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Incorporating Factor Variability into Risk Estimation in Pharmaceutical Manufacturing

In pharmaceutical manufacturing, process optimization and control are critical for ensuring consistent drug product quality and regulatory compliance. In real-world applications, certain study factors are treated as fixed and maintained constant to standardize production conditions. However, it is sometimes inevitable for other factors to exhibit variability, introducing uncertainties that can affect the final drug product. This study presents a statistical framework designed to operate under conditions where variability in the factors, are present. The focus is on incorporating this variability into risk estimation, specifically in evaluating the probability of failing to meet the specifications of a critical quality attribute of the drug product. This study offers valuable insights for practitioners in the pharmaceutical industry, aiming to enhance product quality and ensure compliance with regulatory standards.

Special/ Invited session

Classification

Mainly application

Keywords

risk estimation, variability, pharmaceutical manufacturing,

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