

# HLPC\*: Method Development of Peptides and Proteins

(\*High Performance Liquid Chromatography)

DIRECTED BY

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ACCREDITED

#### **Course Topics Include:**

- The basic theory and purpose of SE-HPLC
  - Effects of flow rate, temperature and mobile phase
  - SEC Method evaluation and optimization
- Overview of Affinity Chromatography
- Overview of Ion-Exchange Chromatography
- Overview of HIC Chromatography

## about the course

This 90-minute accredited course will include discussions of the theory of SEC, Reversed Phase, Ion-Exchange, Hydrophobic Interaction, and Protein Affinity Chromatography. 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 in improving their HPLC methods or personnel who are developing new HPLC methods for Proteins: Biopharmaceuticals, food sciences or any other industry analyzing proteins would be of interest.

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 for proteins.

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:

- Explain the basic theory and purpose behind multiple protein and peptide HPLC Methods
- Begin basic development of protein and peptide HPLC Methods
- Optimize and evaluate the performance of protein and peptide HPLC Methods
- Troubleshoot and prevent basic issues within HPLC Methods

## course outline

## Review of Learning Objectives Module 1: SEC Development

- The basic theory and purpose of SE-HPLC
  - o Column selection, size, secondary interactions (special cases)
- Guard columns and samples preparation
- Basic method starting point and method controls
- Effects of flow rate, temperature and mobile phase
- Method evaluation and optimization

## Module 2: Reverse Phase (RP) Method Development and Hydrophobic Interaction Chromatography (HIC)

- Overview of RP for Proteins and Peptides
- Basic Theory and separation
- Tryptic Digest
- Starting conditions and limitations
- Optimizing the gradient, temperature, and flow rate
- Proper controls for RP method
- Overview of HPC
- Basic Theory of Separation
- When to use HIC

### Module 3 Ion Exchange and Affinity Methods

- Ion-Exchange (anion and cation exchange)
  - Column, Guard Column, and mobile phase selections
  - Sample preparation, starting conditions and optimization
- Overview of Affinity Chromatography
  - Protein Affinity method versus UV Method
  - Starting point, establishing proper standard, optimizing method

## 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'



