



#### Principles of Quality-by-Design in Pharmaceutical Development

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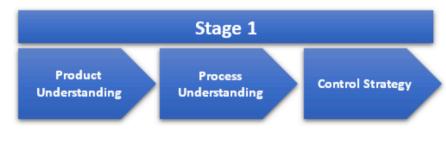
#### What is Quality by Design?

The Quality-by-Design (QbD) concept is a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management [ICH Q8 (R2)].

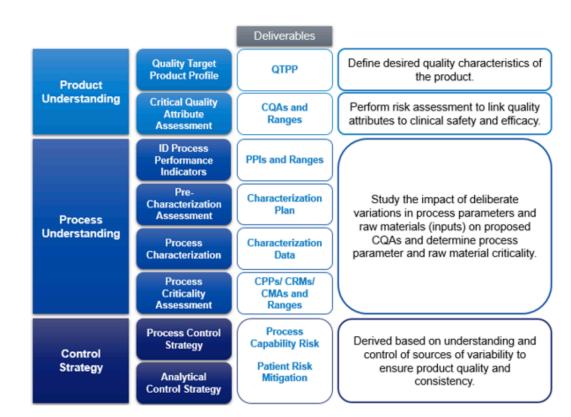
A key assertion of QbD is that quality is controlled not by simply testing the product, but rather by building quality into the manufacturing process by design. This is achieved by a control strategy that is based on both product and process understanding.

# **Practical Implementation of QbD Principles**

Quality-by-Design implementation is facilitated in Stage 1 (Process Design) of the Process Validation Lifecycle.



Within this workflow, there are multiple risk assessments and deliverables that should be met to develop a robust process and analytical control strategy. They are:



These deliverables and risk assessments:

- form the basis of the design of the product;
- establish critical quality attributes (CQAs) and process performance indicators (PPIs);
- · identify process parameters, material attributes, and raw materials with potential impact on CQAs and PPIs; and
- ultimately classify process parameters, material attributes, and raw materials as critical or non-critical.

All together, these items coalesce to create a comprehensive control strategy for the lifecycle of a product. A comprehensive control strategy derived from current product and process understanding assures process performance and consistent, quality production.

## 1. Continuous Improvement

**Advantages of QbD** 

## Continuous improvement is a core focus of QbD. Through this approach, you gain a deeper understanding of

your product as it moves through its lifecycle, making it much easier to spot areas of concern.

Once you identify aspects that need improvement, you can adapt your techniques to create a safer product

and more efficient manufacturing process. The QbD approach allows for ongoing fine-tuning of your operations, even when scaling up from the lab to commercial manufacturing.

## Using QbD helps companies achieve greater batch-to-batch consistency. Maintaining this type of consistency

2. Consistency

Regulators will gain more confidence in you, which may reduce the intensity of their oversight. Consistency also helps companies maintain a high level of pharma manufacturing operational readiness.

leads to desirable outcomes not only from regulatory bodies but also from consumers.

From the consumers' end, they will experience fewer or no recalls, resulting in increased trust and credibility.

# The QbD approach builds quality into the manufacturing process by design, reducing the need for controls.

3. Reduced Controls

Because of this, developers have a good idea of quality even prior to testing. In the end, this can save companies time and money.

## 4. Failure Prevention

The QbD approach sets manufacturing teams up for success by providing a clear and comprehensive

understanding of the parameters involved in the development process and how they work together. This deep understanding helps teams assess risk and act accordingly-significantly reducing the likelihood of failure.

**Final Thoughts** 

A systematic approach like QbD can facilitate continuous improvement and innovation throughout the product lifecycle, maintain consistency of the product, reduce controls, and prevent failure. While different companies may use different QbD workflows, the underlying concept remains the same and is

advantageous to pharmaceutical development.

**Let's Work Together** 

Talk to a QbD Expert

Are you looking to implement a QbD approach? We're ready to help.