

REGISTRATION FORM

Calibration & Validation Group
2-3415 Dixie Rd., Suite 402
Mississauga, Ontario
Canada, L4Y 4J6

Fundamentals in Analytical Biotechnology
Course will be held on:

July 16-18, 2001
Mississauga Convention Centre
75 Derry Road West
Mississauga, Ontario L4M 2B5

Registration: 7:30am-8:15am
Course: 8:15am-5:00pm

Registration fee includes continental
breakfast, lunch and refreshments

CVG Member \$1200.00
Non-Member \$1300.00

Registration Deadline: June 25, 2001

Mail registration form and fee payable to:

Calibration & Validation Group
2-3415 Dixie Road, Suite 402
Mississauga, Ontario
Canada, L4Y 4J6

To register personally or on-line, contact us
at:

Phone: 905-819-3000 ext 6287 (Kirsty Armit)
Fax: 905-819-7197
Website: www.cvg.ca
e-mail: chung_chow_chan@cvg.ca

Goals and Objectives

The purpose of this course is to teach the fundamental principles and practical use of three major instrumental techniques - reverse-phase HPLC, capillary electrophoresis and mass spectrometry - in the analysis and characterization of biotechnology-derived protein therapeutics.

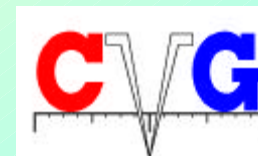
Program

New regulations issued by the US FDA on May 14, 1996 substantially changed the way in which biotechnology-derived pharmaceuticals are regulated, placing greater emphasis on the methodologies used to analyze biotechnology-derived polypeptide therapeutics.

Fundamentals in Analytical Biotechnology immerses those attending in the practical aspects of characterizing and analyzing therapeutic proteins and presents in an adsorbing manner the fundamental principles and practical uses of these three analytical technologies. Those attending leave with a clear sense of where each technology is used and how to most effectively implement each technology in developing and using effective, efficient analytical methods for characterizing and analyzing therapeutic proteins.

Who Should Attend

This workshop will be of value to all regulatory, technical and QA/QC personnel who contribute to the Chemistry, Manufacturing and Controls (CM&C) document of a regulatory submission.



**FUNDAMENTALS IN
ANALYTICAL
BIOTECHNOLOGY**



July 16-18, 2001
8:15am - 5:30pm
Mississauga Convention Centre

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Fundamentals in Analytical Biotechnology

PROGRAM

Day 1

Introduction

Discussion of the history of the regulation of biotechnology-derived biopharmaceuticals focusing on recent changes in regulation of protein therapeutics..

Needs and challenges in the analysis of biotechnology-derived therapeutics will include an overview of peptide mapping, deamidation, oxidation and glycosylation as a foundation to discuss the analytical technologies.

Reversed-phase HPLC.

Basic theory and mechanism of polypeptide separations. Developing an analytical method for the analysis of polypeptides. Deciding on the right column. Selecting the elution solvent including the organic modifier, the ion-pairing reagent, the pH, the flow rate and the gradient conditions. Detection mode. The affect of Temperature. The affect of system hardware. How reversed-phase HPLC is used to meet the needs and challenges of polypeptide characterization and analysis.



Day 2

Alternative Modes of Liquid Chromatography.

Ion Exchange, High pH Anion Exchange for saccharide analysis Hydrophilic Interaction chromatography for glycan analysis Size Exclusion chromatography

Capillary Electrophoresis

Basic principles of CE. Comparison with HPLC and gel electrophoresis. Understanding basic terms in CE: Mobility, Migration, Separation efficiency, and Electroosmotic flow. Basic CE instrumentation. Sample injection. The capillary and temperature control.

Capillary Zone Electrophoresis.

Developing a CZE method including selecting the capillary, choosing the best buffers, the importance of pH, the role of the sample matrix, the use of buffer additives and choosing the correct voltage. Sample stacking, what it is and how to use it.

Capillary Isoelectric focusing. The steps in CIEF. Practical use of CIEF Capillary Gel Electrophoresis.

A brief discussion of Capillary Gel Electrophoresis and how it is used in bioanalytical separations. How capillary electrophoresis is used to meet the needs and challenges of polypeptide characterization and analysis.



Day 3

Mass Spectrometry

Basic principles and terminology of mass spectrometry

Mass analyzers.

Magnet sector. Quadrupole. Ion Trap. Time-of-Flight Ionization sources: Fast Atom Bombardment. Matrix-Assisted Laser Desorption Ionization (MALDI). Electrospray. For each ionization source, a discussion of selecting conditions, the affect of concomitant species and optimizing performance.

Interfacing mass spectrometry to HPLC and CE

Fragmentation of ions in mass spectrometry. Collisionally-Induced Dissociation (CID or CAD). In-source CID in electrospray. Post-source decay in MALDI

How mass spectrometry is used to meet the needs and challenges of polypeptide characterization and analysis. Determination of molecular weight of proteins by electrospray-MS.

Sequencing peptides by electrospray CID MS and by MALDI-MS. Approaches to the analysis and characterization of glycans. Enzyme degradation coupled with mass spectrometry.

Fundamentals in Analytical Biotechnology

Instructor

The course was developed by and will be presented by C. David Carr. David has been involved in High Performance Liquid Chromatography for over thirty years and has specialized in the application of Reversed-phase HPLC to the analysis and characterization of protein therapeutics.

He is the author of the acclaimed "*Handbook of Analysis and Purification of Peptides and Proteins by Reversed-Phase HPLC*" offered by Vydac, a principal supplier of columns for protein analysis. David also teaches courses in HPLC and HPLC-MS.

The course was developed in conjunction with the California Separation Science Society with several Technical Advisors including Bill Hancock, President of CASSS and currently Director of Proteomics at ThermoFinnigan, Rob Garnick, VP of Quality at Genentech, Alan Herman, Director of Analytical Development at Amgen and Ron Orlando of the Complex Carbohydrate Research Center in Athens, Georgia. Many others cooperated in the development of this class making it a well-rounded and well-developed exposition of protein therapeutic analysis.