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.
Q8(R2) - Example QbD Approach

- Quality Target Product Profile (QTPP)
- Determine “potential” critical quality attributes (CQAs)
- Link raw material attributes and process parameters to CQAs and perform risk assessment
- Develop a design space (*optional and not required*)
- Design and implement a control strategy
- Manage product lifecycle, including continual improvement
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

- Risk Assessment
  - Risk Identification
  - Risk Analysis
  - Risk Evaluation

- Risk Control
  - Risk Reduction
  - Risk Acceptance

- Output / Result of the Quality Risk Management Process

- Risk Review
  - Review Events

Process Development
Control Strategy Development
Continual Improvement of the product
Identification of Critical Material Attributes
Risk Priority Scoring
Weight
QbD Matrix
Strategy
Continuous improvement
Design space
Peer review
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.
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

RPN

NEGLIGIBLE

1
Definition of Scoring

Variation of the parameter

Impact on the Critical Quality Attribute

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
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...

Weight from 1 to 4
### QbD Matrix

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<th>WEIGHT</th>
<th>IMPACT</th>
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- **Red**: Critical process parameter
- **Yellow**: Key process parameter
- **Green**: Process parameter
| PARAMETER | Mixing |

In your jobs, what are the parameters to be considered?