

Quality by Design Applications in the Pharmaceutical Industry

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Abstract

A process is well understood when all critical sources of variability are identified and explained, variability is managed by the process, and product quality attributes can be accurately and reliably predicted over the design space. Quality by Design (QbD) is a systematic approach to development of products and processes that begins with predefined objectives and emphasizes product and process understanding and process control based on sound science, statistical methods and quality risk management. In an attempt to curb rising development costs and regulatory barriers to innovation and creativity, the FDA and ICH have recently started promoting QbD in the pharmaceutical industry [1, 3, 7,]. QbD is partially based on the application of multivariate statistical methods [2, 4, 6] and a statistical Design of Experiments strategy [4, 5, 6] to the development of both analytical methods and pharmaceutical formulations. The talk will review the basics of QbD with case studies from the pharmaceutical industry.

References:

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