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Co-Located Event:*
Tenth Annual

PEGS

the essential protein engineering summit

May 5-9 PEGSummit.com

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Cambridge Healthtech Institute,
250 First Avenue, Suite 300,
Needham, MA 02494
www.healthtech.com

May 5 - 7, 2014

Seaport World Trade Center | Boston, MA

Biologics Formulation & Delivery SUMMIT

Shaping the Future of Delivering
Biotherapeutics – What's on the Horizon

PART 1 May 5 - 6

Formulation Strategies for Improved Delivery of Biologics

*Overcoming Challenges in Injectable Drug Delivery
via Breakthrough Delivery and Device Strategies*

PART 2 May 6 - 7

New Technologies for Biologics Delivery and Targeting

*Driving Innovation through New Targets,
Effective Tools, Next-Gen and Alternate
Delivery Technologies*

Special Highlights:

- 30+ Presentations from Distinguished Speakers
- 3 Short Courses
- Poster Session and Poster Award
- 10 Student Fellowship Awards
- 100+ Exhibitors in a Shared Exhibit Hall with PEGS Summit
- Network with 1600+ Attendees in a Joint Grand Opening Reception and Networking Breaks

Featured Speakers:



Omid Farokhzad, M.D., Associate Professor, Laboratory of Nanomedicine and Biomaterials, Department of Anesthesiology, Brigham and Women's Hospital and Harvard Medical School



Julia Rashba-Step, Ph.D., Senior Director, Advanced Drug Delivery, Pfizer, Inc.



Ashutosh Chilkoti, Ph.D., Theo Pilkington Professor of Biomedical Engineering; Director, Center for Biologically Inspired Materials and Materials Systems, Duke University



Mansoor M. Amiji, Ph.D., Distinguished Professor and Chairman, Department of Pharmaceutical Sciences, School of Pharmacy, Northeastern University

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Dear Colleague

On behalf of Cambridge Healthtech Institute (CHI), I invite you to the Inaugural **Biologics Formulation and Delivery Summit**, May 5-7, 2014, at the Seaport World Trade Center in Boston, MA.

This 2-part summit will include expert presentations, case studies, interactive breakout discussion groups, poster session with poster award, workshops and networking opportunities, and will provide a forum for all involved in formulation development and delivery of biologics to share ideas, proven practices, and recent research findings.

The summit is an excellent place to initiate new collaborations and interact with colleagues from around the world who are facing similar challenges and utilizing compelling strategies. The summit is co-located with the 10th Annual PEGS: the essential protein engineering summit providing an opportunity to network with 1600+ attendees in a shared exhibit hall, opening reception, and networking breaks.

CHI's Biologics Formulation and Delivery Summit will be an informative and enjoyable experience for those who attend. I am thankful to all the faculty and program advisors; since without their important contributions and guidance, the summit would not exist.

In addition, we thank you for encouraging your colleagues to attend what we believe will be a dynamic, informative and enjoyable conference experience.

Please review the following conference agendas, and contact me with any questions.

I hope to see you this coming May in Boston!

Sincerely,

Nandini Kashyap
Conference Director
Cambridge Healthtech Institute
Ph: 781-972-5406
Email: nkashyap@healthtech.com

Who Should Attend

VPs, Directors and Senior Scientists specializing in Protein, Peptide and Vaccine Formulation Development, Pre-Formulation, Pharmaceuticals, Drug Delivery, Pharmaceutical R & D, Novel Drug Delivery, Drug and Device Delivery, Devices, Ocular Delivery, Parenteral Delivery, Product Development, Analytical Chemistry, Partnering, Licensing & Alliance Management, Life-Cycle & Portfolio Management, Chemical Engineering, Biomedical Engineering, Regulatory, Intellectual Property

Reasons to Attend

- **Attend** three days of conferences dedicated to challenges and opportunities in protein and peptide delivery from distinguished industry experts from MedImmune, Allergan, Shire, MannKind, Novartis, Pfizer, Northeastern University, Duke University and many more
- **Participate** in three interactive short courses geared towards turning your technologies into successful patient-friendly products
- **Gain** new information, ideas and insights to take home and immediately apply to your lab and your career
- **Progress** your biologics delivery programs by applying the learning from case studies on breakthrough devices and formulation strategies to solve the most pressing challenges in formulation and delivery of high dose biologics formulations
- **Adapt** new technologies and tools to overcome complexities in developing alternate delivery approaches, protein targeting and breaching the blood brain barrier
- **Network** with attendees and exhibitors during the informal problem solving break out discussion sessions, in the vibrant exhibit hall shared with PEGS Summit, during poster sessions and refreshment breaks to find out what's new and happening in macromolecule delivery



Present a Poster

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure a poster board and inclusion in the conference materials, your abstract must be submitted, approved and your registration paid in full by March 14, 2014.

- Your research will be seen by leaders from top pharmaceutical, biotech, academic and government institutes
- Your poster abstract will be published in the conference materials
- Receive \$50 off your registration fee

Student Fellowships

Showcase your research with a poster in front of an international delegation.

Student Fellowship Award Winners will Attend the Biologics Formulation & Delivery Summit for Only \$195.

Full-time graduate students and Ph.D. candidates are encouraged to apply for the **Biologics Formulation & Delivery Student Fellowship**. Ten fellowship award winners will receive a poster presentation slot and a \$950 savings on their registration fee. Apply online by February 14, 2014.

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Short Courses*

SUNDAY, MAY 4
MORNING COURSE | 10:00 AM - 1:00 PM

SC1: Challenges and Opportunities in Protein and Peptide Drug Delivery

Proteins and peptides represent a significant segment of the therapeutics spectrum with many promising candidates under early development or in late-stage clinical trials. Several of these molecules are poised to make a substantial impact, especially in the under-represented or unrepresented categories such as neurological disorders and neurodegenerative diseases. A key challenge to be overcome with protein and peptide based biologics, however, is their effective delivery to the target site while achieving the optimum balance of stability, safety, bioavailability, and patient compliance. This short course will provide a broad overview of the opportunities and challenges in the development of the next generation of protein and peptide therapeutic delivery systems.

Topics to be covered:

- Therapeutic spectrum
 - o Introduction to biologics based on proteins and peptides
 - o Different classes of protein and peptide biologics
 - o Representative examples in clinical use
 - o New molecules under development – next-generation biologics
- Clinical needs and opportunities
 - o Clinical advantages of biologics over small molecules
 - o Current niche served by protein and peptide biologics
 - o Unrepresented clinical indications and opportunities
- Key challenges in protein and peptide delivery
 - o Issues related to stability
 - o Route of administration
 - o Biological barriers (e.g. blood-brain barrier)
 - o Bioavailability for therapeutic benefit
- o Safety/toxicity balance
- New developments in enhancing protein stability
 - o Use of biostable/ synthetic scaffolds
 - o Chemical modifications
 - o Packaging in nano and mesoporous carriers
 - o Molecular chaperones for enhanced serum stability
- New developments in overcoming delivery challenges
 - o Integration of delivery vectors with biologics
 - o Protein/peptide API-based nanomaterials
 - o Alternate routes/interfaces for administration
 - o Transgenic delivery systems
- Future directions in protein and peptide delivery
 - o New clinical indications
 - o Novel delivery systems
 - o New routes of administration

Instructor:

Pankaj Karande, Ph.D., Assistant Professor, Department of Chemical & Biological Engineering, Center for Biotechnology and Interdisciplinary Studies, Rensselaer Polytechnic Institute

AFTERNOON COURSE | 2:00 - 5:00 PM

SC2: Converting Emerging Delivery Technologies into Successful Patient-Friendly Therapies

The discussion will focus on non-injectable technologies such as nasal, pulmonary, and oral delivery technologies, and the challenges and opportunities in development for converting these technologies into successful products. In addition, the discussion will address the category of technologies sometimes referred to as minimally-invasive that has the potential to significantly improve the

patient experience. Technologies in development in this area will be discussed along with the pros and cons. Finally, a number of commercial examples will be reviewed as case studies where non-invasive or minimally invasive technologies have been successfully commercialized.

Topics to be covered:

- When and where to introduce delivery into the product development pipeline
- Technology and strategy selection and implementation
- Opportunities in non-invasive and minimally invasive technology approaches for delivering biologics
 - o Pulmonary inhalation
 - o Nasal spray
 - o Oral delivery systems
 - o Implants
- Emerging approaches using delivery formulation and device strategies
 - o Microneedles
 - o Active transdermal systems
 - o Oral device delivery
- Effect of various technologies on drug product stability and deliverability. What are the strategies and tools for assessment?
- Case studies of late stage development programs and commercial product examples such as Zosano PTH microneedle patch in Phase III, Exubera insulin inhalation, Lupron depot yearly implant, FluMist nasal spray vaccine

Instructors:

Christopher A. Rhodes, Ph.D., President, Christopher A. Rhodes & Associates LLC
Frank Tagliaferri, Ph.D., Vice President, R&D, 4P Therapeutics

TUESDAY, MAY 6 | 6:00 - 9:00 PM

SC3: Development of High-Dose Biologics Dosage Forms (Dinner will be served)

Topics to be covered:

- Why are high concentration dosage forms increasingly becoming important?
- What are the challenges of high doses? What factors define them?
- Viscosity limitations in production and delivery
- Current state of the art with devices for high-volume injections
- Current understanding of what causes high viscosity in mAbs
 - o Studies probing underlying molecular mechanisms
 - o Engineering high viscosity causing molecules
 - o High-throughput (HT) methods for measuring viscosity: Ensuring accuracy and precision
 - o HT screening tools for predicting viscosity
 - o Excipients for reducing viscosity
 - o Aggregation in high-concentration formulations
 - o Temperature dependence of viscosity
- Fill/finish challenges
- Alternate methods of producing high concentration MAb solutions

* Separate Registration Required

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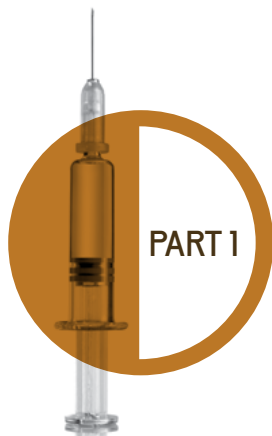
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May 5 - 6, 2014

Cambridge Healthtech Institute's Inaugural

Formulation Strategies for Improved Delivery of Biologics

Overcoming Challenges in Injectable Drug Delivery via Breakthrough Delivery and Device Strategies

The safety and efficacy of protein and peptide therapeutics are limited by *in vitro* and *in vivo* instability, immunogenicity and short circulating half-lives. CHI's inaugural **Formulation Strategies for Improved Delivery of Biologics** conference will discuss new formulation approaches designed to overcome biologics delivery issues such as chemical modifications, new formulations and delivery technologies and advanced analytical tools to characterize protein interactions with excipients. These strategies have the potential to facilitate the development of next-generation peptide and protein therapeutics which are safe, efficacious and promote patient compliance.

SUNDAY, MAY 4

9:00 am – 4:00 pm Pre-Conference Registration

10:00 am – 1:00 pm SHORT COURSE 1: Challenges and Opportunities in Protein and Peptide Drug Delivery*

2:00 – 5:00 pm SHORT COURSE 2: Converting Emerging Delivery Technologies into Successful Patient-Friendly Therapies*

**Separate registration required. See page 3 for details*

MONDAY, MAY 5

7:00 am Registration and Morning Coffee

8:30 Chairperson's Opening Remarks

Christopher A. Rhodes, Ph.D., President, Christopher A. Rhodes & Associates LLC

CHALLENGES AND STRATEGIES FOR FORMULATION AND DELIVERY OF BIOLOGICS

» 8:40 KEYNOTE PRESENTATION: The Growing Role of BioTherapeutics Delivery: Opportunities and Challenges

Julia Rashba-Step, Ph.D., Senior Director, Novel Delivery Technologies, Pfizer, Inc.

There is a rapidly changing environment with the constantly growing role of BioTherapeutics. The presentation will cover thoughts on the future trends on BioTherapeutics and importance of drug delivery in commercial, clinical differentiation and also the need for enabling technologies. Also it will cover strategic plans for current and future delivery reflective of needs of Pfizer's BioTherapeutics portfolio.

9:10 Strategies and Consideration for Developing Parenteral Protein Device Combination Products

Sujit K. Basu, Ph.D., Senior Director, Global Technical Operations, Shire

This talk will discuss various considerations and strategies for developing innovative injectable delivery technologies. Examples will be drawn from our

intrathecal delivery programs to discuss role of new approaches such as protein device combinations in successfully delivering injectable biotherapeutics.

9:40 Formulation Considerations for Various Routes of Drug Administration

Carsten Olbrich, Ph.D., Senior Scientist, Formulation Development, Bayer Pharma AG

Different application routes (iv, sc, ocular) require different drug properties, which can be influenced, at least in part, by an appropriate formulation. Important aspects will be presented accompanied by some practical experiences and case studies.

10:10 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

11:10 A Novel Drug Complex/in situ Gelling Delivery Technology for Oral Biologics

Weiguo Dai, Ph.D., Scientific Director, Fellow, Drug Product Development, Johnson & Johnson

Oral delivery of biologics has been a great challenge for years due to limited absorption and poor stability in the gastrointestinal tract. An approach to incorporate drug complex into an in situ gelling formulation will be presented. This novel drug delivery technology can enhance oral bioavailability significantly and provide a new approach to oral delivery of biologics.

11:40 pH and Excipient Effects on Viscosity and Intermolecular Interactions in High-Concentration Monoclonal Antibody (mAb) Solutions

Sarangapani Prasad, Ph.D., Post Doctoral Research Fellow, MedImmune, Inc.

High solution viscosity is a significant challenge for the development of high-concentration protein formulations. In this presentation, we will discuss the role of pH and excipient effects on viscosity and intermolecular interactions in high-concentration protein solutions such as monoclonal antibody (mAb) solutions.

12:10 pm Sponsored Presentation (Opportunity Available)

12:25 Luncheon Presentation (Opportunity Available) or Enjoy Lunch on Your Own

12:55 Session Break

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DEVELOPING STABLE PROTEIN AND PEPTIDE FORMULATIONS FOR BETTER DELIVERY

2:00 Chairperson's Remarks

2:05 Lyophilized siRNA Nanosome Formulation

Tarun Mandal, Ph.D., McCaffrey/Norwood Endowed Professor of Pharmacy & Director, Center for Nanomedicine & Drug Delivery, College of Pharmacy, Xavier University of Louisiana

Sequence specific gene silencing based on RNA interference (RNAi) holds great promise for molecular-targeted treatment of various diseases. However, delivery of siRNA presents a special challenge due to its rapid *in vivo* degradation, large molecular weight, and polyanionic charge. In this study, cationic lipid (DOTAP)-based non-toxic formulations were developed for the treatment of HCV.

2:35 Highly-Automated Procedures for the Assessment of Protein Formulations

Russell G. Burge, Ph.D., Application Scientist, Freeslate, Inc.

A highly automated process was devised to prepare and analyze samples for the formulation development of proteins. Automation increased efficiency of the activities compared to current methods and procedures. Forty eight protein formulations were generated together with placebos. Automated procedures were employed for appearance (color, turbidity, and particles), viscosity, and pH testing. Spectrophotometry, chromatography and light scattering were performed using semi automated procedures. Performance of the formulations was evaluated after subjecting the vials to stress conditions.

Sponsored by



3:05 Protected Peptide Nanoparticles: Experiments and Brownian Dynamics Simulations of the Energetics of Assembly

Robert K. Prud'homme, Ph.D., Professor and Director Program in Engineering Biology, Department of Chemical & Biological Engineering, Princeton University

Soluble peptides, susceptible to degradation and clearance in therapeutic applications, have been formulated into protected nanoparticles for the first time through the process of kinetically-controlled, block-copolymer-directed rapid precipitation using Flash NanoPrecipitation. Complimentary Brownian dynamics simulations qualitatively model the nanoparticle formation process. Additionally, the influence of the polymer-peptide interaction energy on the efficiency of nanoparticle protection by polymer surface coverage is elucidated in both experiments and simulations. Approaches to encapsulate, and protect more soluble polypeptide constructs using conjugation strategies will be presented.

3:35 Viscous Injection Delivery: A Novel Tapered Needle for Improved Flow Performance, with Unique Tip Geometry to Reduce Penetration Force

Kevin Constable, Director, Technology Development, Global Pharmaceutical Solutions, Terumo Medical Corporation

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4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 Problem Solving Breakout Discussions

5:45 Welcome Reception in the Exhibit Hall with Poster Viewing

6:45 End of Day

TUESDAY, MAY 6

8:00 am Morning Coffee

DEVICES FOR HIGH DOSE / HIGH VOLUME DELIVERY

8:25 Chairperson's Remarks

Russell G. Burge, Ph.D., Application Scientist, Freeslate, Inc.

8:30 Needle-Free Drug Delivery to Specified Tissue Depths Using a High Performance Lorentz-Force Jet Injector

Ian W. Hunter, Ph.D., Hatsopoulos Professor, Department of Mechanical Engineering, Mechanical Engineering, MIT

We will overview the development of a high performance Lorentz-force actuated jet injector (JI). The custom actuator is under closed-loop position (volume) and pressure control via a non-linear control system implemented in an embedded microcontroller. The JI is used in delivery into the middle ear, vitreous humor, joints, skin, and muscle. We overview the JI's use to deliver drugs having a wide range of viscosities into various tissue types in a variety of animals.

9:00 Considerations for Subcutaneous Delivery of Large Volumes

William J. Lambert, Ph.D., Fellow, Drug Delivery and Device Development, MedImmune, Inc.

How can one deliver large doses of a biologic product to a patient in a convenient manner? This is a significant challenge for many biotech scientists and engineers, particularly for self-administration by patients. This presentation will address patient considerations (e.g., injection site pressure and pain) and formulation- and device-based approaches, with particular attention to so-called patch pumps.

PROTEIN DELIVERY TO THE BACK OF THE EYE

9:30 Challenges and Advances in Macromolecular Delivery to the Back of the Eye

Cindy Wu, Ph.D., Principal Scientist, Pharmaceutical Sciences, Allergan, Inc.

Peptides and proteins are showing promise in clinical and preclinical stages of development for treating a wide variety of ophthalmic conditions. Direct intravitreal administration of macromolecules addresses the issues of poor bioavailability, however short half-lives relative to duration of therapy results in a requirement for frequent high dose administrations. In this presentation, the challenges and advances in the delivery of these therapeutic agents will be discussed.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Novel Pentablock Copolymer-Based Compositions for Long Term Delivery of Protein Therapeutics

Ashim K. Mitra, Ph.D., University of Missouri Curators' Professor of Pharmacy, Division of Pharmaceutical Sciences, School of Pharmacy, University of Missouri-Kansas City

Current treatments for posterior segment ocular diseases require frequent intravitreal injections which have undesirable side effects. We have developed novel pentablock copolymers (PBC) which are biodegradable and biocompatible. PBC have been used to develop nanoparticles and thermosensitive gels which can sustain the delivery for a long period of time. This delivery system can be utilized for subcutaneous injection, and hence, represents a versatile platform technology for long-term delivery of biologics.

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11:15 Delivery of Biologic Drugs to the Back of the Eye Using Novel Hydrogels

Amar Sawhney, Ph.D., President & CEO, Ocular Therapeutix, Inc.

Ocular Therapeutix is encapsulating anti-VEGF drugs within its proprietary hydrogels to create sustained release therapies for retinal diseases. The biodegradable hydrogel provides localization and controlled release of the biologic agent over durations up to six months, while its biocompatible nature allows their use in the demanding intravitreal compartment. Such therapies are one of the biggest unmet needs in ophthalmology, with over 2.5 million intravitreal injections in the U.S. each year.

11:45 Long Acting Delivery of Antibody Therapeutics to the Back of the Eye

Robert Kelley, Ph.D., Senior Scientist, Drug Delivery, Genentech, Inc.

Anti-VEGF therapies have proven effective for treatment of wet age-related macular degeneration (AMD). Due to a relatively short half-life of antibody therapeutics in the eye, maximal clinical benefit involves frequent intravitreal injection. Pharmacokinetic studies suggest that diffusion and molecular charge contribute to the vitreal clearance of antibodies. Sustained release formulations and implanted devices are being explored for long-acting delivery of antibodies to the eye. Considerations for molecule selection and formulation to facilitate these strategies will be discussed.

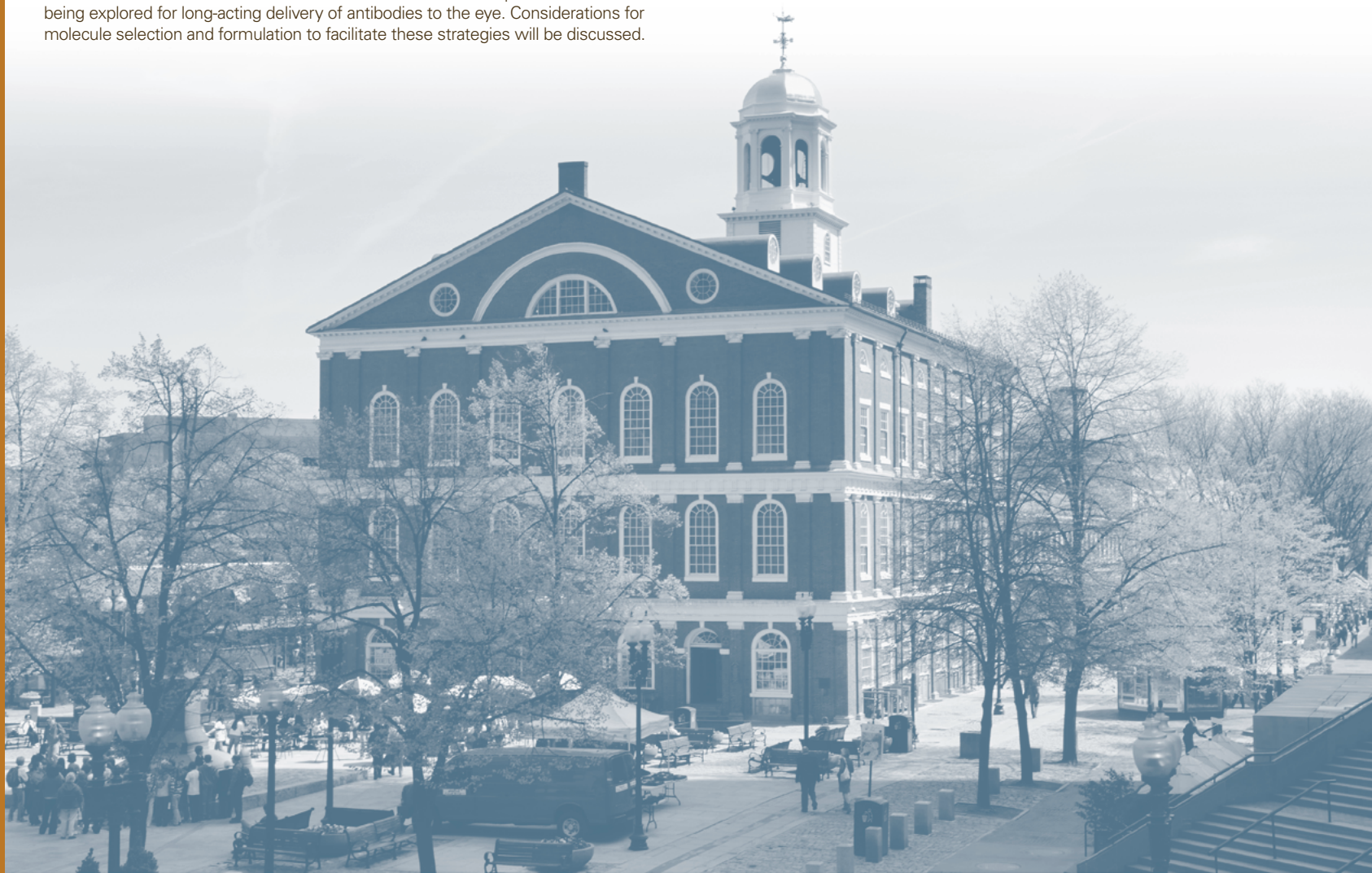
12:15 pm End of Formulation Strategies for Improved Delivery of Biologics

Welcome Reception in the Exhibit Hall with Poster Viewing

Monday, May 5 | 5:45 - 6:45 pm

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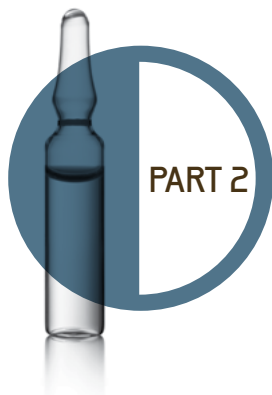
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May 6 - 7, 2014

Cambridge Healthtech Institute's Inaugural

New Technologies for Biologics Delivery and Targeting

Driving Innovation Through New Targets, Effective Tools, Next-Gen and Alternate Delivery Technologies

The drug delivery field is emerging as a key sector in driving innovation to bring new therapies to market and increase profitability. This inaugural conference will cover novel delivery approaches and their roles in developing and delivering biologics, designing targeted delivery approaches and improving efficacy and safety. These strategies are directed to the development of patient-centric therapies.

TUESDAY, MAY 6

1:00 pm Registration

NEW DELIVERY TECHNOLOGIES

2:00 Chairperson's Opening Remarks

» 2:05 KEYNOTE PRESENTATION: Targeted Polymeric Nanoparticles: From Discovery to Clinical Trials

Omid Farokhzad, M.D., Associate Professor, Laboratory of Nanomedicine and Biomaterials, Department of Anesthesiology, Brigham and Women's Hospital and Harvard Medical School

Polymeric nanoparticles can deliver drugs in the optimum dosage over time, thus increasing the efficacy of the drug, maximizing patient compliance and enhancing the ability to use highly toxic, poorly soluble, or relatively unstable drugs. The successful clinical translation of therapeutic nanoparticles requires optimization of many distinct parameters resulting in a large number of potential variables for optimization which is impractical to achieve using a low-throughput approach. The goal of this talk is to review our efforts in the design and optimization of polymeric nanoparticles for medical applications, which formed the foundation for the clinical translation of the first-in-human targeted and controlled-release nanoparticles, BIND-014 and SEL068.

» 2:35 FEATURED PRESENTATION: Conjugation and Fusion Technologies for Delivery of Biologics

Ashutosh Chilkoti, Ph.D., Theo Pilkington Professor of Biomedical Engineering, Director, Center for Biologically Inspired Materials and Materials Systems, Duke University

I will summarize our three new drug delivery systems: 1) Attachment-triggered self-assembly of recombinant peptide polymers—packages small hydrophobic molecules into soluble polymer nanoparticles, and increases the solubility, plasma half-life and tumor accumulation of many hydrophobic small molecule drugs 2) Protease Operated Depot (POD) is an injectable delivery system based on thermally sensitive polypeptides for the sustained and tunable release of peptide drugs from a subcutaneous injection site 3) Instealth™—enables the site-specific *in situ* growth of a PEG-like polymer from the N-or C-terminus of a peptide or protein drug.

3:05 Sponsored Presentation (Opportunity Available)

3:20 Sponsored Presentation (Opportunity Available)

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15 Evaluation and Applications of Heart on a Chip

Donald Cropek, Ph.D., Scientist, Construction Engineering Research Laboratory, Engineering Research and Development Center, U.S. Army Corps of Engineers

Incorporating living cardiomyocytes into microfabricated devices has become a focus of research for applications in tissue engineering, toxicity assessment, diagnostics, and drug screening. Careful consideration of channel dimensions, cell seeding, and hydrogel coatings have enabled contractile myofibers with relevance to *in vivo* functions. We have built multichannel microfluidic devices with an independent beating myofiber in each channel for duplicative rapid testing of small molecule drugs, biologicals, and drug interactions.

4:45 Centyrins: Targeted Delivery for Improved Therapeutics

Drew Elias, Ph.D., Senior Scientist, Centyrex Venture, Johnson & Johnson

Alternative scaffolds share properties with antibodies in terms of their specificity and potency and with small molecules in terms of simplicity and size. The Centyrin platform, a consensus fibronectin domain, has been optimized to enable selection of Centyrins that bind to and inhibit multiple classes of proteins. We will describe how the biophysical properties of Centyrins make them ideal for novel therapeutic applications including drug conjugates and targeted nanoparticles.

5:15 End of Day

5:30 Short course Registration

6:00 - 9:00 pm DINNER SHORT COURSE 3: Development of High-Dose Biologics Dosage Forms*

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WEDNESDAY, MAY 7

8:00 am Registration and Morning Coffee

NANOTECHNOLOGY FOR MACROMOLECULAR DELIVERY

8:30 Chairperson's Remarks

» 8:35 FEATURED PRESENTATION: Translational Nano-Medicine: Targeted Therapeutic Delivery for Cancer and Inflammatory Diseases

Mansoor M. Amiji, Ph.D., Distinguished Professor and Chairman, Department of Pharmaceutical Sciences, School of Pharmacy, Northeastern University

This presentation will focus on the development of multifunctional nanoparticle systems for targeted therapies in the treatment of cancer and inflammatory diseases. Specific examples will address the development of combinatorial-designed nano-systems for tumor drug resistance, anti-inflammatory gene therapy strategy for the treatment of rheumatoid arthritis, and oral RNAi approach for the treatment of inflammatory bowel disease. In each project, there is strong emphasis on use of safe materials and scalable fabrication methods to facilitate clinical translation.

9:10 Evolution of Targeted Delivery Technologies: Past, Present and Future

Ramin Darvari, Ph.D., Principal Research Scientist II, Novel Delivery Technologies, Pfizer, Inc.

The desire for improved safety and efficacy of pharmaceuticals has inspired the targeted delivery approaches. In this presentation, the advancement and new frontiers in targeted delivery technologies will be discussed.

9:40 Bioengineered Nanomaterials in Immunotherapy

Marian Gindy, Ph.D., Director, Pharmaceutical Sciences, Merck Research Laboratories

A wide range of bioengineered nanomaterials have been developed for use in diagnostic and therapeutic applications. By virtue of their size, nanomaterials possess unique properties that facilitate more productive drug delivery to disease cells. In cancer immunotherapy, bioengineered nanomaterials are being combined with tumor antigens to improve antigen stability, tumor penetration, and targeting properties. They are also explored for their antigenic properties as immune stimulating agents. Here, nanomaterial-based opportunities in cancer immunotherapy are discussed.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

ALTERNATE DELIVERY TECHNOLOGIES

10:45 A Simple Approach to Biologics Delivery: Oral Inhalation Isn't Just for Pulmonary Disease

Andrea Leone-Bay, Ph.D., Vice President, Pharmaceutical R&D, MannKind Corp.

Dry powder formulations based on advanced particle engineering and patient-friendly, breath-powered inhalation devices have been integrated to simplify drug delivery by oral inhalation. This approach expands this route of delivery beyond pulmonary disease. These technologies will be exemplified for new biologics product development and life-cycle management in the therapeutic areas of diabetes, pain, and obesity.

11:15 Getting Proteins across the Skin – What Works

Ajay K. Banga, Ph.D., Professor and Department Chair, Pharmaceutical Sciences, Endowed Chair in Transdermal Delivery Systems, College of Pharmacy, Mercer University

Hydrophilic macromolecules like proteins do not normally pass through the skin unless enabling technologies are used. Some of the enabling physical enhancement technologies include iontophoresis, phonophoresis, or the various skin microporation approaches. Recent innovations in these technologies, especially for iontophoresis and microneedles, will be presented. Application, limitations, challenges, and commercialization of these technologies will be discussed.

11:45 Safe and Stable Peptide Nanomedicines Targeted to Treat Rheumatoid Arthritis, Acute Lung Injury and Diabetes

Hayat Onyuksel, Ph.D., Professor of Pharmaceutics and Bioengineering, Department of Biopharmaceutical Sciences, College of Pharmacy, University of Illinois

Delivery of peptide drugs is challenging due to their side effects and short half-life. This presentation will demonstrate how these problems can be overcome using sterically stabilized phospholipid micelles (SSM) as nanocarriers for peptide drugs. Peptides (VIP, GLP-1, PP) efficacies obtained on appropriate animal models of rheumatoid arthritis, acute lung injury and diabetes, when used as nanomedicines, will be shown. These targeted peptide nanomedicines are easy to prepare and scale up, can be freeze-dried without the use of cryo- or lyo-protectants for required half-life, and most importantly safe and stable for i.v. use, with a high potential for translational research.

12:15 pm Delivery of Therapeutic Molecules to the Back of the Eye by Nanomicelles

Ashim K. Mitra, Ph.D., University of Missouri Curators' Professor of Pharmacy, Division of Pharmaceutical Sciences, School of Pharmacy, University of Missouri-Kansas City

Ocular diseases affecting the posterior segment require frequent intravitreal injections which have undesirable side effects. Developing aqueous eye drops of hydrophobic drugs for topical delivery to back of the eye is challenging. We have developed novel nanomicellar aqueous formulations utilizing amphiphilic copolymers. Nanomicelles can entrap the drug and deliver to the retina via transscleral pathway. This platform can serve as a safe, effective and patient compliant route.

12:45 Sponsored Presentation (Opportunity Available)

1:00 Luncheon Presentation (Opportunity Available) or Enjoy Lunch on Your Own

1:30 Session Break

2:00 Chairperson's Remarks

2:05 Novel Technologies for Delivery of Vaccines

Dushyant Varshney, Ph. D., Senior Project Manager, Novartis

Currently most vaccines are delivered subcutaneously or intramuscularly. There has been a growing interest to develop novel delivery technologies utilizing cutaneous respiratory and oral routes of administration that can influence type of immune responses. Such delivery options could improve effectiveness, safety, provide dose-sparing/specific and cost-effective approaches. In this talks will focus on development, challenges, current status, success and future directions in novel vaccine delivery and device technology.

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APPROACHES FOR DELIVERY OF BIOLOGICS ACROSS BLOOD-BRAIN BARRIER

2:35 Development of a Directed Evolution Strategy to Identify Cell Penetrating Peptides (CPPs) for Brain Delivery

Scott Banta, Ph.D., Associate Professor, Department of Chemical Engineering, Columbia University

Cell Penetrating Peptides (CPPs) have received significant attention since they have the ability to deliver various functional cargos to cells and tissues including the brain. In order to identify new CPP sequences we have developed a selection strategy using plasmid display to identify novel CPPs from randomized peptide libraries. This method can be further developed to identify novel sequences with both targeting and delivery capabilities.

3:05 Sponsored Presentation *(Opportunity Available)*

3:20 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Engineering Transport Vectors within Biologics for Delivery to the CNS

Pankaj Karande, Ph.D., Assistant Professor, Department of Chemical & Biological Engineering, Center for Biotechnology and Interdisciplinary Studies, Rensselaer Polytechnic Institute

Drug delivery to the brain has been a long-standing challenge in the treatment of neurological and neurodegenerative disorders due to the formidable blood-brain barrier (BBB). I will specifically discuss the design of peptide vectors that can facilitate the delivery of biologics by hijacking a critical physiological pathway for transport of systemic proteins into the brain. Peptide-mediated delivery is an efficient and significantly less invasive alternative to current methods of CNS delivery.

4:30 Brain Shuttle Module Delivers Antibodies Efficiently to the Brain

Per-Ola Freskgard, Ph.D., Senior Leader and Vice Director, Neuroscience, Roche

Although biotherapeutics have vast potential for treating brain disorders, their use has been limited due to low exposure across the blood-brain barrier (BBB). This talk will describe a Brain Shuttle module, which can be engineered into a standard therapeutic antibody for successful BBB transcytosis based on a monovalent binding mode. These findings will have major implications for the development of biologics-based treatment of brain disorders.

5:00 pm End of Conference



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T: 781-972-5452
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Host Hotel:

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Sunday, May 4	Tuesday Evening, May 6
Challenges and Opportunities in Protein and Peptide Drug Delivery	Development of High-Dose Biologics Dosage Forms
Converting Emerging Delivery Technologies into Successful Patient-Friendly Therapies	

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May 5 - 6, 2014	May 6 - 7, 2014
Part 1: Formulation Strategies for Improved Delivery of Biologics	Part 2: New Technologies for Biologics Delivery and Targeting

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