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What is Quality by Design? (QbD)

QbD is a systematic approach to pharmaceutical drug manufacturing development. QbD is built on a deeper understanding of the causes and effects of variability in the manufacturing process. This understanding is based on sound science and risk management.

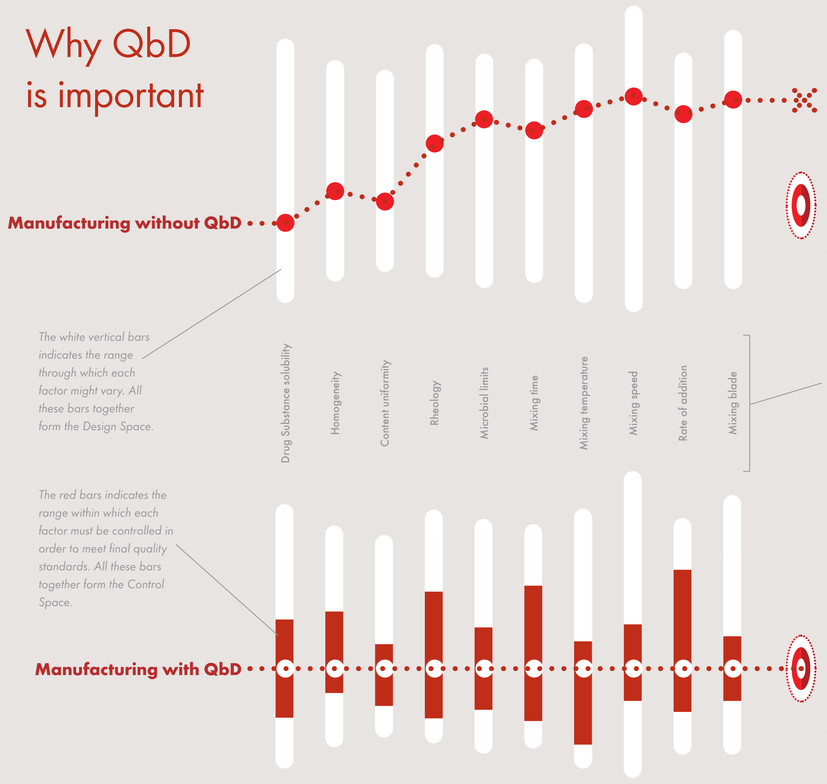
Without QbD, quality must be "inspected in" to a product at the end of the manufacturing cycle. With QbD, the factors that contribute to an approvable, quality product are understood up front. This enables the manufacturing team to quickly address any source of risk, resulting in higher assurance of product quality and additional opportunities for manufacturing efficiency and flexibility.

While the initial investment is higher, QbD reduces costs through the life cycle of the product.

QbD is a growing trend, and regulatory agencies expect that more products will be developed using QbD. Sufficient details of development and manufacturing information must included in regulatory submissions.

QbD incorporates FDA regulatory guidances, including ICH Q8, Q9, Q10.

Why QbD is important



The white vertical bars indicates the range through which each factor might vary. All these bars together form the Design Space.

These factors are representative of all those that affect final product quality. A complete list is too extensive to show here, and will vary by product and product type (e.g. cream vs. parenteral vs. injectable).

The red bars indicates the range within which each factor must be controlled in order to meet final quality standards. All these bars together form the Control Space.

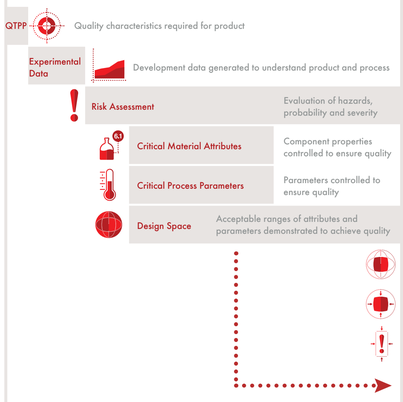
Unacceptable outcome.
Without QbD, quality must be "inspected in" at the end of the manufacturing cycle, by which time it is too late to take corrective action for the batch in question.

Target is here.
An acceptable, approvable quality level is one of the goals of all drug manufacturing. Without understanding the complete impact of variability on the manufacturing process, it can be difficult to predict whether any given batch will hit the quality target.

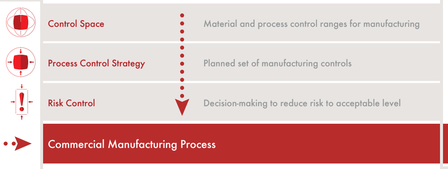
Target is here.
By understanding the design space (the sum total of all variability) and the control space (the sum total of all acceptable variability), and combining this with a scientifically-based risk assessment protocol, the proper quality target can be established and then maintained, despite normal variations in the manufacturing process.

The three phases of QbD

Formulation & Process Development



Formulation & Process Control

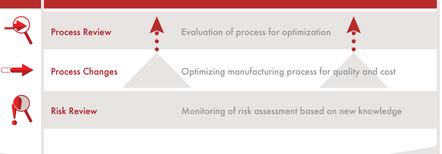


Continual Improvement

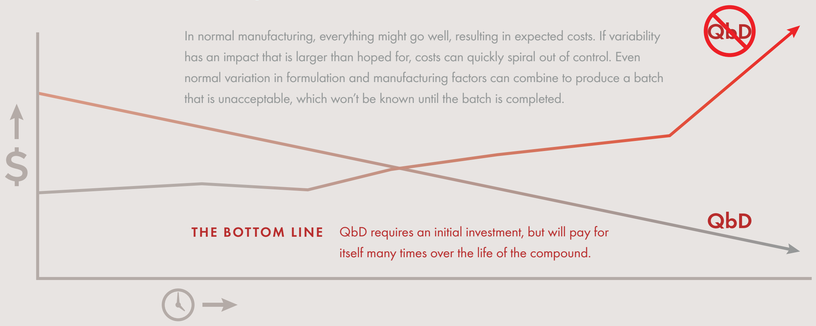
During **Formulation and Process Development**, the QTPP is established and the necessary science and risk assessment is developed in order to determine the Design Space (the sum of all the variability that might affect the quality of the final product).

During **Formulation & Process Control**, Control Strategies are developed to ensure that the manufacturing process will stay within the Control Space (the sum of all variability within which the product can be produced according to quality standards).

During **Continual Improvement**, process improvements can be made to the manufacturing process without threatening the resulting quality of the product.



The financial implications of QbD



In normal manufacturing, everything might go well, resulting in expected costs. If variability has an impact that is larger than hoped for, costs can quickly spiral out of control. Even normal variation in formulation and manufacturing factors can combine to produce a batch that is unacceptable, which won't be known until the batch is completed.

THE BOTTOM LINE QbD requires an initial investment, but will pay for itself many times over the life of the compound.

QbD is based on sound science, which results in a clear understanding of the impact that identified risks will have on the manufacturing process. While this science requires an upfront investment, the resulting formulation and manufacturing process is more robust, delivering many benefits, including better product quality, enhanced process understanding, higher process capability, faster approvals, meaningful regulatory flexibility, fewer regulatory questions, fewer post launch issues, more rapid resolution of post launch deviations, and increased flexibility to implement continuous improvement changes.

Find out if QbD is right for your project. Talk to the experts at 1-866-CALL DPT

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