

## PHARMACEUTICAL STABILITY TESTING TO SUPPORT GLOBAL MARKETS%0A

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This workshop will 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; and

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She is the editor of the Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies and Best Practices, which has been recognized as a practical reference book in the stability community.

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Section I- Stability Studies in a Global Environment.- Regulatory Perspectives on Product Stability.- Current International Harmonization Efforts.- Update on the WHO Stability Guideline.- Development of a Regional Guideline for the Eastern Mediterranean Region.- The Challenge of Diverse Climates: Adequate Stability Testing Conditions for India.- Requirements for South East Asian Markets.- The

Stability Testing Lab - Pharmaceutical Stability Testing ...

Stability testing is integral to developing new pharmaceutical products and active pharmaceutical ingredients, to establish their shelf life or expiry date. It is also equally important along with ongoing routine manufacturing to monitor product quality as a function of time.

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eGMP Pharmaceutical Stability Studies - Intertek GMP pharmaceutical stability studies and ICH storage services supporting your drug product development, commercial stability studies, batch release and quality control testing . Pharmaceutical stability studies are an essential component of the development and lifecycle of pharmaceutical products, in particular, supporting

development and IND / NDA submission activities. They allow evaluation of active pharmaceutical ingredient (API) stability or drug product stability under the influence of  
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Sect. III. Technical concepts for stability program. 14. The concept of quality-by-design / Mark A. Staples -- 15.  
Forced degradation and its relation to real time druct product stability / Steven W. Baertschi -- 16.