Purpose

This SOP defines the approach to Quality Risk Management (QRM) of a GMP site and gives practical examples for tools which may be used to facilitate the process and to aid personnel performing the assessment.

2.0 Scope

Applicable to any process at a GMP site which requires a Risk Management approach. The applicability of QRM methodology and the corresponding level of documentation may vary depending on the individual circumstances. Examples of circumstances to which QRM may be applied in conjunction with existing SOPs include but are not limited to:

- Identification and evaluation of the potential quality and compliance impact of product and/or process deviations, including the impact across multiple and/or divergent markets.
- Evaluation and determination of the scope of [internal and external quality assessments](#) such as quality concern investigation systems, complaint handling, out-of-specification investigation, quality control testing etc.
- Evaluation of design of facilities, equipment, materials of construction, utilities and Preventative Maintenance (PM) programs.
- Determination of the scope and extent of commissioning, qualification and validation activities for facilities, equipment and production processes.
- Risk tools for engineering project evaluation and validation projects are not included in this procedure. References to those tools are made in Appendix 6 and 7 of this procedure.

3.0 Responsibility

The extent to which QRM is used and documented shall be consistent with the complexity and/or criticality of the issue to be addressed.

Site Quality Review Team has oversight responsibilities for all QRM activities.

Department Heads, Process and System Owners and Project Leaders are responsible for ensuring that risks to quality, compliance and other site functions are considered, understood and managed to an appropriate level within the GMP site.

They must ensure that a suitable Quality Risk Management process is implemented and that appropriate resources with the necessary competence are involved. They must also ensure the involvement of all stakeholders.

Department Heads, Process and System Owners and Project Leaders are responsible for ensuring that there is a process for reviewing and approving documented quality risk assessments and that appropriate records are retained.

QA Associates and Laboratory Supervisors involved in deviation, complaint and OOS investigation should follow the risk tool "Risk Ranking and Filtering – Method 1" as demonstrated in appendix 1 for a quick turn around in decision making.

QA Associate, Production and Engineering supervisors or anyone who is involved in manufacturing and [regulatory change management](#), in-house rework, supplier quality audit and other analysis of

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4.2 Initiating Quality Risk Management (QRM) Process

- 4.2.1 Risks are multi-dimensional and a shared understanding is a prerequisite for the success of any risk management process. The initiation phase of the QRM process involves understanding the risk event by defining and agreeing the context, the scope and the tolerability criteria for the quality risk assessment, together with any underlying assumptions.
- 4.2.2 Initiation of QRM process should involve all the stakeholders. All the relevant information is assembled and shared, any gaps are identified and analysis tools are selected.
- 4.2.3 The scope of the quality risk assessment must be clearly defined both in business and technical terms. The scope should clearly establish the boundaries of the process, system, project or activity being assessed and any inherent assumptions that are made. It should consider possible interactions outside the boundary and their potential impacts.
- 4.2.4 The risk assessment process evaluates the tolerability of the identified risks against some defined criteria to determine whether any mitigating actions are required. A common approach to establishing criteria is to divide risks into five categories:
 - A very high risk band where adverse risks are intolerable whatever benefits the activity might bring and risk reduction measures are essential, whatever the cost.
 - A high risk band where the risk would not be generally acceptable unless there were very significant benefits and where reduction measures are expected as the norm.
 - A medium risk band area where costs and benefits are taken into account and opportunities are balanced against potential adverse consequences.
 - A low risk band where positive or negative risks are small and where potential benefits can only be justified at minimum cost.
 - A very low risk band where positive or negative risks are negligible or so small that no risk treatment measures are necessary.
- 4.2.5 A team comprising individuals with the education, training and experience relevant to the issue or situation under evaluation should undertake the risk assessment process. A subject matter expert (SME) should also be consulted or involved to ensure that best practice is followed.
- 4.2.6 Each Risk Assessment is reviewed and approved by appropriate department heads and stakeholders. Consideration should be given to consultation of the EHS team. Quality Assurance Manager or a delegate should review and approve all compliance related Risk Assessments.
- 4.2.7 **Risk Register**
 - For traceability purposes, a reference number is assigned to each Risk Assessment by Quality Assurance personnel.
 - Risk Assessment conducted for deviation, complaint or out of specification investigations do not need a template to follow due to their adherence with the investigation. An entry to Risk Register is also not required.
 - Risk Assessment conducted for calibration interval; supplier assessment and external supplier audit frequency; engineering and validation projects do not need a reference number. Hence, an entry to Risk Register is also not required.
 - All initiated Risk Assessments using the tool “Risk Ranking and Filtering – Method 2” are logged into the Risk Register. The hard copy register is located in the “Risk Assessment and Quality Investigation” folder kept in QA office.

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4.5 Risk Control

The number of tools which may be used to document and assess risk are many and varied and an appropriate tool should be used for the individual circumstances. These tools are described in brief the table below. The formal risk assessment steps and methodologies are described in appropriate **Appendices**.

4.5.1 Risk control describes the actions taken to deal with the identified quality risks and the acceptance of any residual quality risks. Risk control must address the following questions:

- Is the risk acceptable without further action?
- What can be done to reduce, control or eliminate risks.
- What is the appropriate balance among benefits, risks and resources?
- Are new risks introduced as a result of the identified risks being controlled?

4.5.2 **Risk Reduction**

Risk Reduction focuses on processes for mitigation or avoidance of quality risk when the risk exceeds an acceptable level. Risk reduction includes:

- Actions taken to mitigate the severity and probability of risk; or
- Processes or methods that improve the ability to detect risk Implementation of risk reduction measures may introduce new risks into the system or increase the significance of other existing risks. Therefore, the risk assessment must be repeated to identify and evaluate any possible change in the risk profile.

4.5.3 **Risk Acceptance**

Risk Acceptance is a decision to accept risk. The risk acceptance decision shall be:

- A decision to accept known, residual risk;
- A decision to accept residual risks, which are partially assessed, based upon limited information; or
- A combination of these circumstances.

4.5.4 Optimal QRM strategy is designed to reduce risk to an agreed upon acceptable level. This acceptable level will depend on many parameters, shall be decided on a case-by-case basis and managed through identified mitigation tasks.

4.6 Documentation and Communication of the QRM outcome / result to stakeholders

4.6.1 The results of the QRM process must be communicated to the relevant stakeholders, including management and those operating the process or system who may be affected by those results. This requires that each step of the risk management process be documented at an appropriate level. The purpose of the output from the risk management process is:

- To share and communicate information about the risks and how they are controlled.
- To obtain the appropriate approval of the decisions taken.
- To demonstrate to stakeholders that there has been a properly conducted systematic approach.
- To provide a record of the risks that enables decisions to be reviewed and the process to be audited.
- To facilitate ongoing monitoring and review and to sustain the process.

4.6.2 The output from the risk assessment must specify a risk owner i.e. a person responsible for ensuring that any actions are entered into CAPA database located in G:\QA\CAPA Database and all identified corrective actions are implemented in full and that the risk is managed.

4.7 Risk Review

4.7.1 QRM is an iterative process that must be sustained throughout the life cycle of the product, A

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Appendix 1: Risk Ranking and Filtering – Method 1

Applicable to Risk Events:	Quality concern Investigations such as Deviation, Complaint, Out-of-Specification . The tool can also be used for any other quality and compliance issues where a risk assessment is deemed to be necessary
Risk Assessment Tool:	Risk Ranking and Filtering – Method 1
Entry on Risk Registry:	Not Applicable
Assessment Frequency:	Each time a Deviation, Complaint or OOS investigation is processed
Reference SOPs:	QMS-035 Deviation Management System QMS-055 Product Complaint Procedure LAB-055 Laboratory Out Of Specification Investigation Procedure
Template Location:	#:\QA\RISK ASSESSMENTS\Risk Assessment Templates

Following risk matrix can be used effectively to assess risks derived from a quality incident such as Deviation, Complaint or Out of Specification investigation. The matrix is based on two variables. On the vertical axis the variable is the impact of risk event on the product quality and GMP. The horizontal axis represents the probability of recurrence of risk event and delectability of the event if occur again.

Risk Matrix:

Impact on Product Quality and GMP	4									
	3							Level3		
	2					Level2				
	1									
	0		Level1							
		0	1	2	3	4	5	6	7	8

Probability = Probability of recurrence + Probability of detection

Risk Levels

For the ease of assessing risk any deviation / complaint / OOS event can be classified into one of the three levels 1, 2 & 3 based on the magnitude and seriousness of an event.

Level 3: Critical (High Risk, shaded by red colour)

A risk event that might creates immediate and [significant risk to product quality](#), user safety or data integrity or a combination/repetition of major deficiencies that indicate a critical failure of systems

Level 2: Serious (Medium to high Risk, shaded by yellow colour)

A risk event that might potentially creates significant risk to product quality, user safety or data integrity or could potentially result in significant observations from a regulatory agency or a combination / repetition of "other" deficiencies that indicate a failure of system(s).

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Appendix 2: Risk Ranking and Filtering – Method 2

Applicable to Risk Events:	Risk Assessment as part of Change Management . The tool can also be used for analysing a manufacturing process to identify high risk steps / critical parameters.
Risk Assessment Tool:	Risk Ranking and Filtering – Method 2
Entry on Risk Registry:	Next available number taken from the Risk Registry
Assessment Frequency:	Varied. As required.
Reference SOPs:	QMS-065 Manufacturing Rework Procedure QMS-125 Change Management System
Template Location:	# : \QA\RISK ASSESSMENTS\Risk Assessment Templates

Risk Overview:

Risk Event Information	
Risk Title:	<i>[Enter a short title of the risk]</i>
Issue/Event:	<i>[Detail the issue / event that necessitates this assessment]</i>
Risk Question:	<i>[Formulate the most appropriate risk question for which this assessment is justified. For example "what are the potential risks associated with changing the frequency of weighing device performance verification testing from the current schedule (e.g. daily) to an alternate, longer period"]</i>
Scope:	<i>[Enter the scope of this assessment]</i>

Facts/Arguments Which Form the Basis of this Assessment:

[Enter all background information and arguments associated with this risk event]

Severity Ranking Scale:

Rank	Description	
	User Safety / Product quality	Regulatory Compliance
1	No Adverse Event / No quality impact	No Action Taken
2	Reversible Minor Health Issue / minor quality impact	Discussion Point
3	Reversible Major Health Issue / difficult to maintain quality	Observation / Mandated Recall
4	Permanent Health Issue / critical quality compromised	Warning Letter
5	Death / escalate to recall	Consent Decree

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Risk Analysis:

Function	Sub Function/s	Assessment of Risk			Mitigation Measures
		Severity (S)	Probability (P)	Risk Score (S*P)	
[Enter the broad area of function / system that appears to be a risk]	[Divide each function into several related sub functions that is identified to be a risk and must be assessed]	[Enter severity score taken from the severity rank scale]	[Enter probability score taken from the probability rank scale]	[Multiply severity and probability score to get risk score]	[List the possible corrective and preventive actions in order to mitigate the risk factor]
	Rational: [Explain the rational for scoring decision]				

Actions to be Undertaken:

[Enter the list of actions identified during assessment]

Actions to be undertaken	Responsible person	Due date

Summary:

[Enter a brief summary of the assessment. Enter the rationales for all identified risk factors which are assessed and actions taken as mitigation measures]

Authorization:

	Name	Sign	Date
Completed by:			
Approved by:			

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Risk Assessment Based on FMEA

Probability of Instrument Failure (MTBF = mean time between failures)				
	Risk Level →	Low	Medium	High
	Numeric Ranking →	(1)	(2)	(3)
History	This instrument (The intent is to use history as an indicator of probability)	Have more than 2 years of records, history shows low rate of calibration OOT (Out of tolerance) (MTBF >24 months)	Have less than 2 years of records, history shows low rate of Calibration OOT	Have no historical records or records show MTBF <24 months
	Identical Instrument (make and model)	Have 3 or more identical instruments (MTBF > 24 months)	Have 1 or 2 identical instruments (MTBF > 24 months)	Have no identical instruments to benchmark
	Similar Instruments (The concept is to determine if there are instruments of similar design and functionality utilized in the intended environment that may yield performance data for use as a predictor, i.e. show low risk based on demonstrated reliability)	Have several (e.g.10) similar (in type, technology, range) instruments in similar environments (MTBF > 24 months)	Have a few similar instruments in similar environments (MTBF > 24 months)	Have no similar instruments in similar environments
Environment	Temperature and Humidity (both operating and storage conditions)	Temperature and humidity are stable and are within manufacturer's recommended range	Temperature and humidity vary, but always stay within manufacturer's range	Temperature and humidity are not known or may exceed manufacturer's range
	Power line / electrical Disturbances	Instrument is non-electric	Instrument is battery powered or well-filtered and protected from power disturbances and lighting	Instrument is located in an electrically "noisy environment or may be susceptible to sags, surges, spikes, and severe electro-magnetic interference (EMI)
	Dust / Dirt / Chemical Wash down	Instrument is located in a clean, dry, area that does not get washed down	Instrument is in a protected cabinet, or removed for area wash down. light dust and no chemical exposure	Instrument is in an exposed, dirty environment subjected to frequent wash downs or chemical exposure
	Vibration and shock	Instrument is permanently mounted in a stable environment	Instrument is portable and moved frequently or may be exposed to occasional vibration or shock	Instrument is subjected to severe shock and vibration
	Physical Damage	Instrument is kept in a segregated or protected area	Instrument is located in a moderate traffic area and potentially susceptible to	Instrument is located in a high traffic area and susceptible to

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Numerical Ranking	Probability of Risk (Table I) Criteria used: Instrument history, environment, range of use, & age	Severity of Risk (Table II) Criteria used: Impact on human safety, environmental, GMP / Product, production, cost, energy	Detectability of Risk (Table III) Criteria used: Automatic / Manual operation, Operator verification	Maximum Risk Score
1	Low	Low	Low	1
2	Medium	Medium	Medium	8
3	High	High	High	27

Risk illustration:

To assign the appropriate level of risk, a simple Low, Medium, High model with a corresponding numerical designation of 1, 2 and 3 will be used. Each criterion (probability, severity, detectability) can therefore have a numerical rating of 1, 2 or 3 that will determine the risk score. The risk score for each failure mode is obtained by multiplying the individual scores for each criterion. **For example:**

$$\text{Probability} \times \text{Severity} \times \text{Detectability} = \text{Risk Score}$$

Recommended frequency for Instrument Calibration Intervals change – The frequency selected will all be relative to the risk score resulting from the assessment.

Low score will justify broader or less frequent calibration verification from the established guidance table.

High risk score will require adherence to the calibration table or perhaps Team review to tighter than published guidance.

Example only: Change of calibration frequency period based on risk score

Risk Score Examples	Overall Risk Description	Suggested Calibration Frequency Interval change
01	Negligible	Consider extending calibration interval up to 36 months
02	Very Low	Consider extending calibration interval up to 24 months
03-06	Low	Consider extending the calibration interval x 2 (up to a maximum of 24 months) (i.e. 6 months → 12 months)
08	Medium	Consider extending the calibration interval by a factor of 1.2x to 1.5x (up to a maximum of 18 months) (i.e. 3 months → 4 months. 12 months → 18 months)
09-12	Med / High	Maintain the same calibration interval. (re-evaluate the risk score in 12 months)
18	High	Consider shortening the calibration interval by a factor of x 0.5 (i.e. 12 months → 6 months)
27	Very high	Consider shortening the calibration interval to a very short period (i.e. 3 months) and consider re-engineering the instrument system to reduce the risk score

Examples of Instrument Calibration Interval Change Request

The sample risk assessments below are to serve as “examples” only and used as illustration of the approach. Actual situation requires a team assessment and review of site coordinator.

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Example: #3

Instrument: Humidity Transmitter

Application: Ambient humidity sensor in a conditioned room. ***This transmitter is an alarm point only.*** The Building Management System (BMS) controls the temperature and humidity and a chart recorder records them, providing very easy detect ability of failure.

Basis for change:

Instrument Type	Instrument class. Critical Y or N	Associated System	Probability of Occurrence	Severity of Failure	Detect ability of Failure	Risk Score (Failure Mode)	Recommended Calibration Period (months) from table	Basis for change calibration interval: Since it is low probability and easily detected, consider increasing the calibration interval to 24 months.
Humidity Transmitter	Y	Packout Room	1	3	1	3 (Low)	12 months	24 months

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	<ul style="list-style-type: none"> Does the supplier have experience in supplying the pharmaceutical industry?
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Threshold interpretation

Risk Level	Total Quality Risk Score
High Risk	≥ 64
Medium Risk	Between 37 and 64
Low Risk	≤ 37

Table 2: Supplier Quality Risk Assessment Form

Supplier Name:	Supplier Location:
Material/s Purchased:	Prepared By: Date:

Comments:

Instructions: Read the questions in sequential order and determine the first question that can be answered with a 'yes'. Enter the corresponding quality risk value in the Quality Risk Score row. After completing all five sections, sum the individual Quality Risk Scores to calculate the Total Quality Risk Score. Complete the Supplier Quality Risk Evaluation by comparing the Total Quality Risk Score to the high, medium and low risk level ranges to determine the Supplier Quality Risk Level

	Answer
1. Intended Purpose	
a. Is the material a finished Drug Product, Active Pharmaceutical Ingredient (API), excipient for a parenteral product or does it have specific tiled regulatory requirements?	If yes. High Risk. enter 5
b. Is the material a non-sterile excipient, primary packaging, regulated printed packaging, registered starting material or reagent contributing to significant molecule structure?	If yes. Medium Risk. enter 2.5

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h.	Is there an Acceptable Site quality audit rating with unresolved Critical and Major Findings allowed?	
OR		
i.	Is there inconsistent history of responsiveness to Site requests?	
j.	Does the supplier Quality System have an established history of being consistently effective?	If yes. Low Risk, enter 2.5
AND		
k.	Is there an Acceptable Site quality audit rating with No unresolved Critical and Major Findings?	
Quality Risk Score: <i>(i.e. medium / high / low)</i>		
4. Quality Knowledge		
a.	Is the supplier not willing to accept Site terms in a Quality Agreement where required?	If yes. High Risk. enter 25
OR		
b.	Are there significant deviation(s) from an established Quality Agreement?	
OR		
c.	Over the past four years or six lots have there been repeat non-conformances detected by Site that the Supplier should have detected?	
OR		If yes, Medium Risk, enter 12.5
d.	If in a regulated industry, is the supplier known to have outstanding, significant adverse regulatory events, impacting the site of interest?	
OR		
e.	Does the supplier have no background in supplying the pharmaceutical industry?	
f.	Over the past four years or six lots has there been no more than one non conformance detected by Site that should have been detected by the supplier?	
OR		If Low Risk. enter 2.5
g.	If in a regulated industry, does the supplier have no demonstrated regulatory audit performance and cannot therefore be readily assessed against industry /regulatory standards?	
h.	If in a regulated industry, does the supplier have a reliable history of good regulatory compliance and acceptable audit outcomes?	
OR		
i.	Is the supplier a well-respected supplier to the pharmaceutical industry?	
Quality Risk Score: <i>(i.e. medium / high / low)</i>		
5. Non-conformance detected by Site		
a.	Are there non-conformances detected by the end user that should have been detected by the supplier?	If yes. High Risk enter 25
OR		
b.	For Drug Products. API and excipients, is there no specific ID or potency testing performed by Site (i.e. testing for impurities, identification testing using methods with	

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Appendix 5: Risk Assessment Process to Establish External Supplier Quality Audit Frequency

Applicable to Risk Events:	Establishing Ext. Supplier Quality Audit Frequency
Risk Assessment Tool:	Risk Ranking and Filtering
Entry on Risk Registry:	Yes
Assessment Frequency:	Assessed individually for each Supplier
Reference SOPs:	QMS-080 GMP Audit Procedure

Template Location: # :QA\RISK ASSESSMENTS\Risk Assessment Templates

Risk Assessment Process

1. **Collect and organize relevant information.**

The following represents suggested data to gather prior to performing the assessment:

- Listing of material suppliers, materials sourced and where used
- Prior audit records
- Performance data related to material (lots rejected/finished product issues related to material)
- Correspondences with supplier related to changes in operation or process Regulatory inspection records for material supplier, if available.

2. **Identify the Risk Question**

The Quality Risk Management (QRM) process is guided by the establishment of a risk question that identifies the scope, sought outcome and areas of focus (risk factors) for the assessment. For example:
"How should supplier audits be prioritized and scheduled as a function of their risks to product safety, quality and market share (business)"

OR

"What are the patients, product quality and business risks associated with materials / components /services used in the production of medicinal products in relation to their supplier's audits and how could these audits be prioritized and scheduled to minimize such risks?"

3. **Determine the Potential Risk Factors and related Hazards.**

In order to determine the potential risk factors and related hazards, one might need to answer:

- What are the risk factors* (e.g. patient safety, regulatory compliance and business) from which each scenario must be viewed to ensure that all potential or related hazards are identified?
 - What are the sources of potential harm related to each risk factor?
 - Could the material sourced have a potential impact on patient safety?
 - Could the material sourced have a potential impact on product quality and conformance to registered specifications?
 - Could the supply of the material have an adverse impact on the business?
- What are the related hazards?*
 For the purpose of prioritizing the external supplier audit schedule, each [material supplier](#) represents a potential risk to the finished product(s) in which the material(s) sourced are used, therefore, all material suppliers can be viewed as hazards for the purpose of this assessment.

Table 1: Examples of Risk Factors and Severity (this list is not all inclusive)

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Table 3: Examples of Severity Scale

Severity			Scale
General	Quality/Regulatory compliance	Business	
Type of material/ component/ service	Minor excipients (<20%)	The materials have 0% to 50% production impact	1
	Tertiary Packaging		
	Major excipients (20%)	The materials have 50% to 80% production impact	3
	Secondary packaging		
	API/critical excipients (e.g. antimicrobial agent/preservative)	The materials have 80% to 100% production impact	5
	Sterility Assurance (HEPA Certification, sterilizing filters, irradiation, etc.)		
	Labelling/Inserts		
	Primary packaging (product contact)		

b. Probability

Probability is a measure of the likelihood for a “harm” to occur. The probability as it relates to materials’ suppliers could be based the following questions:

- What is the historical performance of an individual material supplier (hazard)? Since the last audit, what has the material supplier’s performance been?
- How many material suppliers’ lots have failed to meet specifications upon receipt or have been linked to nonconforming finished product (Product Quality)?
- How often have there been supply issues where material that meets specifications was not available to meet the production schedule demands (Business)?
- What is the material supplier’s regulatory inspection history and last audit outcome?

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For example, the supplier of HDPE bottles, Ajax, has a probability score of 3, taking into account that this supplier has been inspected by Site, there have been as many as 7 observations and the observations have not been responded to and/or responses have not been accepted by Site as indicated by Table 4.

In addition, the HDPE bottles are used as primary packaging components which correlates with a severity score of 5 as indicated in Table 3. Table 5 summarizes examples of the executed assessment for the Ajax supplier.

To continue with the risk assessment, all material suppliers shown in Site Supplier List will be assessed as previously indicated. Table 6 summarizes examples in how the Suppliers Quality Audit Prioritization and Frequencies can be reported.

Table 5: Examples of Assessment of Probability and Severity

Risk Factor		Potential Hazard		Risk Analysis		Risk Evaluation
		Name	Material /Service	Severity (S)	Probability (P)	Risk Score (S*P)
Patient	Adverse Reaction	Ajax	HDPE Bottles	3	4	12 (Medium)
	Lack of Efficacy	ABC	IFC's	2	1	2 (Low)
Compliance	Non conformance with filed product formulation	Acme	Labels	5	5	25 (High)

Table 6: Examples of Ext. Supplier Audit Prioritization and Frequency Report

Hazard (Supplier's List)		Risk Assessment Scale Results				Risk Control
Name	Material/ Service	Severity (S)	Probability (P)	Total Risk (S*P)	Risk Category	Proposed Audit Frequency
Ajax	HDPE Bottles	3	4	12	Medium	Every 3 years
ABC	IFC's	2	1	2	Low	Every 5 years
Acme	Labels	5	5	25	High	Annual
Astro	Boric acid	1	1	1	Low	Every 5 years
Steritech	Irradiation	5	1	5	Medium	Every 3 years