WHITEPAPER

How to Increase Regulatory Flexibility and Production Efficiency

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The goal of every pharmaceutical developer is to create quality products which generate consumer satisfaction, require low-cost, and have low-risk. Quality starts from the moment of conception of an idea and continues throughout production. Before QbD, quality was often tested for after the design was completed, but with the Food and Drug Administration adoption and promotion of the Quality by Design process, it has become an increasingly popular and necessary approach to pharmaceutical design and manufacturing.

QbD creates a thorough understanding of each factor that goes into the finished product and their effect on finished product. It utilizes a holistic approach that creates an understanding between the quality of the finished products and the variations in components and processes. The benefits of using QbD are clear: better understanding and control of process changes, less batch failure, and more flexible regulatory approaches. So, how do you implement it?

The first step to any project or experiment is to define the objective, or the Product Design Goal. Then you build Quality Target Product Profile (QTPP) which outlines the expectations for the final product. The QTPP will help you identify the critical quality attributes (CQAs) such as bioavailability, shelf life, or potency, giving you a better understanding of the factors and characteristics that influence your desired end product the most. After this, you have to create the Design Space for your formulation and process. The Design Space is a range of combinations of process parameters and materials that still guarantee the quality of the finished product. Defining, critical process parameters (CPPs) will determine where the acceptable range of process variation lies. Designating a design space approved by the FDA allows manufacturers to work within a flexible range without requiring additional regulatory review to changes made within those parameters, such as, formulation or process changes to optimize processing or finished product performance. Instead of operating at specific parameters in an approved process, you can get a range of parameters approved. The design space also allows for consistent improvement of the product and innovation. To create your design space, experimental design is used to more quickly test potential interactions and provide statistically relevant information to base further decision making on. By utilizing an experimental design, you can decrease the number of experiments required instead of using "one-change-at-a-time" approaches, which are more costly and time consuming.

The Quality by Design process to creating pharmaceutical formulations increases regulatory flexibility while also ensuring a quality product through each step of the formulation process. Truly understanding the manufacturing process and how each part affects the final product decreases the risk of batch failure and recalls. Though initially QbD may seem time consuming and expensive, with the decrease in inefficiencies with QbD, pharmaceutical products will become less expensive to produce.

By following QbD and knowing how critical formulations and process parameters can affect the finished product, the root causes of quality issues can be more easily identified. Manufacturers can more easily prevent and decrease unproductive delays in production and have room in production for variability in materials and process parameters. QbD requires knowing the physicochemical properties of each component of your formulation. Understanding this, Micromeritics works to bring you instruments that can provide you with reproducible data with ease. Micromeritics also offers a variety of lab services that can assist you in gathering data about CQAs and follow the QbD process. Quality by Design embodies building quality into your product. With the support of the FDA, QbD seems to be the best approach to pharmaceutical development for manufacturers, regulators, and consumers.

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