SeerPharma®
CONFIDENCE IN COMPLIANCE

E-LEARNING

G(QC)LP

7

Stability Programs

This module introduces you to the requirements for stability programs, their purpose, and how they are reviewed. Basic requirements for scheduling tests will be presented.

Objectives:

- Describe the purpose and value of stability programs
- List the different standards and cGMP requirements for stability programs
- Set up a schedule for a stability program
- List which stability indicating tests are expected for which dose forms
- Assign a shelf life based on typical stability regression lines
- State why methods need to be stability indicating in nature

Course Outline

OVERVIEW
- o Welcome
- o Objectives
- o Introduction
- o International stability testing guidance
- o Importance
- o Purpose of stability studies
- o Stability and container closure systems
- o Stability and degradation products
- o Forced degradation profile
- o Kinetic models
- o Review

STABILITY PROTOCOLS AND SCHEDULES
- o Introduction
- o Stability studies
- o Real-time studies
- o Accelerated studies
- o Significant changes
- o Importance of stability protocols
- o Stability protocols
- o Bracketing
- o Matrix design
- o Testing frequency
- o Review

STORAGE CONDITIONS AND TESTS
- o Introduction
- o Storage conditions
- o Stability trial storage conditions
- o Active raw materials
- o Finished dose forms
- o Expected tests
- o Presentation of results
- o Review

STABILITY RESULTS AND SHELF LIFE
- o Introduction
- o Stability trial design
- o Evaluation of results
- o Typical problems
- o Nominating shelf life
- o Calculating shelf life
- o Review

STABILITY INDICATING METHODS
- o Introduction
- o Stability indicating methods
- o Test methods I
- o Test methods II
- o Review

SUMMARY
- o Summary

Contact us for more information

SeerPharma®
CONFIDENCE IN COMPLIANCE