EPTM
EASTERN PHARMACEUTICAL TECHNOLOGY MEETING

The Future of Pharmaceutical Business-Academic-Industry Collaboration for Better Innovation

As drug discovery is moving forward, the pharmaceutical industry is constantly under fire to produce novel and superior quality drug products using innovative technologies for the benefit of patients. In recent years the pharmaceutical industry has focused on stronger ties with academia to speed up drug development with lower cost and limited resource. In this conference we are inviting the leaders and scientific experts from industries and academics for an open discussion on the future of drug development processes and challenges. This conference will provide insight into novel solutions into different areas such as Drug Delivery for Small and Large molecules, Bio-pharmaceutics challenges, Personalized medicine, Quality by Design, etc. With the significant increase of poorly soluble compounds from the discovery phase, enabling drug delivery systems are essential to deliver these molecules in adequate concentration to the specific sites for therapeutic efficacy. At the same time, bio-pharmaceutical challenges becomes a critical factor for dealing with such type of compounds. Similarly, personalized medicine promises to revolutionize the global healthcare industry for improving patient compliance. Finally, the recent focus of health authority on quality by design opened an enormous opportunity for collaboration between industry and academic for future drug development. Enjoy!

EPTM
EASTERN PHARMACEUTICAL TECHNOLOGY MEETING

Program

7:30 AM	Registration
8:00 AM	Introduction: Committee Members and EPTM Mission *Narendra Desai (Pfizer Alumni), EPTM Chair*
	Introduction: Symposium Theme *Indrajit Ghosh (Celgene) EPTM Program Chair*
8:15 AM	Personalized Medicine *Dr. Patrick Sinko, Associate VP of Research & Distinguished Professor, Pharmaceutics Dept., Rutgers University*
9:00 AM	Enabling Pharmaceutical Products Utilizing Extrusion Technologies *Dr. Chad Brown, Principal Scientist, Merck*
9:45 AM	Coffee Break
10:15 AM	The Future of Pharmaceutical Business-Academic-Industry Collaboration: Biopharmaceutics Challenges in Drug Delivery of Small Molecules and Biologics & Areas for Collaboration *Dr. Munir Hussain, Distinguished Research Fellow, Bristol Myers Squibb*
11:00 AM	Platinum Sponsor Presentation *Terry Robinson, Executive Director, Catalent Pharma Solutions*
11:15 AM	Don't Leave Money on the Table: Collaborative Product Development for Better Patient Outcomes *Cornell Stamoran, VP of Strategy and Corporate Development, Catalent Pharma Solutions*
12: 00 PM	Lunch
1:30 PM	Tumor-Targeted Nanotherapeutics *Dr. Tamara Minko, Distinguished Professor and Chair, Pharmaceutics Dept., Rutgers University*
2:15 PM	Prospects and Case Studies of Amorphous Solid Dispersion, A Leading Solubilization Technology *Dr. Vivian Bi, Technical Director of Solubilization and Contract Services, Ashland Inc.*
3:00 PM	Coffee Break
3:30 PM	Round Table
4:00 PM	Closing and Thank You

EASTERN PHARMACEUTICAL TECHNOLOGY MEETING

Patrick Sinko, PhD

Associate VP of Research &
Distinguished Professor
Dept. of Pharmaceutics
Rutgers University

Biography

Dr. Patrick J. Sinko is a Pharmacist (BS, Rutgers) and a Pharmaceutical Scientist (PhD, Pharmaceutics, University of Michigan). He is Associate Vice President for Research at Rutgers – The State University of New Jersey, has the academic rank of Distinguished Professor and is the Parke-Davis Chair Professor in the Ernest Mario School of Pharmacy. Dr. Sinko has served on numerous scientific advisory and review panels in the United States and Europe. He also serves on a Scientific Advisory Committee for the PhRMA Foundation. Dr. Sinko was Section Editor for the European Journal of Pharmaceutical Sciences and is an Editorial Advisory Board member for several journals. Dr. Sinko was elevated to Fellow status in the AAPS and AAAS. He was the founding Chair of the AAPS Nanotechnology Focus Group and served on the Controlled Release Society's Board of Scientific Advisors. Dr. Sinko was also elected to serve on the Council of the American Association for the Advancement of Science. He maintains an active research program focusing on biopharmaceutics and nanoscale drug delivery with specific applications to AIDS, breast and lung cancer, chemical terrorism countermeasures and TB. Dr. Sinko has authored numerous peer-reviewed scientific papers, books, book chapters, abstracts and has numerous issued and pending patents. Dr. Sinko has received several awards for his research and teaching during his career including the Rutgers University Board of Trustees Award for Excellence in Research and a highly selective NIH MERIT Award for his research group's efforts in developing nanocarriers to fight HIV infection.

Personalized Medicine

EASTERN PHARMACEUTICAL TECHNOLOGY MEETING

Chad Brown, PhD

Principal Scientist
Merck

Biography

Chad Brown is a Principal Scientist at Merck where he has led a global extrusion technology development team for six years. Chad has a PhD in bioengineering from the University of Washington and a BS in Chemical Engineering from Colorado State University. Chad has experience utilizing extrusion technologies from gram-scale prototype development and feasibility to metric ton manufacture in preparation of commercial launch.

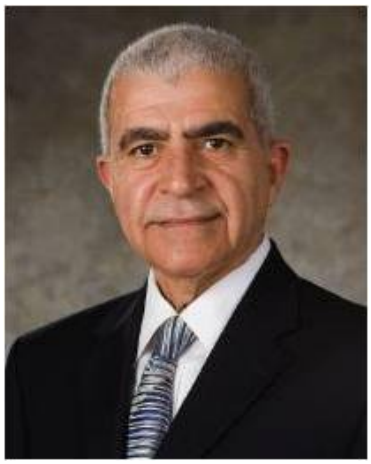
Enabling Pharmaceutical Products Utilizing Extrusion Technologies

Solid solutions of pharmaceutically active compounds where the drug substance is dissolved in and stabilized by a polymeric carrier have been used successfully in the pharmaceutical industry to increase apparent aqueous solubility and thus oral bioavailability. Compounding in a co-rotating twin screw extruder is an efficient and commercially viable means to produce uniformly blended solid solutions of pharmaceutical intermediates. Scale-up is rapid and the factors that are critical to maintaining quality are well-understood. In addition, these quality attributes can be monitored using process analytical tools, potentially allowing for increased process robustness and process control.

Solid solution intermediates can be utilized to design diverse pharmaceutical products. In addition to milling extrudate intermediates to produce traditional immediate release tablets, alternative formulations can also be developed to extend life-cycle value, such as modified release formulations, and suspension preparations. Furthermore, economically favorable continuous processing techniques such as profile extrusion, calendaring, or injection molding can be called upon to manufacture high drug load tablet formulations, complex combination products, or aid in anti-counterfeiting strategies.

Finally, by utilizing ancillary extrusion technologies, such as devolatilization and foaming, additional technical and economic benefits can be realized. Traditional devolatilization techniques to remove solvents during compounding can be implemented to replace inefficient drying steps during the manufacture of active ingredients or enable the rejection of impurities via solvate formation. Chemical or physical foaming of extrudate can be employed to improve milling performance and provide more rapid dissolution through increased surface area.

EPTM
EASTERN PHARMACEUTICAL TECHNOLOGY MEETING



Munir Hussain, PhD

Distinguished Research Fellow
Bristol Myers Squibb

Biography

With about 30 years of experience in pharmaceutical development, Dr. Munir Hussain is currently a Distinguished Research Fellow in Drug Product Science & Technology at Bristol-Myers Squibb Company. His research interests include drug delivery, preformulation, dissolution, formulation development and scale-up, and mechanisms of degradation and stabilizations of drugs. Some of his major contributions include development of products such as Cozaar/Hyzaar tablets, Sustiva tablet, and Atripla tablet. He holds/held adjunct professor appointments at the School of Pharmacy, Duquesne University; College of Pharmacy, University of Kentucky; School of Pharmacy, Temple University; College of Pharmacy, University of Tennessee; and served as a board member, College of Pharmacy and Pharmaceutical Sciences, Florida A&M University. He serves/served as a member on many graduate students' research committees; and other external committees such as PQRI, NIH, and USP. He is a member of the editorial boards of the Journal of Pharmaceutical Sciences, Journals of Pharmaceutical Development and Technology and AAPS PharmSciTech. He is the author/co-author of over 100 refereed publications in different areas of pharmaceutical sciences, over 100 abstracts/national and international seminars, and 14 issued patents. He is a Fellow of the American Association of Pharmaceutical Scientists (1993); Life Science Leadership-Inspiring Innovation in the Life Sciences, New Jersey Association for Biomedical Research (2010); and is a committee member for USP 2010-2015 – General Chapters "Dosage Form Expert Committee".

The Future of Pharmaceutical Business-Academic-Industry Collaboration: Biopharmaceutics Challenges in Drug Delivery of Small Molecules and Biologics & Areas of Collaboration

Currently there is an increased need for collaboration between industry and academia for many reasons including the current economic environment that leads to selective research spending; reduced hiring by industry; growing expertise in academia that is directly relevant to pharmaceutical R&D; complementary skills /expertise in areas such as modeling that is widely and increasingly used in the industry. Areas for collaboration in product development and dosage form design will be discussed and highlighted with case studies. Also, a process for managing the collaboration by industry will be suggested. For small molecules, biopharmaceutical challenges that result in compromised oral absorption of poorly water-soluble drugs and approaches to enhance absorption based on the underlying mechanism will be discussed. Recurring drug delivery risks such as food-effect and pH-effect, formulation challenges with fixed dose combinations, and prediction of powder/tablet sticking issues will be covered. For large molecules/biologics protein aggregation and research towards development of high concentration protein formulation for S.C. administration will be discussed.

EASTERN PHARMACEUTICAL TECHNOLOGY MEETING

Terry Robinson

Executive Director
Catalent Applied Drug Delivery Institute
Catalent Pharma Solutions

Biography

Terry Robinson was named Executive Director of the Catalent Applied Drug Delivery Institute as of February 2013. Terry is responsible for establishing industry relations, academic programs, education and technology development. Ms. Robinson has over 25 years of experience in pharmaceutical strategy, development and account management. Her expertise includes bringing business and technical leaders together to create shared vision and achieve mutual objectives. Prior to her current role, Ms. Robinson was Executive Director of Global Accounts responsible for Catalent's largest strategic customers. She joined Catalent in 2008 as Director of Global Accounts. Prior to Catalent, Ms. Robinson worked for Amgen, Inc. as a Sr. Manager of Corporate Accounts. Previously, she held a number of positions at Eli Lilly & Company serving as a member of their Business to Business team focused on retail drug chains, drug wholesalers and hospital health systems. Ms. Robinson holds a Bachelor's degree in Psychobiology as well as a Certificate in Aging Studies from The University of Virginia. from The University of Virginia

Platinum Sponsor Presentation

EASTERN PHARMACEUTICAL TECHNOLOGY MEETING

Cornell Stamoran

Founding Board Member
VP of Strategy & Corporate Development
Catalent Pharma Solutions

Biography

Cornell Stamoran serves as Vice President of Strategy & Corporate Development for Catalent Pharma Solutions, the leading global provider of development solutions and advanced delivery technologies for drugs, biologics, and consumer health products. Mr. Stamoran leads Catalent's strategic planning and market intelligence efforts, as well as supporting its global M&A and technology acquisition activities. He also serves at Catalent's investor relations officer, and a Director of Catalent's Applied Drug Delivery Institute. Cornell has spent nearly 25 years engaged with the health care industry, including 20 years in advanced drug and biologic delivery. Cornell has directly participated in the development of drug design-enabled adherence and outcomes enhancement strategies for more than 150 branded drugs over the last 10 years. During his 20 year tenure at Catalent, Mr. Stamoran has held many roles across a variety of disciplines, strategic business and technology planning; sales/business development; market intelligence; corporate development; marketing and branding; innovation; IT; and public and investor relations. He holds several professional certifications, including Certified Licensing Professional, Certified Management Accountant, Certified Public Accountant, and Certified Information Systems Auditor, and is a graduate of the University of Michigan.

Don't Leave Money on the Table: Collaboarative Product Development for Better Patient Outcomes

This discussion will take a controversial look at the payor/physician/patient perspective on sub-optimal recent drug performance. The speakers will focus on the following areas during this presentation:

- Providing a solution to sub-optimal drug performance:
  - Show the understanding of this REAL WORLD situation,
  - Explain why it is important to not just solve immediate problem, but optimize
- Describe how COLLABORATION with both DRUG DELIVERY Providers (for dose design optimization and basic disease state understanding) AND Academia (for advanced clinical input) EARLY IN DEVLEOPMENT can give them a better return on R&D spend, and minimize clinical/payor risk
- Showcase a practical "how-to" guide of the above process
- Introduce Terry Robinson & the Catalent Institute, and she will elaborate on how to build these bridges and knowledge for the industry/academia

EASTERN PHARMACEUTICAL TECHNOLOGY MEETING

Tamara Minko, PhD

Distinguished Professor and Chair
Department of Pharmaceutics
Rutgers University

Biography

Dr. Tamara Minko is a Distinguished Professor and Chair of the Department of Pharmaceutics, Rutgers, The State University of New Jersey. Her current research interests include nanoascale-based targeted delivery of drugs, peptides, siRNA and antisense oligonucleotides; biopharmaceutics; nanotechnology (polymers, dendrimers, liposomes, etc.) for detection and treatment of various pathological conditions including cancer and fibrosis; molecular targeting; mechanisms of multidrug resistance; intracellular fate and molecular mechanisms of action of anticancer drugs: apoptosis and necrosis, signal transduction, antiapoptotic cellular defensive mechanisms; preclinical evaluation of anticancer drugs; tumor hypoxia; modulation of cell death mechanisms during hypoxia. Professor Minko is an author and co-author of more than 400 publications including peer-reviewed papers, book and textbook chapters, conference proceedings and patents. Dr. Minko is a Member-at-Large and member of Board of Directors of the Controlled Release Society, AAPS Fellow, recipient of numerous awards, Editor of Pharmaceutical Research, member of editorial board of nine scientific journals and a member of study sections at NIH, DOD and other review panels. Her research is supported by grants from NIH, NSF, DOD and other national and international sources.

Tumor-Targeted Nanotherapeutics

Directing anticancer agents specifically to tumors and/or cancer cells by targeting specific extracellular receptors fulfills the following three most important tasks: (1) preventing or at least substantially limiting adverse side effects on healthy tissues, (2) enhancing drug internalization by cancer cells, and (3) overcoming (at least in part) resistance mechanisms that are based on the active efflux of exogenous drugs from cancer cells.

We developed several tumor-targeted nanoscale-based formulations that include in different experiments: various nanocarriers (liposomes, lipid nanoparticles, dendrimers, polymers, quantum dots, mesoporous silica and supermagnetic iron oxide nanoparticles); different anticancer drugs (doxorubicin, paclitaxel, camptothecin, and cisplatin); suppressors of cellular drug resistance and tumor grows (antisense oligonucleotides or siRNA targeted to BCL2, MDR1, MRP1, HIF1A, CD44 mRNA); and tumor-targeting agent - luteinizing hormone-releasing hormone (LHRH).

The proposed nanotherapeutics were tested *in vitro* and *in vivo* using established lung and ovarian cancer cell lines and highly metastatic cancer cells isolated from malignant intraperitoneal ascites from patients with advanced ovarian carcinoma. These cells were used to initiate subcutaneous tumor xenografts in nude mice that were often accompanied by the development of intraperitoneal metastases. Treatment with these therapeutics led to the suppression of targeted proteins, efficient induction of cell death, effective tumor shrinkage and additionally, prevented the development of metastases.

EASTERN PHARMACEUTICAL TECHNOLOGY MEETING

Vivian Bi

Technical Director of Solubilization and Contract Services
Ashland Specialty Ingredients
Ashland Inc.

Biography

Dr. Vivian Bi is the Technical Director of Solubilization and Contract Services at Ashland Specialty Ingredient (ASI). She has held various positions in Pfizer Global R&D, Vertex Pharmaceuticals and AstraZeneca Pharmaceuticals before joining ASI. In her most recent role at AstraZeneca, she was the head formulator of Medicine Evaluation in US/UK region and led global formulation network. She also led the global team to build the lipid-based drug delivery systems (LBDDS) capacity within the company. Her research interests are oral and parenteral drug delivery systems. Dr. Bi has published over 50 research papers, abstracts and patents. Dr. Bi obtained her B.Eng. degree from Shenyang Pharmaceutical University in China, and completed her Ph.D. in Pharmaceutical Science from Meijo University in Japan. She has served as reviewer for peer-reviewed journals such as Pharmaceutical Research and Journal of Pharmaceutical Sciences, a steering committee member of the LBDDS focus group of AAPS, and a co-advisor of a Ph.D. student in Temple University.

Prospects and Case Studies of Amorphous Solid Dispersion, A Leading Solubilization Technology

As poorly soluble compounds became one of the major challenges in drug development, solubilization technologies, such as solid dispersions, complexation, size reduction and lipid-based formulations, have been significantly advanced in recent years. The selection the right solubilization technologies not only requires a thorough understanding on the APIs itself, but also required extensive knowledge on the interplay of solubility and permeability when different technologies are used. In addition, thorough understanding on excipients and processes are essential. In this presentation rational formulation design for poorly soluble compounds will be discussed by covering the following topics:

- How to choose suitable formulation technologies for poorly soluble APIs: Interplay of solubility and permeability
- What should be considered when selecting excipient to maximize formulation performance: Physicochemical properties, processability, regulatory considerations and beyond
- When should formulation process be considered and how does this impact formulation selection: Understand advantages and limitations of different process technologies
- Art of formulating poorly soluble compounds: Case studies

EPTM
EASTERN PHARMACEUTICAL TECHNOLOGY MEETING

A Generous Thank You To All Our Sponsors

Catalent
APPLIED DRUG DELIVERY INSTITUTE

MEGGLE
EXCIPIENTS & TECHNOLOGY

ASHLAND
With good chemistry great things happen.™

Colorcon

Celgene

BASF
The Chemical Company

Your support has brought us today's program