



Stability Analysis

(8 hours)

Course Description:

A key component of pharmaceutical, medical device and biotechnology product development is to determine product stability and shelf life. In this course, the basic statistical assumptions, tests and life prediction methods will be presented with examples. Determination of whether to pool data, use a common slope or fit the data individually will be presented. Sample size selection and stability estimation in compliance with FDA guidance is discussed.

Audience:

This Course is designed for all scientist, engineers and quality professionals who actively work on all aspects of discovery, product and process development where the goal is to characterize, optimize, and improve product and process performance.

Course Objectives:

Upon completion of the course the participants will be able to:

- Design and analyze stability studies
- Determine the appropriate fitting method for any stability data set
- Determine shelf life
- Select appropriate analysis technique based on type of data
- Use and interpret the stability script and associate report

Prerequisites: Engineering Statistics and Data Analysis is a recommended prerequisite for this course

Software: JMP

Course Outline:

Stability Definition and Introduction

FDA Guidelines

Stability Study Design

Sample Size

Test conditions

Stability Data Analysis and Life Prediction

Extendibility and Confidence Intervals

Shelf Life Determination

All batches pooled

All batches with individual fits

Common slope

Common Intercept

Stress Testing