- "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. Assess Method to be Used
There are several simple to intermediate QRM tools that could be applied to this assessment; for this example we are using Risk Ranking and Filtering (RRF). In using this simple tool we will limit the assessment to a review of the severity and probability associated with each hazard.

4. Determine the Potential Risk Factors and related Hazards
In order to determine the potential risk factors and related hazards, one might need to answer:

   a. 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?

   b. What are the related hazards?
      For the purpose of prioritizing the EQAA 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.

5. Define the Risk Assessment Scales for Probability and Severity
In order to perform an assessment of the risk posed by each hazard (material supplier) the probability and severity characteristic of each hazard must be defined.
Severity and probability scales must first be defined by determining the range of possibilities and differentiations for each as indicated below:

   a. **Severity:** Severity is the measure of the consequence (impact) that a defect or failure borne of the material supplier (hazard) may have on your operation/products.

      Assessing the severity requires an understanding of how the material supplier might impact the risk factor. For example, when looking at material suppliers and their potential impact on finished product quality, an API supplier may be assigned a higher severity scale than a tertiary packaging supplier since the API may impact potency or dissolution of the

