

# MODULE 5

## QUALITY BY DESIGN

QbD

Quality by Design (QbD) – A systematic approach that begins with predefined objectives, emphasizes product/process understanding and process control, and is based on sound science and quality risk management. The QbD approach allows one to build in the quality through product lifecycle rather than testing it.

How ICH Q8, Q9, Q10 guidelines are working together throughout the product life cycle

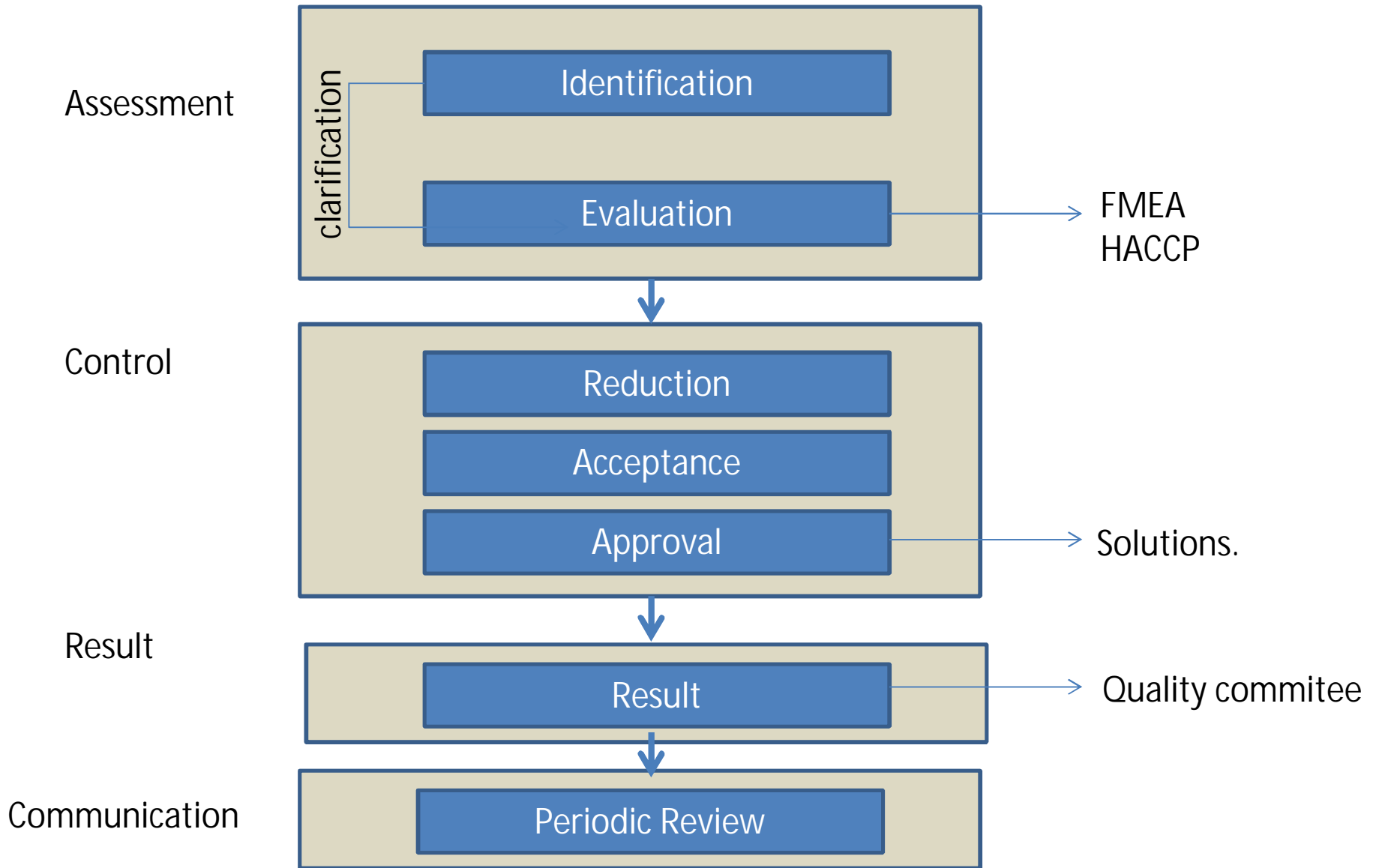
## Q8(R2) - Example QbD Approach



**ICH HARMONISED TRIPARTITE GUIDELINE**

**QUALITY RISK MANAGEMENT**

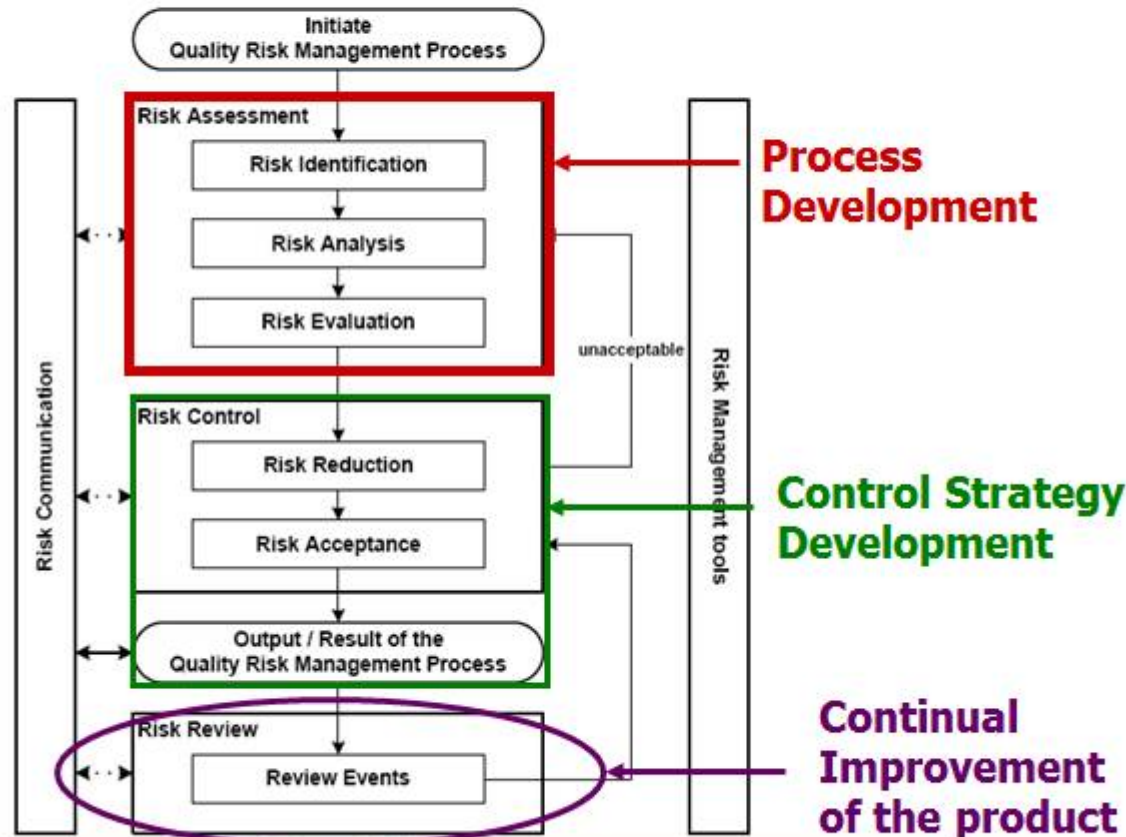
**Q9**



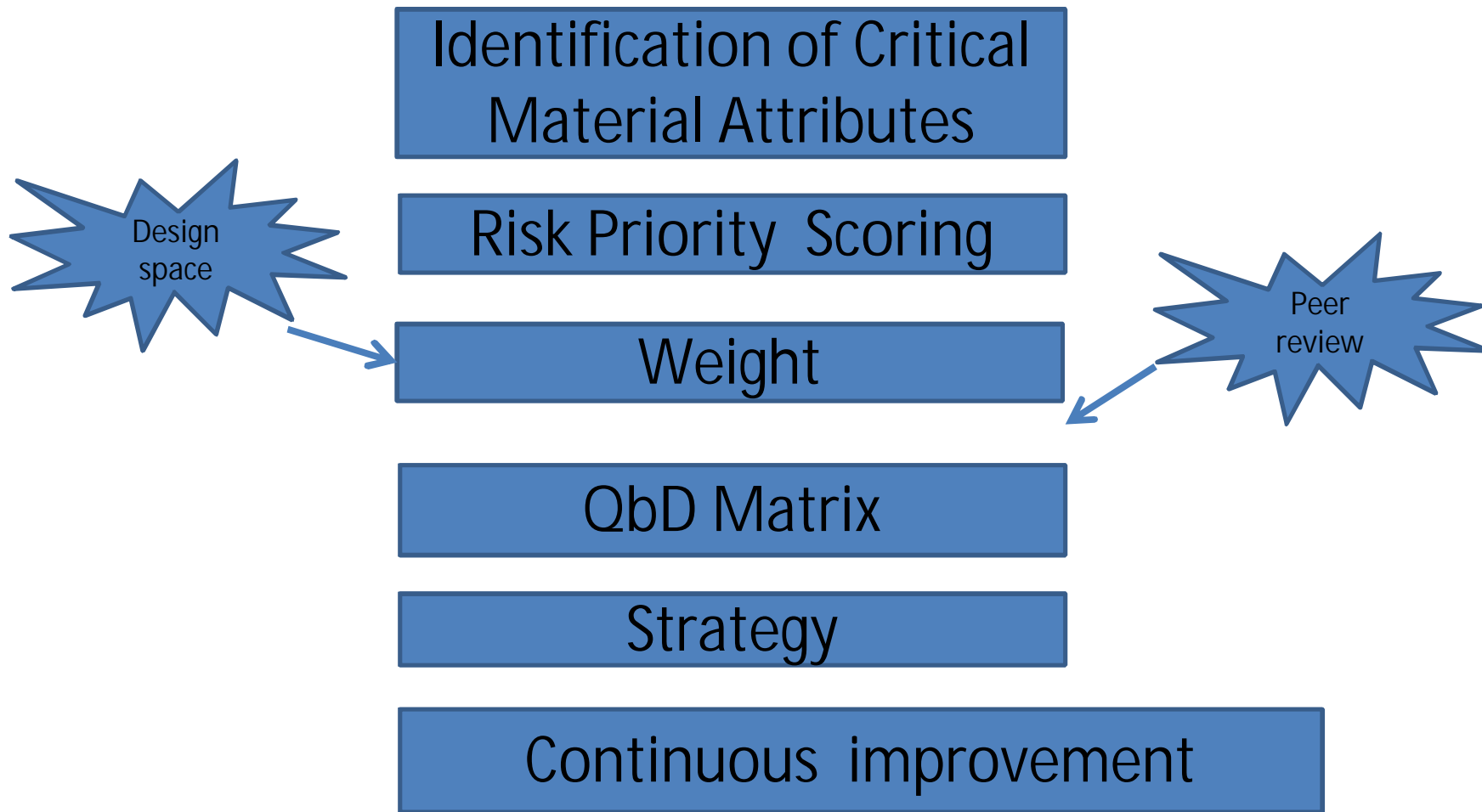
## Quality Risk Management – Q9

- Describes systematic processes for the assessment, control, communication and review of quality risks
- Applies over product lifecycle: development, manufacturing and distribution
- Includes principles, methodologies and examples of tools for quality risk management
- Assessment of risk to quality should:
  - Be based on scientific knowledge
  - Link to the protection of the patient
  - Extend over the lifecycle of the product

# Quality Risk Management Process - Q9



# WORKFLOW QUALITY BY DESIGN





## Identification of Critical Material Attributes

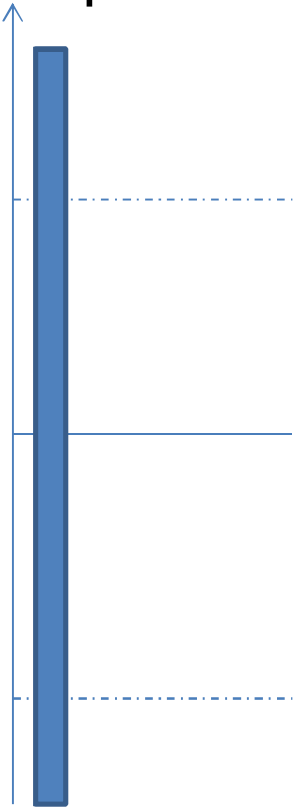
- 1. identify attributes impacting the products through the processing steps.*
- 2. Review the acceptance criteria and evaluate by a risk assessment the impact on the product.*

## Risk Priority Scoring

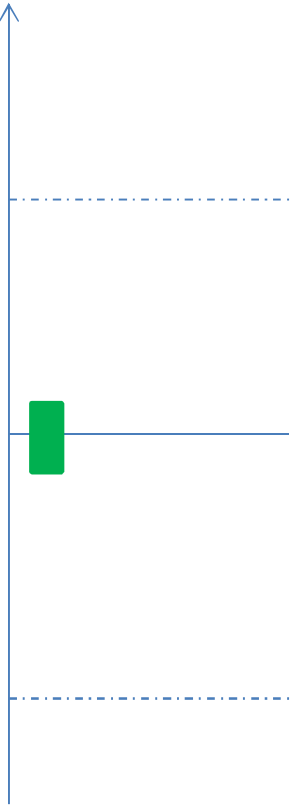
1. Identify the process parameters that will impact the quality attribute
2. Define a scale of impact.
3. Assign an impact for the parameter.
4. The impact represents the severity of the effect.

Definition of Scoring

Variation of the parameter



Impact on the Critical Quality Attribute



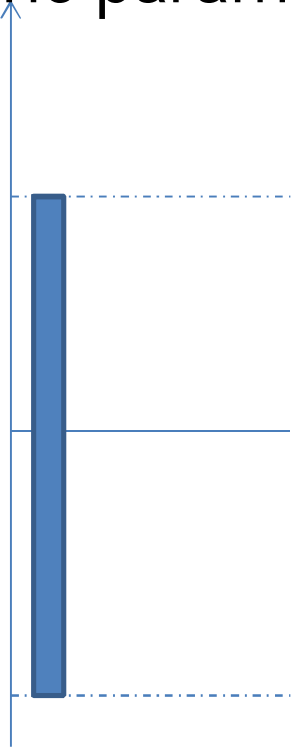
NEGLIGIBLE

RPN

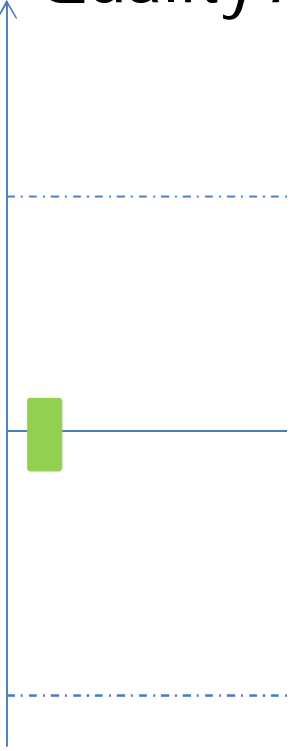
1

Definition of Scoring

Variation of the parameter



Impact on the Critical Quality Attribute

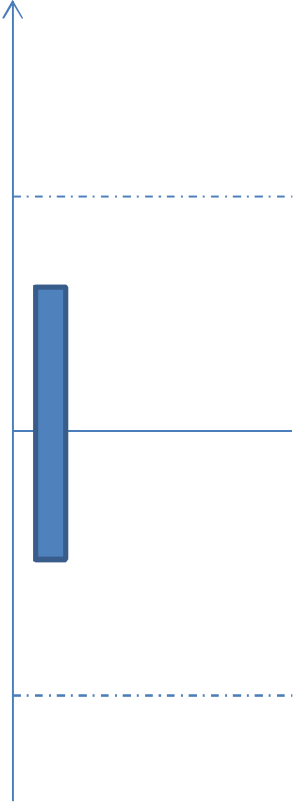


RPN  
LOW  
2

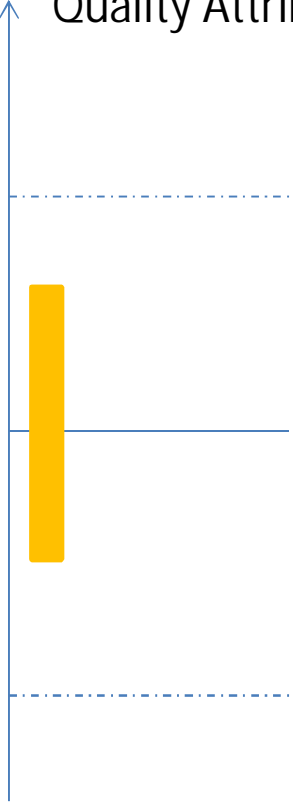
Keeping the parameter within the defined limits ensures the process is run consistently and provides a quality product.

# Definition of Scoring

Variation of the parameter



Impact on the Critical Quality Attribute

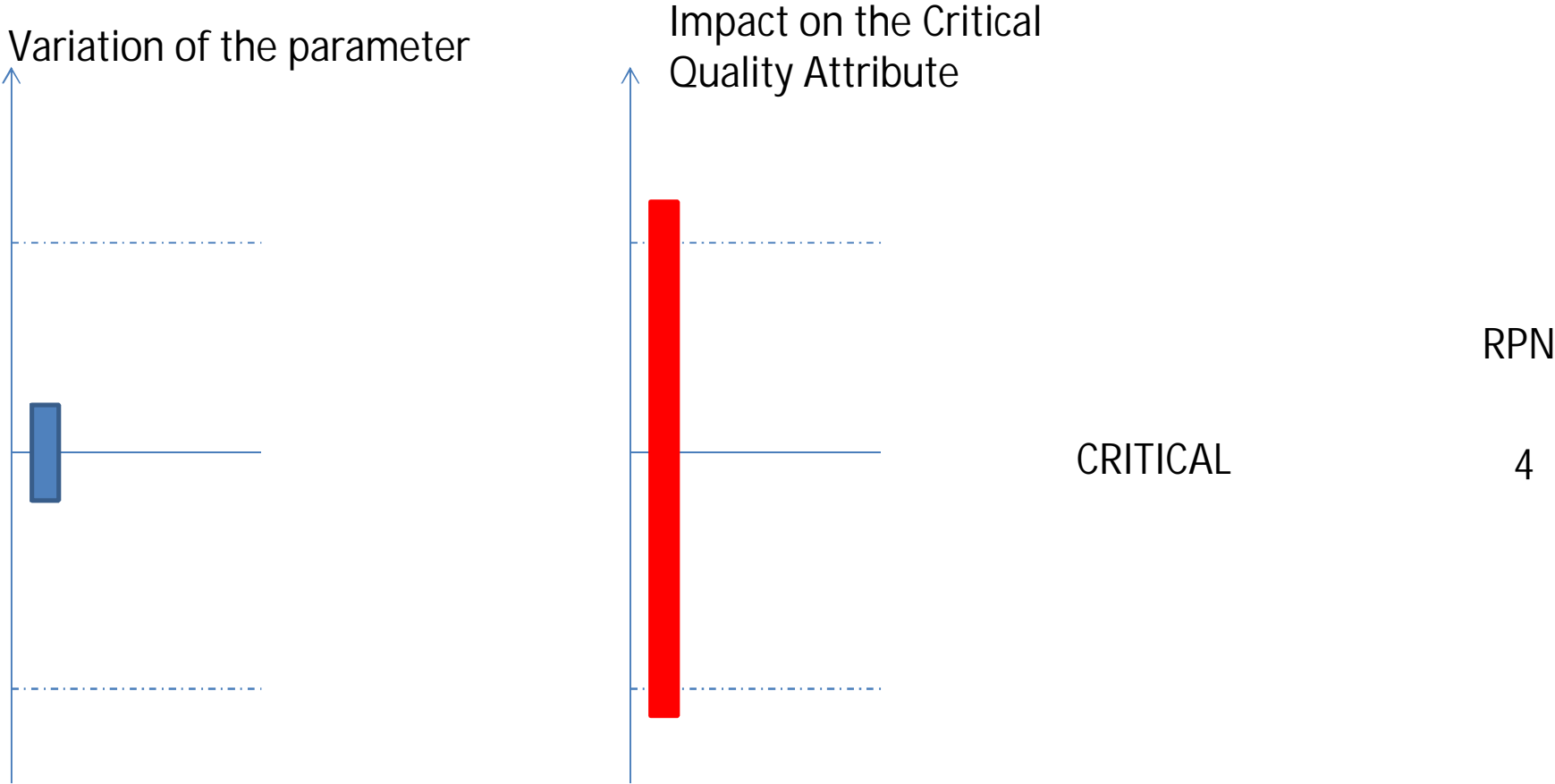


MODERATE

RPN

3

Definition of Scoring



**Small variability has an impact on a critical quality attribute.**

Weight

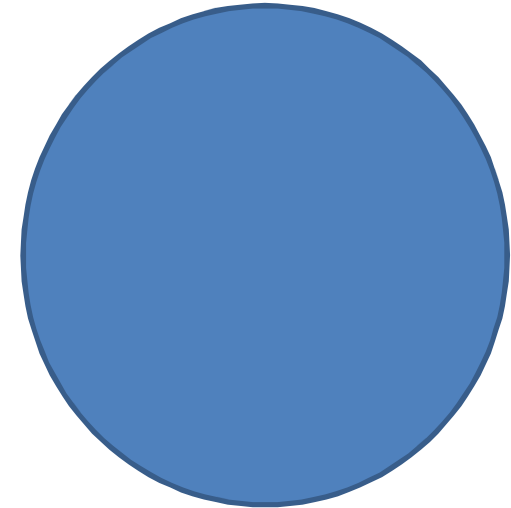
New technology VS Proven tgy

Similar processes

Level of confidence in  
the evaluation

Severity of the impact

ETC...





W


Weight from 1 to 4

# QbD Matrix

		IMPACT			
		1	2	3	4
WEIGHT	1	Process parameter	Process parameter	Key process parameter	Key process parameter
	2	Process parameter	Process parameter	Key process parameter	Critical process parameter
	3	Process parameter	Key process parameter	Critical process parameter	Critical process parameter
	4	Key process parameter	Key process parameter	Critical process parameter	Critical process parameter

 Critical process parameter

 Key process parameter

 Process parameter



