

HLPC*: Method Development

(*High Performance Liquid Chromatography)

DIRECTED BY

Rachel Monsef — Consultant to the biopharmaceutical and pharmaceutical industry



ACCREDITED COURSE

Course Topics Include:

- The basic theory behind reverse and normal phase chromatography
- Mobile phase, temperature and column effects for reverse and normal phase
- Developing Reversed Phase method with ionic samples
- Method Development of Ion-Exchange Chromatography
- How to handle method development of complex samples
- Ensuring good method performance

about the course

This HPLC course will benefit the personnel with some HPLC experience who are developing or optimizing HPLC methods. This 90-minute accredited course will include discussions of the theory of Reversed and Normal Phase, Ion Pairing, and Ion-Exchange Methods. It will also give basic starting points on method development and method evaluation of these methods. The course is designed to give personnel with some HPLC experience a broader scope for how to use this invaluable analytical tool.

who should attend

This online training will be most useful for people with some HPLC experience who are interested improving their HPLC methods or personnel who are beginning to develop new HPLC methods or who have taken the first course in this series. This course will benefit laboratory personnel in many industries including: pharmaceutical – traditional and phytochemical, food, beverage, environmental, chemical, and personal products.

The potential job functions would be entry to mid-level laboratory personnel with some HPLC experience, or laboratory personnel with degrees in other disciplines who need to start developing HPLC methods.

The departments in companies involved with the use of HPLC in research/development or quality control/quality assurance should insist their personnel attend if they are not being trained in-house or as a supplement to their in-house training.



learning objectives

Upon completion of this course, you will be able to:

- Describe the theory behind basic HLPC methods (specifically reversed and normal phase, ion-pairing, and ion exchange)
- Begin development of HPLC methods
- Optimize and evaluate the performance of HPLC methods
- Troubleshoot and prevent basic issues with HPLC methods

course outline

Review of Learning Objectives

Module 1: Reverse Phase and Normal phase Method Development

- The Basic theory behind reverse and normal phase chromatography
- Choosing between reverse and normal phase chromatography
- Mobile Phase, temperature and column effects for reverse and normal phase
- Initial conditions and evaluation of both normal and reverse phase using gradient and isocratic methods

Module 2: Ion-Pair, Ion Exchange: When to use these method types

- What chromatography should you use with ionic samples?
- What problems can happen in reversed-phase with ionic samples?
- Developing Reversed Phase method with ionic samples
- Benefits and basic theory of Ion-Pair Chromatography
- Developing a method with Ion-Pair Chromatography
- Ion-Exchange Chromatography (Another option to Ion-Pairing)
- Method Development of Ion-Exchange Chromatography
- Other Methods to be aware of (HIC, Chiral)

Module 3: Complex samples and ensuring good method performance

- How to handle method development of complex samples
- Systematic approach to developing the method
- Ensuring good method performance
 - Trending method information over time
 - o Identify critical parameters of the method
- Systematic approach to identifying issues that may arise

Question and Answer Session Assessment Opportunity

course instructor

Rachel Monsef is a consultant to the biopharmaceutical and pharmaceutical industry for analytical and quality control. She has 22 years of experience working with many types of assays for all stages of drug development. Ms. Monsef has been responsible for method development, method qualification, method validation, method transfers, characterization work, and stability studies. She has been involved in method troubleshooting and assisting with "troubled" validations. Ms. Monsef has worked extensively with coordinating method development and validation work at CMO's as well as troubleshooting methods that do not have the robustness needed for regulatory compliance. She previously worked for Alder (now Lundbeck) and Seagen and is now consulting for both companies



Accreditations

International Accreditors for Continuing Education and Training (IACET)



Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 1.5 contact hours, or .2 CEUs. For further information, visit www.iacet.org

