Ligand Binding Assay — An AAPS DVD-ROM Training Program For Your Computer

Originally presented at the 2008 National Biotechnology Conference in Toronto

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A menu-driven, interactive course on DVD-ROM data disc containing 13 hours of video (synchronized PowerPoint slides with audio lecture, printable pdf files for each presenter, and mp3 audio files for transfer to your favorite digital audio player. On-screen instructions for each menu selection; no complicated manual needed!

Course Goals and Objectives:

Even though this training course will include LBA theory, it will emphasize practical aspects of LBAs to enable attendees to apply learning immediately following course completion. We will provide an intensive learning experience for the basic principles and regulatory (GLP) considerations of LBAs to support the bioanalysis of biopharmaceuticals.

The course spans all LBA stages from method conception, through design/optimization, validation, and implementation with test samples (preclinical through clinical) and statistical considerations.

The important aspects of LBAs for quantitative determination of therapeutic proteins and monoclonal antibodies in biological matrices will be covered.

The course will also offer an introduction to basic pharmacokinetic principles and concepts with an emphasis on biotherapeutic drug products.

Who Should Participate?

This course is intended for current pharma/biotec BS/MS lab scientists who perform or have an interest in developing/performing LBAs, recent graduates/new hires who wish to perform LBAs, non-lab scientists and professionals who want in-depth LBA training, pharmacokineticists who utilize LBA data, and regulatory professionals in the biotech field.

Course Outline:

Introduction: Ronald R. Bowsher, Ph.D. (Moderator) Millipore Corporation, B2S Consulting (00:40:00)

Module 1: ***Introduction to Biopharmaceuticals,*** Marie T. Rock, Ph.D. Midwest BioResearch, LLC (2:20:00)

Module 2: ***Basics of Macromolecule Protein Chemistry and Immunochemistry for Application to Ligand Binding Assay Development***, Bonita J. Rup, Ph.D. Wyeth Research (2:00:00)

Module 3: ***Development and Optimization of Ligand Binding Assays to Support Pharmacokinetic Assessment of Biopharmaceuticals,*** Jeffrey M. Sailstad, Sailstad & Associates (1:24:00)

Q&A (1:04:00)

Module 4: ***Pre-study and In-study Validation of Ligand Binding Assays to Support Pharmacokinetic Assessment of Biopharmaceuticals,*** Binodh S. DeSilva, Ph.D., Amgen Inc. (1:49:00)

Module 5: ***Introduction to PK/PD Analysis of Biopharmaceuticals,*** Andrew M. Vick, Ph.D. Millipore Corporation (1:49:00)

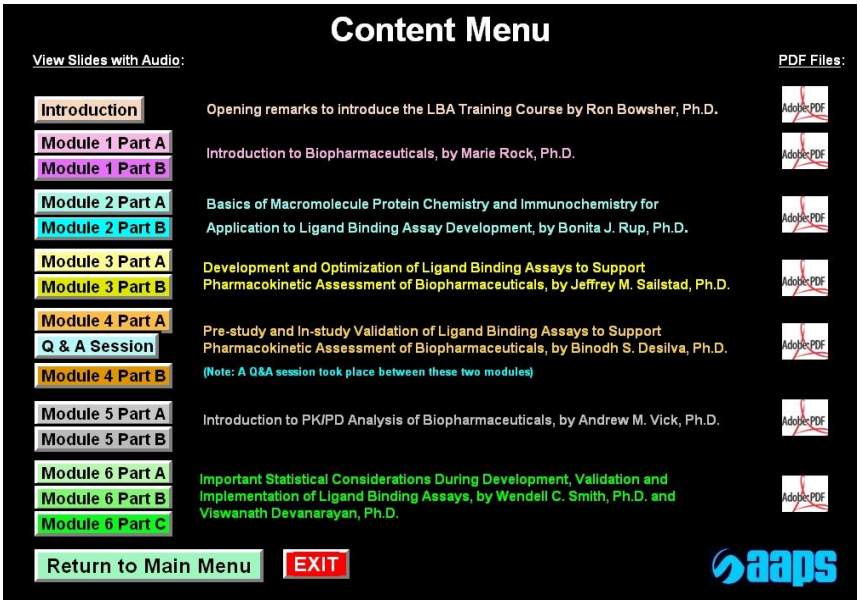
Module 6: ***Important Statistical Considerations During Development, Validation and Implementation of Ligand Binding Assays***, Wendell C. Smith, Ph.D.B2S Consulting *and* Viswanath Devanarayan, Ph.D., Abbott Laboratories (2:49:00)

PC Requirements:

Requirements include a 486 or faster PC running any version of Windows (including VISTA), a DVD-ROM player, sound card, and speakers. Windows Media Player should be installed on your computer (it probably already is), or you may obtain it free of charge at: www.microsoft.com/windows/windowsmedia/. Viewing and printing of pdf files require Adobe Acrobat or the free Adobe Reader, available at www.adobe.com

Screen Shot of Main Menu

Screen Shot of Content Menu



The LBA Training Course Faculty

Purchase Price: AAPS Members: $250. Nonmembers: $375

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