

Guidance Number: 79

Table 2: Examples of Risk Factors and Severity (this list is not all inclusive)

Hazard	RISK FACTOR	SEVERITY	
		General /Specific	
Material Supplier	Quality/ Regulatory compliance	a. Type of material/component/service	
		1) APIs	
		2) Labeling/Inserts	
		3) Raw Materials (e.g., Excipients, Processing Aids, Solvents, Gases, Lubricants, Cleaning Agents)	
		4) Packaging Materials, Primary and Secondary	
		5) Service providers such as contract laboratories, metrology, calibration, HEPA certification, and gamma irradiation services	
		6) Distributors/Warehouses/Brokers	
	Business	b. Number of products involved/volume of material involved (quantity and/or cost)	

Table 3: Example of Severity Scale

SEVERITY			SCALE
General	Quality/Regulatory	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.)		
	Labeling/Inserts		
	Primary packaging (product contact)		

Table 4: Examples of Risk Factors and Probability (this list is not all inclusive)

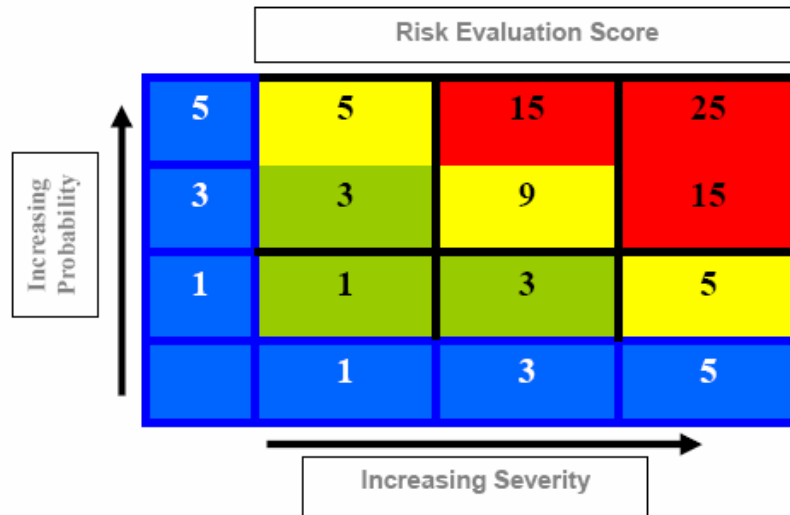
Hazard	RISK FACTOR	PROBABILITY
Material Supplier	Quality/ Regulatory compliance	a. cGMP/regulatory compliance supplier history
		b. Licenses, inspection and audit outcomes
		c. Certifications and/or accreditations
	Quality/ Regulatory compliance	d. Quality audit type and number of findings, open/closed
	Business	a. Volume (lots consumed per years or number of times service used per year)
		b. Length of time supplier has been used for material/service
c. Service history delays, complaints, deliveries on time and/or scheduled		

Table 5: Example of Probability Scale

Hazard	Risk	PROBABILITY		SCALE
		Quality/Regulatory	Business	
Material Supplier	General			
	cGMP/ regulatory compliance supplier history	Supplier has been inspected within the last six months.	The materials have been in stock	1
		<ul style="list-style-type: none"> There have been few or no observations. 		
		<ul style="list-style-type: none"> Observations have been responded to and/or responses have been accepted 		
		Supplier has been inspected	The materials have been short stocked	3
		<ul style="list-style-type: none"> There have been some (more than 5) Mandatory Action Required observations. 		
		<ul style="list-style-type: none"> Observations have not been responded to and/or responses have not been accepted 		
		Supplier has been inspected	The materials have been back ordered	5
		There have been many (more than 10) Mandatory Action Required observations		
		<ul style="list-style-type: none"> Observations have not been responded to and/or responses have not been accepted 		
<ul style="list-style-type: none"> Supplier has been issued a warning letter or has been placed under a consent decree. 				
OR Supplier has never been inspected				

Mandatory action required observations are Major and Critical Findings

Figure 1: Example of Risk Evaluation Matrix



Threshold Interpretation: need to include how threshold was determined (i.e. rationale)



Scale 1-4 represents: LOW risk
Audit every 5 years



Scale 5-14 represents: MEDIUM risk (Action Threshold)
Audit every 3 years



Scale 15-25 represents: HIGH risk
Audit every year

Table 6: Example 2 of Assessment of Probability and Severity

Risk Factor		Potential Hazards		Risk Analysis		Risk Evaluation
		Name	Material/Service	Severity (S)	Probability (P)	Risk Score (S x P)
Patient	Adverse Reaction	Ajax	LDPE Bottles	3	4	12 (Medium)
	Lack of Efficacy	ABC	IFC's	2	1	2 (Low)
Compliance	Non-conformance with filed product formulation	Acme	Labels	6	5	30 (High)

Table 7: Example of Suppliers EQAA Prioritization and Frequencies

Hazard (Supplier's List)		Risk Assessment Scale Results				Risk Control
Name	Material/ Service	Probability (P)	Severity (S)	Total Risk (PxS)	Risk Category	Proposed Audit Frequency
Ajax	LDPE Bottles	3	5	15	High	Annual
ABC	IFC's	1	3	3	Low	Every 5 years
Acme	Labels	1	5	5	Medium	Every 3 years
Astro	Boric acid	1	1	1	Low	Every 5 years
Zap It	Irradiation	1	5	5	Medium	Every 3 years