

AAPS Connection

American Association of Pharmaceutical Scientists

October 2014

AAPS Launches Three New eCourses



AAPS eCourses have been designed to address perceived training gaps in the pharmaceutical and biopharmaceutical sciences and strive to provide extensive and novel educational material to the pharmaceutical science and related communities. These eCourses are comprehensive online offerings that provide the convenience of self-paced learning. Facilitated by top researchers in the field, AAPS eCourses provide practical perspectives from practicing scientists and allow participants the opportunity to receive a Certificate of Completion.

We invite you to visit the eCourse page to learn more about these exciting projects and to view the introductory video on our YouTube channel. Check these four courses online today!



AAPS BIOTECHNOLOGY 101

Launched in 2011



AAPS REGULATORY AFFAIRS 101



AAPS IMMUNOGENICITY 101



AAPS TRANSLATIONAL SCIENCES 101

For more information visit www.aaps.org/eCourses.



AAPS members receive a discount on ecourses!



AAPS is offering a new member benefit by offering CE credits with completion of any of the three new AAPS eCourses. Look for the ACPE logo for credit hour information.

Submit an eCourse Proposal

AAPS will be accepting submissions three times a year for eCourses. The proposal submission form requires details such as proposed objectives, topics, audiences, speakers, *etc.* The AAPS Electronic Program Development Committee will review all proposals and make their selections. AAPS' goal is to increase its eCourse offerings by at least 2–3 eCourses every year.

Thank you for helping AAPS develop valuable educational opportunities for pharmaceutical scientists.

For a Proposal Submission Form visit www.aaps.org/eCourses.
Direct any inquiries to: Stacey May, MayS@aaps.org

AAPS Workshop on Improving Oral Bioavailability by Lipid-Based Delivery

November 1–2, 2014

San Diego Convention Center
San Diego

This program delves into the physico-chemical as well as the biopharmaceutical aspects of lipid formulations including: solubilization, lipolysis, and supersaturation in the gut; interactions with enterocyte-based transport processes; recruitment of the intestinal lymphatic transport for highly lipophilic compounds; advances in formulation strategies and technology platforms; and the emergence of biorelevant models for predicting lipid formulation performance *in vivo*.

Goals and Objectives

Declining drug pipelines are linked to high attrition rates and burgeoning drug development costs. Poor druggability of the pharmaceutical active molecules is by far the biggest challenge, riddled with poor aqueous solubility and/or poor permeability, variable absorption and food effects.

Many current approaches to oral bioavailability enhancement are aqueous solubility-driven, leading to a systematic exclusion of highly lipophilic drugs from development. Meanwhile, the therapeutic efficacy of emerging drugs may be traded off with enhanced aqueous solubility by altering the drugs' physical/chemical properties, adding to the cost and time of development.

Expanding the development window are lipid-based drug delivery platforms that tackle several challenges at once.

Lipid-based drug delivery systems are known to simultaneously address problems relating to drug solubility and dissolution, intestinal permeability, food effect, and variability in absorption.

The lipid approach offers also unlimited options in formulation design. From oily solutions in capsules to more complex dispersions including self-nano emulsifying drug delivery systems; solid lipid nanoparticles; adsorption on silica matrices; and melt congealing. Other recent and promising strategies involve amorphous solid dispersions by use of lipids in combination with polymers.

This workshop will provide an up to date and in-depth understanding of the lipid approach to oral bioavailability enhancement. The program covers the biopharmaceutical role of lipid excipients in oral delivery; selection of the appropriate excipient/formulation platform for different drug active types; tools for classification and characterization of formulations; and predictive *in vitro* models for assessing formulation performance.

Topics covered will include:

- Role of Lipids in Oral Absorption
- Lipids that Induce Lymphatic Transport
- Mechanisms for Intestinal Permeation
- Formulation Design and Characterization
- Supersaturation
- Nanoparticles
- SNEDDS for Insoluble Molecules
- Solid SNEDDS by Silica Matrices
- Solid Dispersions in Melt Extrusion
- Predictive Models and Tools
- Biorelevant Media Testing
- Industrial perspectives
- Stability and Process Considerations
- QbD: Lipid Formulation and Processing
- Oral Delivery of Vaccines and Peptides
- Reducing R&D Timelines and Cost
- Regulatory

For more information, please visit www.aaps.org/Lipids.

AAPS Workshop on Facing the Safety and Regulatory Challenges of Natural Products

November 2, 2014

San Diego Convention Center
San Diego

Natural products and dietary supplements, whether used by a concerned and informed end consumer or

recommended by an alternative or holistic medical practitioner, has become a large consumer market that bridges between nutritional foods and medicines. Natural products are also being actively explored as new therapeutic targets in discovery activities by pharmaceutical and biopharmaceutical organizations. The manufacturing quality and safety controls for these products are of major concern for end consumers and have become a focus for the U.S. Food and Drug Administration (FDA). The FDA applied full GMP implementation for the dietary supplement industry since October 2011. Now is a perfect time to bring together the researchers, manufacturers, and regulators to promote a full and open discussion of the future of botanical drugs and dietary supplements.

This workshop will raise awareness and provide updates on:

- insights into global trends and best practices in natural products research and manufacturing,
- major global concerns and challenges about quality and safety control of natural products and botanical drugs,
- FDA GMP regulation efforts for the dietary supplement industry,
- on how research institutions, industry, analytical vendors, and regulatory authorities can collaborate and discuss challenges, address regulatory needs and requirements, and reach global harmonization.

For more information, please visit www.aaps.org/SRC.

AAPS Workshop on Emerging Trends in Nucleic Acid and Cell-Based Therapeutics

November 2, 2014

San Diego Convention Center
San Diego

Advancements in smart polymers and more efficient carriers systems have propelled RNAi therapeutics closer to the clinic. They have also posed many unanswered questions pertaining to the relative roles and therapeutic potentials of small-interfering RNA (siRNA), short hairpin RNA (shRNA), microRNA (miRNA), antisense oligonucleotides (ODNs), plasmid DNA (pDNA) and RNA/DNA aptamers. Identification of the most effective delivering and targeting strategies of these nucleic acids remains a major hurdle in turning them into therapeutics. Moreover, the emergence of stem cell-based therapies (mesenchymal stem cells, embryonic stem cells and induced pluripotent stem cells) has added a new dimension to medical interventions. This workshop will assemble the leading experts to address the latest advances in nucleic acid therapy, from basic research to pre-clinical testing to clinical applications. It

will provide a multidisciplinary forum, wherein scientists can educate, interact and discuss the recent advances and challenges in various aspects of cell and gene therapy.

- Provide the latest update on RNAi-based and stem cell-based therapeutics.
- Discuss the critical issues regarding the delivery of siRNA, shRNA, miRNA and pDNA.
- Discuss the roles of stem cells in immune tolerance and their use as gene delivery vehicles.
- Share insights into the bottlenecks of the clinical translation of RNAi-based and stem cell-based therapeutics.
- Engage and inspire more scientists to address the challenges in these research fields.

For more information, please visit www.aaps.org/NucleicAcid.



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