Information on Open Forums, Short Courses and Workshops

Saturday, June 23

8:30 am – 4:00 pm
TRAINING COURSE: Development and Validation of Quantitative Ligand Binding Assays

2 Day Event

An additional fee is required to attend this 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).
- We will cover important aspects of LBAs for quantitative determination of therapeutic proteins and monoclonal antibodies in biological matrices.
- This course is intended for current pharma/biotech 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.

8:30 am – 5:00 pm
BIOTEC OPEN FORUM: Flakes and Clumps: Cause, Detection, and Impact of Particulates During Bioprocessingt

An additional fee is required to attend this course.

During bioprocessing, it is not uncommon for particulates of the protein to form. These large aggregates may be caused by a variety of factors, including insolubility under processing conditions and surface denaturation. The presence of these particles can reduce the yield, impact the ability to further process, or compromise the quality of the final product. Topics of discussion for this open forum session will include the observations of particulates during bioprocessing and their impact to the product, determination of cause of the particulate formation, and the methods used to detect and characterize the particulates.

Goals and Objectives

This open forum describes the causes of large protein aggregates during bioprocessing and storage, and the challenges of accurately characterizing the size of these particulates, particularly those greater than 100 nm in size. The challenges, issues, and technological hurdles that will be discussed will provide a foundation of current knowledge and a forum for interactive discussion between attendees and presenters.

Who Should Attend

This program will benefit process development, formulation, and bioanalytical scientists in industry as well as students in pharmaceutical biotechnology programs.

Sunday, June 24

8:30 am – 4:00 pm
TRAINING COURSE: Development and Validation of Quantitative Ligand Binding Assays

(Day 2: Course Conclusion)

2 Day Event

An additional fee is required to attend this course.

8:30 am – 5:00 pm
PT OPEN FORUM: Biostabilization by Drying: Materials Science and Drying Methodologiest

An additional fee is required to attend this course.

Proteins and other biopolymers frequently do not have sufficient stability in aqueous solution to withstand the rigors of shipping and storage, even when refrigerated. Furthermore, interest in room temperature stable products has been increased by the growing importance of third world and military applications. Thus, stability remains an active area of research where there has been significant progress in the past few years. Much of this progress has involved studies that provide a better understanding of the properties of the glassy state that determine stability. The nature of the drying process may also be a critical stability variable, partly because variation in drying method can impact structural and dynamic properties of the resulting glassy material. Although drying technologies for proteins and biologicals have been focused on freeze-drying for many decades, alternatives do exist that may, under some scenarios, provide advantages relative to conventional freeze drying. This open forum is focused on understanding the stability indicating properties of glassy pharmaceuticals and the variations in these properties as the drying methodology changes, and will discuss advances in Process Analytical Technology (PAT) for freeze-drying.

8:30 am - 9:00 am
Thermodynamic and Dynamic Factors in the Stability of Native Protein Structure
John J. Hill
Amgen, Inc.

9:00 am - 9:30 am
Fast Dynamics and Protein Stability in the Solid State
Marc Cicerone
NIST

9:30 am - 10:00 am
Phase Transitions During Freeze Drying: Impact on Processing and Stability
Evgenyi Shalaev
Pfizer, Inc.

10:00 am - 10:30 am
Coffee Break

10:30 am - 11:00 am
The Quest for Complete Conformational Characterization of Proteins in the Solid State: Past Success/Failures and Future Promise
Sampath Krishnan
Amgen, Inc.

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11:00 am - 11:30 am
Relaxation, Free Volume, and Stability in Glassy Protein Formulations
Michael Pikal, Ph.D.
University of Connecticut

11:30 am - 12:00 pm
General Discussion

1:00 pm - 1:30 pm
Spray Drying of Proteins
David Lechuga
Nektar Therapeutics

1:30 pm - 2:00 pm
Spray Freeze Drying the Texas Way: A Novel Alternative to Conventional Freeze Drying
Bill Williams
Keith P. Johnston
University of Texas

2:00 pm - 2:30 pm
Foam Drying and Foam Freeze Drying: When Do We Expect Superior Stability?
Reinhard Vehring
MedImmune

2:30 pm - 3:00 pm
Coffee Break

3:00 pm - 3:30 pm
Low Temperature Spray Drying of Temperature Sensitive Products with Carbon Dioxide-assisted Nebulization
Jim Searles
Aktiv-Dry

3:30 pm - 4:00 pm
Process Analytical Technology in Drying Operations: Applications to Freeze Drying and Beyond
Henning Gieseler
University of Erlangen

4:00 pm - 5:00 pm
General Discussion and Participant Presentations
Participant presentations limited to 3 overheads or 5 minutes, whichever comes first.

Join AAPS – Your Formula for Success

8:30 am – 5:00 pm
BIOTEC OPEN FORUM: Neutralizing Antibodies to Protein Therapeutics—Assessment, Characterization, and Clinical Implications Background

An additional fee is required to attend this course.

The administration of biological therapeutics can evoke some level of immune response to the drug product in the treated subjects. A number of cases have demonstrated that immune responses comprised of neutralizing antibodies can lead to loss of efficacy or potentially more serious clinical sequelae. Therefore, it is widely accepted that the development program for a biological therapeutic should include strategies for monitoring study subjects for antibodies specific for the therapeutic product, and for assessing neutralizing potential of the antibodies should they develop. However, there is still much to be discussed regarding the optimal strategies to incorporate the monitoring into the development program, the methods used to conduct this monitoring, interpretation of the results, assessment of clinical implications, and applications to risk management and future use of the therapeutic.

Goals and Objectives
This open forum will present the challenges of monitoring for neutralizing antibodies to therapeutic proteins. The forum will cover the scope of challenges from determining a testing strategy; developing, validating and implementing the methods; interpreting of results and determining the clinical relevance; application of the information learned in risk management and future product use.

8:30 am - 8:45 am
Introductions

8:45 am – 9:15 am
Overview of Challenges of Neutralizing Antibody Assessments
Speaker to be Announced

9:15 am – 12:00 pm
SESSION I: Testing and Method Development Strategies

9:15 am – 10:00 am
Development and Validation of the Methods: Recommendations and Areas of Controversy
Speaker to be Announced

?:?? pm - ?:?? pm
Coffee Break

10:00 am - 10:30 am
Case Study – Development Challenges for a Cell Based Neutralizing Antibody Assay
Speaker to be Announced

10:30 am - 11:00 am
Case Study – Validation and Application of a Bioassay-based Neutralizing Antibody Assay
Speaker to be Announced

11:00 am - 11:30 am
Case Study—Ligand Binding vs. Bioassaybased Neutralizing Antibody Assessments
Speaker to be Announced

11:30 am - 12:00 pm
PANEL DISCUSSION: Technical Issues in the Development and Application of Neutralizing Antibody Assays

12:00 pm - 1:00 pm
Lunch

1:00 pm – 5:00 pm
SESSION II: Neutralizing Antibody Assessments in Non-clinical and Clinical Studies

1:00 pm - 1:45 pm
Immunogenicity Risk Assessments and Application to Development of Immunogenicity Testing Strategies
Speaker to be Announced

1:45 pm - 2:30 pm
Clinical Impact of Neutralizing Antibody Development
Speaker to be Announced

2:30 pm - 3:00 pm
Regulatory Expectations for Neutralizing Antibody Assessment
Speaker to be Announced

3:00 pm - 3:15 pm
Coffee Break

3:30 pm - 4:30 pm
Case Studies: Interpretation of Results, Application to Risk Management Strategies
Speaker to be Announced

4:15 pm - 5:00 pm
PANEL DISCUSSION: Implementation, Interpretation and Application of Results

8:30 am – 5:00 pm
SHORT COURSE #1: Where Did My Biologic Go – And Why?
An additional fee is required to attend this course.

Goals and Objectives

- To review the current understanding of the absorption, distribution, metabolism, and elimination (ADME) of biotherapeutics and its role in drug development; and
- To discuss the tools available for the study of the ADME of biotherapeutics rationale.

The efficacy and toxicity of biotherapeutics can be greatly influenced by their ADME properties. Understanding the processes governing these properties may allow the design of molecules with enhancements in absorption, slower clearance, or more targeted distribution. The first half of the course will provide the audience with a review of the relevance of ADME for biotherapeutic molecules, and specific discussions of the major classes of molecules. The rapid development of imaging technologies has provided researchers with a number of powerful tools for the study of ADME of biotherapeutics. In addition, imaging modalities have shown promise in serving as a bridge from nonclinical to clinical studies, allowing the prediction of the ADME of biotherapeutics in humans. With the breadth of imaging and distribution technologies now available, it is critical for the pharmaceutical scientist to choose the method that will provide the most relevant data, and allow informed decision-making. The second half of this course will focus on some of the tools available to investigators studying the distribution and fate of biotherapeutics. Each speaker will highlight the unique capabilities of these tools, with emphasis on new applications and examples demonstrating their utility in the study of the ADME of biotherapeutics.

Thursday, June 28

SHORT COURSES

8:30 am – 5:00 pm
SHORT COURSE #2: Exploring 3D Macromolecular Structures Using NCBI Tools
An additional fee is required to attend this course.

The National Center for Biotechnology Information (NCBI) presents exploring 3D molecular structures using NCBI tools, a course including lectures and computer workshops on effectively using the NCBI databases, search services, and analysis tools that focus on 3D macromolecular structure data.

Title to be Announced
Eric W. Sayers, Ph.D.
National Institutes of Health

Title to be Announced
Medha Bhagwat, Ph.D.
National Institutes of Health

8:30 am – 5:00 pm
SHORT COURSE #3: Controlled Release Formulation Strategies for Protein and Peptide Therapeutics
An additional fee is required to attend this course.

Most of the commercialized protein and peptide products are designed almost exclusively for parenteral administration, with the drawback of short half-lives and repeated administration. Parenteral delivery of proteins and peptides would benefit from the application of controlled release technology. In order to develop sustained release systems for non-parenteral protein delivery, it is critical to overcome all technical hurdles related to protein instability from formulation to site of release, and low permeability of tissue membranes to proteins. Novel formulation strategies must address all hurdles simultaneously. The short course will review the latest development by experts in this field.

Titles and Speakers to be Announced

8:30 am – 5:00 pm
SHORT COURSE #4: Critical Path Initiative Role of PK/PD for Biotechnology Products
2 Day Short Course

Organizers & Moderators
Nelson Jumbe, Ph.D.
Genentech, Inc.

Mark Peterson, Ph.D.
Amgen, Inc.

DAY 1: Oncology Targeted Therapies FOCUS

Pharmacokinetic/Pharmacodynamic (PK/PD) modeling has, thus far, been less prevalent and has had little impact on the drug development of anticancer drugs compared to antibiotics, antihypertensives, antiarrythmics, and psychotropic drugs. Among the reasons for this paucity are the difficulty in translating pre-clinical data to the clinic, the often imprecise measures of clinical efficacy (partial response), the time delay between drug administration and response/toxicity, and the nearly universal use of combination therapies. The FDA's Critical Path Initiative will hopefully provide additional impetus for intentional inclusion of modeling and simulation in the development paradigm of targeted oncology biotechnology products. Talks will cover ongoing efforts to integrate modeling and simulation into the development cycle of oncology targeted biotech products as demonstrated by novel approaches being put forward from academia and industry.

Critical Path Initiative: Role in Drug Development—FDA Perspective
Lawrence Lesko, Ph.D. *(invited)*
U.S. Food Drug Administration

Tumor Targeting: Tumor Growth Kinetics and Drug Tumor Penetration
Dane Wittrup, Ph.D. *(invited)*
Massachusetts Institute of Technology

Use of PD Biomarkers in Oncology: Challenges and Opportunities
William Manning, Ph.D.
Genentech, Inc.

Translational Modeling for Dose Selection for Oncology Molecules
Nelson 'Shasha' Jumbe, Ph.D.
Genentech, Inc.

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Model-based Predictions of Tumor Growth Dynamics in Clinical Oncology Studies
Rene Bruno, Ph.D. *(invited)*
Pharsight Corporation

Use of Dose-dense Chemotherapy in the Management of Breast Cancer
Larry Norton, M.D. *(invited)*
Memorial Sloan-Kettering Cancer Center

PANEL DISCUSSION: Challenges to Implementing Novel Approaches to Drug Development

Friday, June 29

An additional fee is required to attend this event.

8:30 am – 5:00 pm
SHORT COURSE #4: (continued)
Critical Path Initiative Role of PK/PD for Biotechnology Products

Day 2: Fast-Track Focus

Given the guidance from the FDA's Critical Path Initiative, it is important to highlight areas in Biotech drug development that have applied innovative approaches to decision making and/or acceleration of development programs. Quicker/more efficient transitioning from pre-IND, Phase I, Phase II, and Phase III can be facilitated by an integrated approach to drug development. The accessibility of PD biomarkers and similarities for same-class biologics provide opportunities to leverage knowledge from continuously growing data sets. An integrated drug development approach could include some combination of the following: PK/PD, exposure/effect, disease progression modeling and/or clinical trial simulation for leveraging all currently available information. Three broad areas of interest (drug effect modeling, PD biomarkers, and second generation molecules) will be covered followed by a panel discussion on challenges and opportunities.

Critical Path Initiative: Role in Drug Development—Industry Perspective
Diane Jorkasky *(invited)*
Pfizer, Inc.

Drug Disease Modeling
Jogarao Gobburu, Ph.D.
U.S. Food and Drug Administration

Use of PD Biomarkers: Challenges and Opportunities
Binodh De Silva, Ph.D.
Amgen, Inc.

Applied Mechanistic Modeling for Molecule Fast Tracking
Steve Martin, Ph.D.
Pfizer, Inc.

Translational PK/PD for Second Generation Molecule Development
Paul Fielder
Genentech, Inc.

PANEL DISCUSSION: When Several Molecules Target the Same Receptor: Leveraging Available data for Therapeutic Protein Design

Upcoming AAPS Meetings in 2007

JANUARY 21–26
42nd Annual Pharmaceutical Arden Conference - Best Practices for Parenteral Dosage Forms: Formulation and Process Development, Package Selection, and Manufacturing
The Thayer Hotel
West Point, NY

FEBRUARY 28–MARCH 2
FDA Pharmaceutical Quality Initiatives – A Modern Risk-Based Approach Co-Sponsored with: FDA, AAPS and ISPE
Bethesda North Marriott Hotel and Conference Center
North Bethesda, MD

MARCH 3–MARCH 6
AAPS Workshop on Effective Utilization of Lipid-Based Systems to Enhance the Delivery of Poorly Soluble Drugs: Physicochemical, Biopharmaceutical and Product Development Considerations
Bethesda North Marriott Hotel and Conference Center
North Bethesda, MD

MARCH 5–MARCH 7
AAPS Workshop on Drug Transporters in ADME: From the Bench to the Bedside
Bethesda North Marriott Hotel and Conference Center
North Bethesda, MD

MAY 22–23
AAPS Workshop on BE, BCS , and Beyond
Bethesda North Marriott Hotel and Conference Center
North Bethesda, MD

NOVEMBER 11–15
2007 AAPS Annual Meeting and Exposition
San Diego Convention Center
San Diego, CA

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