

Validation of analytical methods Syllabus Rev.1

Day 1

Module	Topics
Session Kick-Off	• Introductions • Course objectives and expectations
Regulatory requirements	• ICH documents: ICH Q7 and ICH Q2 • Pharmacopeial chapters: <1224>, <1225>, <1226> • Tests categories and validation parameters
Definitions	• Validation parameters definition and procedure
Validation parameters	• Detailed explanation and examples • Identification • Assay and content uniformity • Impurities and degradation determination • Dissolution • Biological methods
Session Wrap-Up	• Feedback • Summary