

Approaches to assessing risk

Approach 1

System assessment approach

The following factors should be evaluated through a series of risk questions:

- Regulatory requirements and cGMPs
- Direct impact system
- Direct product quality impact
- 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