Pharmaceutical Stability Testing to Support Global Markets

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This book is a proceedings of the AAPS Stability Workshop. This workshop provide an understanding of the regulatory perspective of stability testing and position the stability program for 21st century globally by: learning regulatory initiatives on global stability submission; stability testing in challenging storage environment such as ASEAN or Caribbean region; exploring concept of Quality by Design as it applies to stability testing; understanding stability challenges of biologics, generics, nutraceutical, and other new product technology; setting specifications for drug substances as well as various type of drug products; exploring concerns on changes of stability profiles such as repackaged products, split tablets; discussing safety and toxicology concerns of emerging impurities; understanding physical effects on product stability; stability to support temperature excursion during shipping; assessing impurities and degradation product in development; leveraging stability data to expedite regulatory approval; and managing relationship with contract research organizations.

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