

Pharmaceutical Stability (Classroom)

Art. ID	USP-CM-GMP-01
Unit	Each
Deliverydetails	No Dangerous Good

Description

Learn about essential components for designing global stability programs for pharmaceutical products: regulations, operations, testing and investigations. Topics include cGMP, USP, FDA, ICH and WHO stability requirements for establishing expiration dating and label storage criteria, technical and regulatory aspects that may affect design cost-effectiveness and compliance, and stability indicating methods for monitoring product quality throughout its shelf life. Matrix and bracketing options to reduce testing, stability data evaluation and investigation of out-of-trend and out-of-specifications are also addressed. This course will also cover USP <1225> Validation, USP <1226> Verification.