

Stability Sessions – Abstracts

Stability Programs 101: Regulations, Guidances, and Goals

Boyce Johnson, Mayne Pharma

This presentation discusses an overview of the importance of a vibrant stability program in a modern pharmaceutical facility. This is an attempt to provide the “why” as far as the need for stability storage and testing. The regulatory requirements are discussed as well as harmonization throughout the world including overall high-level guidance that reaches down to define company policies and procedures. The impact of the stability program is defined in relation to the overall lifecycle of a product. The information obtained during stability studies is outlined as well as how this information affects the overall viability of the product from both an analytical and economic perspective. Examples of quality questions are also provided.

Stability Study Design by Phase of Clinical Development

Geoff Carr, Patheon by Thermo Fisher Scientific (Ontario)

There are several regulatory guidelines that describe how to conduct stability studies in support of commercialization of pharmaceutical products eg ICH Q1A(R2) and associated guidelines. However during early development of new pharmaceutical chemical entities and associated products, various stability studies are required in order to ensure that good quality robust products are created. In this presentation, in order to demonstrate how these studies are used, it is intended to provide examples of some of the stability studies that are of importance here including:

- Studies in support of Powder in Bottle products for Phase 1 clinical programs
- Drug Excipient Compatibility Studies
- Stability Studies for placebo products and clinical comparators

Adulterated to Misbranded: When Stability Gets a Warning Letter

Jennifer Alligood, CMP Pharma

GMP violations for stability testing have increased between 2018 and 2019. For fiscal year Oct 2018 to June 2019 stability testing was cited in 17 warning letters. The primary target of this presentation is to share specific warning letters to make companies aware of the deficiencies and provide some key insights for risk management. There will be an open forum discussion at the conclusion of the presentation between attendees.

Stability Data Evaluation and Shelf-life Projection

Craig Hamilton, H&A Scientific

ICH Q1E provides recommendations on the use of stability data to propose retest periods/shelf life. ICH Q1E will be discussed and examples given for shelf life projections, including single and multiple batch analysis. Data variability and evaluation of OOT results will be discussed. A few observations concerning the use of degradation kinetics will also be presented.

Special Purpose Stability Studies

Vonda Sheppard, Mayne Pharma

Going beyond typical ICH stability storage to evaluate stability samples in action. A look at some special purpose stability studies and how data obtained from these studies could influence packaging, storage, or transport of pharmaceutical products.

Packaging Configuration and Product Type Impact on Stability Testing Requirements

Kristi Pittman, Fresenius-Kabi

Stability testing requirements are impacted by Packaging Configuration (primary and secondary packaging components) and Product Type. The potential interaction of the manufactured drug with the packaging component materials in which it is produced for commercial sale must be challenged through its shelf-life and possible extension. These requirements will be reviewed and explained based on industry standards and regulation requirements per FDA and ICH guidelines.