Process Validation with focus on Quality Aspects
Rev.1

Day 1	
Module	**Topics**
Session Kick-Off	• Introductions • Course objectives and expectations
WHAT IS PROCESS VALIDATION. **WHAT ARE THE REGULATORS REQUIREMENTS.** **MAJOR PROCESS VALIDATION VIOLATIONS**	• History of process validation, few definitions • Annex 15 and FDA 2011 guide for industry • FDA vs. EMA Terminology • Process validation - Glossary • Bracketing approach examples
HOW TO DO THINGS RIGHT	• Process development and QbD (QTPP, CQAs, CPPs) • Quality by Design • Design stage • Process validation risk assessments • Investigations as part of process validation studies • Process validation implementation • Validation requirements for process changes • Continuous process verification • Reprocessing during the API production
Session Wrap-Up	• Feedback • Questions and discussion