Table 5: Example of Probability Scale

Hazard	Risk	PROBABILITY		SCALE
	General	Quality/Regulatory	Business	
Material Supplier	cGMP/ regulatory compliance supplier history	Supplier has been inspected within the last six months. • There have been few or no observations. • Observations have been responded to and/or responses have been accepted	The materials have been in stock	1
		Supplier has been inspected • There have been some (more than 5) Mandatory Action Required observations. • Observations have not been responded to and/or responses have not been accepted	The materials have been short stocked	3
		Supplier has been inspected There have been many (more than 10) Mandatory Action Required observations • Observations have not been responded to and/or responses have not been accepted • Supplier has been issued a warning letter or has been placed under a consent decree. OR Supplier has never been inspected	The materials have been back ordered	5

Mandatory action required observations are Major and Critical Findings

6. Define the Risk Evaluation Matrix and Determine the Action Thresholds
Prior to completing the risk assessment using the scales established for severity and, probability an evaluation matrix must be constructed to aid in evaluation of the total risk scores (severity x probability) derived for each hazard.

The matrix is constructed by populating the y-axis with the number range from the probability scale in ascending order (bottom to top). The x-axis is populated with the severity scale, again, in ascending order (left to right). The cells of the resulting matrix are then populated by multiplying the intersecting values from the y-and x-axes. The resulting matrix should contain all possible total risk scores.

The next step is to establish the thresholds. For the purposes of establishing a risk

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