

# Validating HPLC Methods (1 day)

## Who should take this course?

If you are now, or will be, developing HPLC methods and have questions about method validation, documentation, and regulatory compliance issues, then this is the course for you. Attendees should have attended an Advanced HPLC Method Development course or have equivalent experience (at least one year of HPLC Method Development work). This course is not for novices.

## What does it cover?

In this intensive one-day course, you will learn both how to avoid expensive validation problems and how to take advantage of the information provided by a well-designed, well-implemented validation. This course includes:

- How to adapt, qualify, and modify USP methods
- How to validate methods in ways that will minimise method transfer problems
- How to develop a robust HPLC method and fulfill the FDA's requirements in the QC operations in pharmaceutical, biotechnology, and related industries
- How to avoid unpleasant "surprises" during validation
- How to avoid regulatory problems with FDA or EPA during audits by having proper documentation for all your submissions
- Learn the ins and outs of the FDA's New Millennium Directives, cGMP requirements and the Guidance for Validation of Analytical Methods
- Familiarising yourself with safe and sound approaches for validating your HPLC method right from the beginning
- Learning about the Guidance for Laboratory Controls Systems as outlined in the CFR and elsewhere from FDA
- Familiarise yourself with the contents and format of submission packages related to NDA, IND, ANDA, and other stages of drug discovery, development, and marketing
- Learning about documentation strategies to meet FDA requirements

## Course Outline

Introduction and Basic Concepts

Overview: General Approach to Validation

Measurement Process and Errors

- Classification of Errors
- Analytical Methods, Purpose, and Errors Involved
- Measurement Resolution

Incorporating Validation into the Method Development Process

Definitions of Key Validation Parameters: General, USP, ICH, FDA

Regulatory Guidelines

- Tables of Data and Acceptance Criteria
- FDA Guidelines for IND, NDA, ANDA, and Submission Packages
- Practical Examples

Conclusion

**Available as an in-house or off-site course. Contact us for details**