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AAPS Connection

American Association of Pharmaceutical Scientists December 2011

AAPS Biotechnology 101

Fundamentals of Biotherapeutics Development eLearning Series

The American Association of Pharmaceutical Scientists has launched an exciting new comprehensive and readily available online lecture series for students and pharmaceutical industry employees interested in learning more about the field of biologic development.

Advances in genomics, proteomics, and bioinformatics have propelled the fast growth of the biopharmaceutical industry. To support work force demand, more students are interested in this field, and workers in small molecules want to learn biotech skills to be more marketable. However, there are training gaps that need to be addressed.

Drug development of biotech products is quite different from that of small molecules, and current biotechnology curricula may lack the practical drug development aspects to prepare students for the biopharmaceutical industry.

AAPS Biotechnology 101 eLearning Series will address this gap by providing career development for workers in pharmaceuticals to expand into biopharmaceuticals, and it will augment biotech training for college students and faculties in biopharmaceutical drug development. The eLearning series contains 26 lectures in 5 modules.

For more information visit
http://www.aaps.org/Educational_Resources.

Be a Part of AAPS on LinkedIn

Over 7,000 professionals in the pharmaceutical sciences industry have joined the conversation on the official AAPS LinkedIn group. AAPS members and non-members from all over the world are able to interact with their peers and discuss the most prominent topics in the field. Topics of conversation include white papers from the latest scientific meetings, reactions to FDA and EMA guidances, and breakthrough methods targeted at treating the world's most challenging diseases.

The AAPS LinkedIn group provides a dynamic, online social avenue for you to have your voice heard on issues important to your work and expand your professional network. Members of the LinkedIn group can also engage in more targeted discussion by joining one or more of the 19 subgroups comprised from AAPS sections, focus groups, and discussion groups. Join today to begin sharing your thoughts on the pharmaceutical sciences in a new and exciting way.

Join today at http://linkd.in/osnmRO.

47th Annual Pharmaceutical Technologies Arden House Conference Nanoscience in Pharmaceuticals: Translating Fundamental Understanding to Practical Application in Drug and Device Development

March 11–14, 2012
The Thayer Hotel, West Point, NY

The unique physicochemical properties of materials on the nanoscale introduce certain challenges into most aspects of pharmaceutical R&D. For example, the ADMET properties of compounds administered as nanoparticles are very different from the same molecules dosed using macro- and microparticulate systems for reasons directly attributable to their size and surface chemistry. Fundamental understanding of the chemistry and engineering of nanomaterials and nanoparticles in

relation to their in vitro/in vivo performance, along with manufacturing and toxicity considerations, is critical to their wider acceptance and applications in drug and device development. Promising scientific strategies and approaches such as those that combine disease diagnosis with therapy (nanotheragnostics) and delivery systems for small molecules and macromolecules are progressing from bench to clinic to commercialization with the potential to profoundly affect human health. Particular emphasis will be placed on establishing and distinguishing among what is being accomplished now based on marketed products and what is feasible based on drugs and devices and combinations thereof in clinical and preclinical development. Emerging nanotherapeutics and nanodevices based on early preclinical data will be included in the discussion. There are safety concerns on the interaction of nanomaterials and nanoparticles with the human body. Other areas of concern and future development are nanoparticle pharmacokinetics, formulation and process development, and manufacturing. Quality control and regulatory aspects of nanopharmaceuticals will be highlighted throughout the conference and specifically discussed towards the end in a regulatory roundtable.

For more information visit
http://www.aaps.org/Arden2012.

AAPS Workshop on Lipid-Based Delivery for Improving Drug Absorption: Mechanistic Understanding and Practical Approaches

April 23–24, 2012
Sheraton Inner Harbor Hotel, Baltimore, MD

Goals and Objectives

This workshop aims to update the participants on the present state-of-the-art of lipid based drug delivery. The use of lipid-based drug delivery systems (LBDDS) for oral delivery is increasing, both as a result of the increasing number of poorly soluble drugs in development, and also as a result of the resent success of lipid-based system for the delivery of peptides and proteins.

The workshop will be divided into four parts focusing on the concepts and principles of LBDDS, predictive tools for development of LBDDS, practical approaches to formulate LBDDS, and the use of lipid to increase drug permeability.

For more information visit http://www.aaps.org/Lipids.

AAPS Workshop on Formulation Strategies for Nonparenteral Drug Delivery of Biotherapeutics

May 19–20, 2012
Sheraton San Diego Hotel and Marina, San Diego, CA

Goals and Objectives

Unfavorable physiochemical and pharmacokinetic properties of therapeutic peptides, proteins, and nucleic acids represent unique challenges for the development of safe and efficacious medications intended for human use. Inherent instability, combined with the macromolecular nature of this class of biotherapeutics, most often translates into preparation of lyophilized parenteral formulations. Since parenteral administration bypasses important protective barriers of the body, manufacturers have to comply with the highest FDA standards associated with parenteral drug delivery systems. This limits the use of formulation excipients and significantly increases the cost of goods. Furthermore, patients do not prefer parenteral dosage forms, as they are invasive and less suitable for self-administration. Over the past decade, novel scientific concepts have been explored to develop nonparenteral formulations for biotherapeutics that produce acceptable therapeutic efficacy. The primary objective of the workshop is to highlight promising approaches that have emerged from these efforts (e.g., oral, nasal, and pulmonary delivery systems) and successfully entered clinical development.

For more information visit
http://www.aaps.org/Formulation.

AAPS Workshop on Clinical Pharmacology and ADME Biotherapeutic Proteins

May 19–20, 2012
Sheraton San Diego Hotel and Marina, San Diego, CA

Goals and Objectives

The objectives of early clinical development of therapeutic proteins are the same as for small molecules. Researchers investigate the molecule in a manner that will gain necessary knowledge about its tolerability, pharmacokinetics (PK), pharmacodynamics (PD), safety, and efficacy. However, there are specific features of proteins that must be considered when designing clinical pharmacology studies.

This workshop provides a general overview and current thinking of the myriad factors that are relevant when designing clinical studies for therapeutic proteins. It will cover all aspects of clinical pharmacology of biotherapeutics, study design, drug-drug interactions, QT assessment, immunogenicity, pediatric studies, comparability, special populations (elderly, pregnancy, hepatic and liver failure), PK and PD bioanalysis, regulatory expectations of PK and PD characterization, as well as reviewing factors which influence the ADME of biotherapeutics.

For more information visit http://www.aaps.org/ClinPharm.