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Qualitative Measures of Pharmaceutical Formulations in Pharma Industries

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Commentary

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DESCRIPTION

Pharmaceutical formulation development or improvement requires a large number of raw materials and process variables that interact in a complex manner, making control and optimization difficult. For decades, pharmaceutical development has been attempted through trial and error, with the formulator's prior experience and knowledge supplementing the process. Final testing ensured that the formulation was of high quality. As a result, 'acceptable formulations' were released to the market, and some are still commercially available.

Companies, on the other hand, frequently report issues related to changes in raw material or batch suppliers, or in the manufacturing process, which affect the quality of the formulations and render them unacceptable. Such issues may arise because, while the formulations meet standard requirements, the complex relationships between all of the variables involved and the responses are not fully understood and controlled.

Optimization methods, which rely on systematic Design of Experiments and statistical analysis, began to partially replace such trial and error procedures. In the 1980s, the use of experimental designs, particularly factorial designs, in the development of solid dosage forms became common practice, and appropriate statistical treatments allowed the determination of critical parameters of complex processes, material comparison, or formulation improvement or optimization. Some of these works were published, but the vast majorities are still used internally by pharmaceutical companies.

In 2002, the FDA announced a new initiative aimed at modernizing its pharmaceutical quality regulations for human drugs and establishing a new regulatory framework focused on Quality by Design (QbD), risk management, and quality systems.

QbD, according to the International Conference on Harmonization, is a systemic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, all

while being grounded in sound science and quality risk management. QbD requires an understanding of how formulation and process variables influence product quality (knowledge space), as well as a definition of the design space within the knowledge space. To ensure process performance and product quality, the formulator should identify and differentiate between critical and non-critical variables when developing a new formulation, define the design space, and define a control strategy.

For the pharmaceutical industry, QbD adoption represents both an opportunity and a challenge. This method should save money and time while increasing process efficiency and formulation quality. Furthermore, operating within the design space is not considered a formulation change and does not require regulatory approval, whereas movements outside of the design space are considered changes and require regulatory approval.

Recent and significant technological advances in pharmaceutical development have resulted in an unprecedented influx of large data sets from various types of variables (binomial, discrete, and continuous) and nominal factors, rendering traditional methodologies like response surface methodology obsolete (RSM). Although nominal factors cannot be included in those designs, RSM, which includes statistical experimental designs and multiple linear regression analysis under a set of constrained equations, is a recommended method for determining 'the design space.' A viable alternative strategy in such cases would be to repeat the response surface design for each discrete factor level.