

G(QC)LP



# Analytical Method Validation

This module is designed to provide you with techniques and procedures for the validation, analysis and control of analytical test methods. The presentation covers such topics as definitions of performance parameters and their acceptance criteria and how to set up for cost efficient accuracy, precision and linearity studies, etc.

## Objectives:

- List performance parameters required and their acceptance criteria
- Identify what is involved in an analytical method validation protocol
- List the requirements for an interlaboratory method transfer
- Understand the requirements of stability indicating assays
- Understand why compendial methods need to be validated

# Course Outline

## INTRODUCTION

- o Introduction
- o Analytical method users
- o Regulatory standards
- o ICH standards
- o Summary
- o Review

## VALIDATION PHILOSOPHY

- o Introduction
- o Basic validation philosophy
- o Pre-requisites
- o Analytic methods
- o Performance parameters
- o Protocol structure

## METHOD PERFORMANCE PARAMETERS

- o Introduction
- o Performance parameters
- o Precision I
- o Precision II
- o Accuracy I
- o Accuracy II
- o Method capability
- o Method specificity
- o Linearity and Range
- o Sensitivity, LOD and LOQ I
- o Sensitivity, LOD and LOQ II
- o Sensitivity, LOD and LOQ III
- o Ruggedness/robustness
- o Review

## METHOD TRANSFER

- o Method transfer verification
- o Requirements
- o Review

## STABILITY INDICATING ASSAYS

- o Requirements
- o Review

## COMPENDIAL METHOD VALIDATION

- o Pharmacopoeial methods

## CONCLUSION

- o Summary