Guidance 083 Quality Risk Management (QRM) application to identify deviations vs. events
- Risk to patient

The quality risk management approach as applied to the identification of deviations vs. events
illustrated in this guidance not only identifies the different risk factors to consider when performing the evaluation but also demonstrates a simple tool (depicted in tabular format) for determining how to group potential risks into low, moderate, or high categories. For the purpose of this evaluation, two risk factors, probability and severity, will be examined for each perceived risk associated with the defined risk scenario.

Recommendations and Rationale
Risk Question
In this case the criticality of an issue drives the creation of the risk question. Our risk question becomes, "*what are the potential risks associated with identifying an issue as a deviation which requires investigation vs. event which requires notification only*"?

Risk Assessment Tool
Given the nature of the data to be used for the assessment, the Risk Ranking and Filtering method has been selected to aid in the assessment of risks associated with categorizing the issues. Risk Ranking and Filtering (RRF) focuses on two separate
risk factors, probability and severity, associated with each potential risk relevant to an issue.

Risk Assessment
Identification, analysis, and evaluation of potential risks. The potential risks associated with the identification of deviations vs. events were derived through completion of a brainstorming exercise and are listed below:

Regulatory expectations– the formalized requirements pertaining to investigations should be reviewed and understood to determine the potential risk of non-compliance. Risks may vary from one market to another, it is suggested that the expectations for the most stringent market served be used for the assessment of a minor regulatory deviation when multiple markets are involved. Note that repeat deviations, albeit minor in nature, may require a variation to be submitted as recommended by EMEA position paper on QP discretion.

cGMP expectations – the unwritten expectations that are generally accepted as "standard practice" should be considered. Many times these expectations are verbally expressed by regulatory inspectors during facility inspections. As with Regulatory expectations the assessment should be based on the most restrictive GMP expectations.

Direct impact system – it is expected that the site has performed and documented an assessment of all systems. The impact classification is utilized in this assessment**.**

Direct product quality impact – this encompasses all factors that could have a direct impact on product quality such as out of specification result, stability failures, foreign matter, etc.

Risk to patient – this encompasses all factors that could be harmful to the patient such as cross contamination of product, mislabeling, etc
For each of the above stated risks related to the identification of deviations vs. events the individual risk factors or components must be assessed. As identified previously, each potential risk has an associated probability and a severity. The probability represents the likelihood of the risk being realized while the severity is a measure of how much impact it would have if it did occur.

