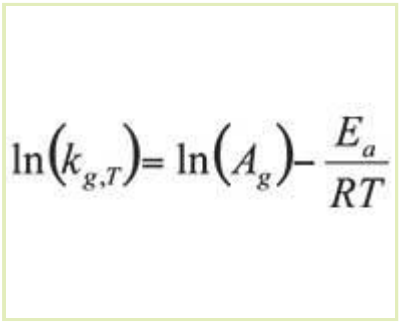
Stability by Design

By **William R. Porter May 11, 2013 12:04 pm EDT**



ABSTRACT

Factors impacting the achievement of drug product stability by design are reviewed. A strategy for the development team is proposed using the standard quality by design pathway developed by Juran. Stability goals are established after consultation with suppliers, teammates, and stakeholders. Virtual failure mode analysis is used to identify the “known knowns” (i.e., facts and theoretical predictions). Stress experiments are used to study the “known unknowns” (i.e., detectable but not quantifiable changes in critical quality attributes over time) using heat, moisture, pH changes, light, and oxidizing agents to accelerate aging. Effects of the “unknown unknowns” (i.e., early undetectable changes in quality attributes that only become observable later) are anticipated by combining theoretical knowledge with appropriately designed stress degradation experiments.

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