Standard Operating Procedure

Title: Guidance for the use of Risk Assessment in Validation

Department	Validation/Technical Services		Document no	VAL-185	
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1. APPLICATION

This procedure details the standard methodology used to perform GMP/Quality Risk Assessments during Validation activities.

2. RESPONSIBILITY AND AUTHORITY

The Validation Supervisor is responsible for appointing personnel to and coordinating Risk Assessments. The Validation Manager will be responsible for the development of the Validation Risk Management plan, the implementation/execution of the plan and the documentation of the activities associated with the plan.

3. SAFETY AND PROCESS SPECIFIC INFORMATION

All safety requirements for relevant areas at any GMP facility must be followed at all times.

4. PROCEDURE

4.1

The Risk Assessment shall be conducted to determine the level of inherit risk within a given process or product. The Risk assessment should be developed to suit the type of Validation undertaken and should be used to determine the level at which Validation is performed. Validation should not be conducted where steps in a process do not impact the safety or quality of the final product and no perceivable risks are identified.

4.2 Describe the product and process

A full description of the product and the process should be drawn up, including relevant quality information such as the composition, physical/chemical properties, structure, pH, temperatures, method of cleaning, bactericidal/bacteriostatic treatments (e.g. heat-treatment), drying, screening, mixing, blending, packaging, and the storage conditions. The method of distribution and transport should also be described.

4.3 Describe the intended use of the product

The intended use should be based on the expected uses of the product by the end user or consumer. The end use of the product can have a significant impact on the severity of any hazards that are identified and the extent to which Validation may be applied.

4.4 Construct a flow diagram

A flow diagram should be constructed and should cover all operations and decisions in a process. When applying risk assessment to a given operation, the steps preceding and following that operation should also be considered. A block-type diagram may be sufficiently descriptive.

4.5 Identify steps in the process that may impact on safety and product quality

List all the hazards that may be reasonably expected to occur at each step from production, testing and distribution up to the point of use. A hazard analysis should then be conducted to identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential.

A thorough hazard analysis is required to ensure an effective assessment of all potential risks. A list of the potential hazards which may be introduced, increased or controlled in each step should be drawn up.

Rate as **MEDIUM** if the hazard relates to situations where:

- The hazard may be identified through in process checks

Rate as **LOW** if the hazard relates to situations where:

- The hazard is not likely to be easily identified.

4.5.2 Defining the class and priority of the hazard

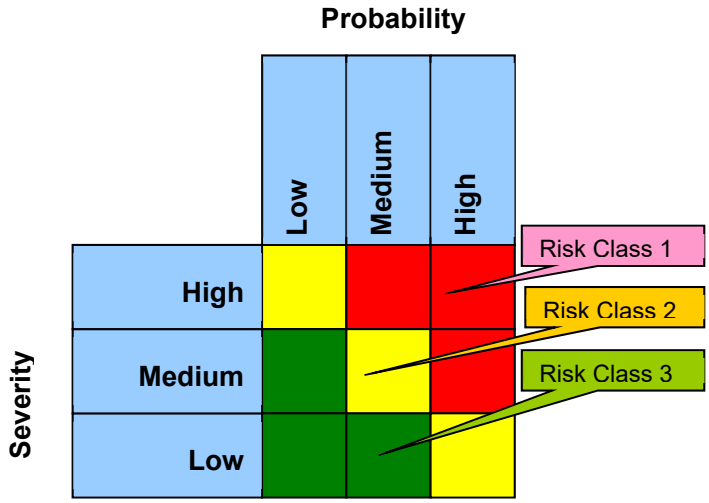
The hazard can then be assigned a Risk Class number. To determine the risk class the severity rate and the probability rate are multiplied (See Figure 1 – Risk Class). Once the Risk Class has been assessed the Risk Priority can be determined. The Risk Priority is derived by multiply the Risk Class with the likely hood of hazard detectability (See Figure 2 – Risk Priority).

At the completion of the Hazard assessment process each Hazard should be rated as HIGH, MEDIUM and LOW priority. The following actions should then be conduction for each of the following priorities:

HIGH – Where the hazard has been assessed as high for a given step a Critical Control (CC) should be established and the control Validated or Verified (each time the step is performed).

MEDIUM - Where a hazard has been assessed as medium for a given step a Critical Control (CC) should be considered and the control may be Validated or Verified (each time the step is performed).

LOW – Where a hazard has been assessed as low for a given step procedures the development of procedures to handle the risk should be considered.



Severity = Impact on Patient Safety and Product Quality.
Probability = Likely hood of Hazard occurrence
Risk Class = Severity X Probability

Figure 1: Risk Class

Figure 4: Validation – Critical Control Point Decision Tree