DAY ONE - MONDAY, MAY 6, 2019

8:00 am
Registration and Morning Coffee/Tea

8:30 am
Co-Chair’s Opening Remarks
Ann Daugherty, PhD
Senior Manager, Drug Delivery, Genentech
James Cunningham, PhD
Executive Director, Drug Delivery, Allergan

Keynotes, Intracellular Delivery, Brain Delivery, Peptide & Ophthalmology Delivery Alternatives and Pharma Delivery Needs

8:40 am
Keynote: State of the Industry Address & Nano-medicine’s Current Clinical Reality: An Analysis of Recent Results
David W Grainger, PhD
University Distinguished Professor, Chair, Department of Biomedical Engineering, Department of Pharmaceutics and Pharmaceutical Chemistry, University of Utah

9:20 am
Intracellular and Tissue Specific Delivery of Therapeutic Payloads
The Targeted Therapeutics team at Janssen is focused on addressing the challenges of intracellular and tissue specific delivery across modality spectrum.
This session will include:
• A focus on understanding parameters of receptor-specific uptake and internalization and using relevant assays for proper ligand selection
• Examples of using these methods for specific functional delivery of nucleic acids and nanoparticles
Vadim Dudkin, PhD
Head of Targeted Therapeutics at Janssen Discovery Sciences, Johnson & Johnson

9:40 am
Grand Opening of the Exhibit & Networking Café

10:20 am
Keynote: MRI-Guided Focused Ultrasound and the Delivery of Therapeutics to the Brain
Dr Isabelle Aubert, University of Toronto, will provide an introduction to MRI-guided focused ultrasound (MRigFUS), which in presence of intravenously injected phospholipid microspheres is used to increase the permeability of the blood-brain barrier (BBB) in a localized, controlled, and transient manner. She will review applications in preclinical models of neurodegenerative disorders where therapeutic molecules, gene therapy vectors, and progenitor cells are injected intravenously and delivered from the blood to targeted areas of the brain with MRigFUS. Dr Aubert will describe the seminal work of the Sunnybrook team on MRigFUS-BBB modulation, without exogenous therapeutic, leading to glial plasticity, amyloid pathology reduction, hippocampal neurogenesis and improved cognitive functions in a preclinical model of Alzheimer’s disease (AD). The presentation will conclude with the clinical evaluation of MRigFUS and BBB modulation in people with AD.
Isabelle Aubert, PhD
Professor, Department of Laboratory Medicine and Pathobiology, University of Toronto

10:50 am
Keynote: Updates on Alternative Administration of Peptides - Bioavailability and Capability of Delivering Peptides and Non Small Molecules Through the Oral Route
• What are the delivery options outside the traditional subcutaneous injections moving forward?
• What strategies are showing success in improving the oral absorption of peptide-based drugs?
Randall Mrsny, PhD
Professor’s Chair, Department of Pharmacy and Pharmacology, University of Bath

11:10 am
Ophthalmology: Exploring Other Routes of Administration
• Barriers/challenges associated with drug delivery to the back of the eye
• Prolonging delivery & reducing frequency of administration
• Alternative/less invasive routes of administration for delivery to the back of the eye
• Delivery for emerging modalities
• Impact of delivery system design choices on development/scalability
• How to effectively assess novel delivery approaches
Moderated by:
James Cunningham, PhD
Executive Director, Drug Delivery, Allergan

Panelists:
James E Chastain, PhD
Executive Director, PK Sciences - Ophthalmology, Novartis
Institutes for BioMedical Research, Inc
Susan "Susie" Crowell, PhD
Scientist, Preclinical and Translational PKPD, Genentech
Viral Kansara, PhD
VP, Discovery, Clearside Bio
11:50 am
Pharma Spotlights on Drug Delivery Needs
In this session, pharma companies discuss their current needs, partnering philosophy and scouting interests, as related to drug delivery.

Nima Akhavein
Associate Fellow and Scientific Leader, GSK

Lani Hack
Engineer I, ASO Formulation Development & Manufacturing, Biogen

Simon Geißler, PhD
Director Drug Delivery and Innovation, Healthcare R&D, CPD, Pharmaceutical Technologies, EMD Serono

12:35 pm
Transforming Cardiovascular Treatment with Pulmonary Delivery: Every Breath You Take is Shot Through the Heart
• Pioneering a novel approach for treating cardiovascular conditions by the oral inhalation route
• Will be the ONLY non-invasive, self administered product for acute management of Paroxysmal Atrial Fibrillation, providing rapid cardioversion
• In Phase 2: Dose dependent conversion observed
• Working on enhancements to greatly improve speed of delivery

Carlos Schuler, PhD
COO, CTO and Co-Founder, Incarda Therapeutics

12:50 pm
Networking Lunch & Partnering Meetings

1:50 pm
How to Realize your Next Drug Delivery Innovation: A Practical Guide to Getting your Innovation to Market

Uri Baruch
Director, Head of Drug Delivery, Cambridge Design Partners

2:10 pm
Delivering an Innovative, Patient-Centric Delivery System as a Result of Strong Collaborations Between Flex and Amgen
A new way of doing business was required to achieve the mission of serving patients suffering from rheumatoid arthritis. Learn how Amgen and Flex created an integrated, single team with co-executive sponsorship and overarching program management that enabled the successful development and launch of a novel combination product.

Daniele Fazio
VP, Design & Engineering, Flex

William (Bill) Rich
VP, Final Drug Product Technologies, Amgen

Tech Presentations
The afternoon sessions feature companies enabling the delivery of small and large molecules across a broad range of technologies including: Needle-free Delivery Systems, Enabling Injectable Systems, Oral Platform Technologies and Injectable Formulation & Devices. These are “quick fire” presentations, with Q&A following each presentation. Half way into the tech presentations, we will have an “ice cream delivery” break.

Chaired by:
Mitch Zhao, PhD
Business Development Manager, Harro Höfliger

Overcoming Microsphere Scale-Up Challenges
This presentation will provide real-life challenges, solutions, and examples of scaling a Microsphere process from a beaker in the lab to a multi-kilogram global commercial product.

Michael Strozewski
Formulation Scientist II, Oakwood Labs

Controllable Force Autoinjector
Battelle has developed several novel approaches to enable delivery of challenging drug formulations. One of these, the controllable-force autoinjector (CFAI) technology addresses several key drawbacks of conventional spring mechanisms to better deliver new drug formulations that are higher in dose volume and/or viscosity. CFAI can deliver fluids with a constant or controllable force across the entire delivery process providing: reduced insertion impact force; decreased delivery times; the ability to deliver much higher viscosity; and improved reliability and consistency, particularly near the end of the stroke where most conventional spring driven systems are weakest.

Bill Atterbury
Research Leader, Medical Devices and Health Analytics, Battelle

Implications of Shifting Therapy from the Clinic to the Home
The shift of healthcare delivery from the clinic to the home has several implications for the biopharmaceutical industry. Drug delivery can play a significant role by empowering patients in order to enable this trend, specifically by creating preferred devices and increasing touch points.

Dave Siet
Director of Business Development, Portal Instruments
Drug Delivery Experts and Baywind Bioventures present Propel Biologics™ JetCAP™ Revolutionary Oral Delivery Technology
The JetCAP™ oral capsule device offers a needle-free fluid dynamics solution to deliver payload into or onto the wall of the gut for both topical gut delivery and systemic bioavailability. With a liquid reservoir up to 0.3 ml, JetCAP™ offers high drug delivery capacity with the flexibility of solution and suspension formulations.
Christopher Rhodes, PhD
President & CEO, Drug Delivery Experts

3:35 pm
Ice Cream Delivery Break

3:50 pm
Drug Delivery Presentations: Part II

BioQ Pharma’s invenious™ Platform – Making Infusible Drugs Truly Ready-to-use via Proprietary Connect-and-go Technology
BioQ Pharma’s invenious™ platform comprises a bespoke ‘connect-and-go’ delivery solution for infusible medicines – with all-in-one, pre-filled, ready-to-use and adaptable functions suited to specific dosing regimens. Our proprietary invenious™ delivery systems are particularly well suited for hard to prepare and/or administer infusibles.
Josh Kriesel, PhD
CEO, BioQ Pharma

DEP – Developing Enhanced Therapies
Starpharma’s proprietary DEP technology provides enhanced therapeutic and commercial benefits for existing drugs and NCE’s, enhancing efficacy (alone and as part of a combination therapy approach), safety and new parent life. DEP drugs are in the clinic with the most advanced in Phase 2 clinical trials.
Tony Eglezos PhD, MBA
VP, Business Development, Starpharma

Innovative Device Solutions in Response to Specific Market Needs
Credence MedSystems, a developer of innovative injection devices, continues to expand its device platform with customized injection systems to support growth of specific therapeutic applications.
Mark Hassett
VP, Business Development, Credence MedSystems

Why Oral Thin Films Can Be Exactly What You Are Looking For: Case Studies on the Mcufilm® and the Rapidfilm®
Oral films are innovative dosage forms and highly patient centric. Whether the patient, physicians & caregiver or the pharmaceutical industry: everyone has a stake in the value proposition of oral thin films: Physicians and caregivers may use this dosage form in a highly individualized manner, for adults oral films are extremely convenient (no swallowing and high compliance), for patients with special needs, oral films can be life saving in very critical moments, even children made their statement “we want films”*, and above all: one formulation for various doses! How that works will be also presented during this session.
Ahmad Ghoniem, PhD
Pharmacist, Manager Business Development & Sales, tesa Labtec

Novel Exosome-based Delivery of Therapeutic Proteins
ILIAS Biologics has recently developed an opto-genetically engineered exosome system, named ‘exosomes for protein loading via optically reversible protein–protein interaction’ (EXPLOR) that can deliver soluble proteins into the cytosol of target cells via controlled, reversible protein–protein interactions (PPI). This presentation will introduce the basic principles of EXPLOR technology and follow-up studies for therapeutic applications including sepsis.
Chulhee Choi, MD, PhD
CEO, ILIAS Biologics

5:00 pm
End of Day One & Networking Reception

DAY TWO - TUESDAY, MAY 7, 2019

8:00 am
Morning Coffee/Tea

8:30 am
Co-Chair’s Opening Remarks
Ann Daugherty, PhD
Senior Manager, Drug Delivery, Genentech
James Cunningham, PhD
Executive Director, Drug Delivery, Allergan

Keynotes, Investment Decision Making, Precision Medicine, Digital and Connected Delivery and Nanostructured Materials

8:40 am
Panel: Investor Perspectives on Drug Delivery Needs and Investments
• What are VCs investing in, trends they are seeing, competition and concerns?
• Before VCs invest, what decision making criteria are they using?
• What VCs think is important and what pharma thinks is important. Those don’t always match up, how can we better align. What are those differences and what are the rationales?
• Is there a specific revenue target for a startup company that they would look at before making an investment?

Moderated by:
David Allison, PhD
Partner, 5am Ventures

Panelists:
Andrew ElBardissi, MD
Principal, Deerfield Management
Karim Helmy, MD, PhD
VP, Healthcare Investor, Venrock
Lori Hu, MBA
Principal, Vertex Ventures HC
Aaron Royston, MD, MBA
Partner, venBio

*Clinical study: Acceptability of orodispersible films for delivery of medicines to newborns and infants.
Ahmad Ghoniem, PhD
Pharmacist, Manager Business Development & Sales, tesa Labtec
AGENDA

9:20 am
Keynote: Leveraging Physiology for Bioresponsive Precision Drug Delivery & The Future Impact of Precision Medicine on Drug Delivery
Spurred by recent advances in materials chemistry, molecular pharmaceutics and nanobiotechnology, stimuli-responsive “smart” systems offer opportunities for precisely delivering drugs in dose-, spatial- and temporal-controlled manners. In this talk, Dr Zhen Gu, UCSF, will discuss:
- The ongoing efforts in developing physiological signal-triggered bioinspired drug delivery systems
- Glucose-responsive synthetic systems for biomimetic delivery of insulin for diabetes treatment
- Bioresponsive microneedle patches and vesicle fusion-mediated synthetic beta cells will be emphasized
- Local and targeted delivery of immunomodulatory therapeutics for enhanced cancer therapy
- An introduction to their latest study utilizing platelets, cell conjugates and sprayable gels for delivery of immune checkpoint inhibitors
- Insights on the future of precision medicine and the impact on drug delivery moving forward
Zhen Gu, PhD
Professor, Department of Bioengineering, California NanoSystems Institute (CNSI), University of California, Los Angeles (UCLA)

9:50 am
Morning Networking Break & Partnering Meetings

10:35 am
Keynote: Nanostructured Materials for Enhanced Therapeutic Delivery
In this session, Dr Tejal Desai, UCSF, will discuss recent advances in using micro and nanotechnology to enhance the delivery of therapeutics across biologic barriers.
Tejal Desai, PhD
Ernest L. Prien Endowed Professor and Chair, Department of Bioengineering and Therapeutic Sciences, UCSF Schools of Pharmacy and Medicine

11:05 am
Industry Keynote: Harnessing the Digital Exhaust: Incorporating Wellness into the Pharma Model
For more than a decade, the pharmaceutical industry has been caught up discussing its role in “beyond the pill” solutions, it will now need to realize a rapid evolution of its current business model in order to remain competitive. At the core of such an evolved model will certainly be a dynamic patient interface which leads to extraordinary patient engagement. A review of the current and future state along with perspective and case studies will be provided in order to help shed light on the areas of needed focus and corresponding opportunity for “beyond the pill solutions”.
Justin M Wright, PhD
Global Head of Innovation, Novartis

11:35 am
Navigating Across Classifications: The Connected Device Regulatory Landscape
Kimberly Ringenberger, PhD
Associate Engineering Advisor, Eli Lilly

12:05 pm
Advancing the Connected and Smart Drug Delivery Ecosystem: A Path Forward
The connected drug delivery device market is expected to grow tremendously with emerging technologies that connect patients, physicians, researchers, health systems, etc, while reducing burden to all. Drug delivery manufacturers of inhalers to treat asthma and chronic lung disease for example are fast developing the next generation of smart devices with sensors to monitor if patients are using their devices correctly. In this panel discussion, we focus on next generation emerging technologies, design needs and challenges, and regulatory hurdles to advance the drug delivery smart and connected world.
Moderated by:
Justin M Wright, PhD
Global Head of Innovation, Novartis
Panelists:
Kimberly Ringenberger, PhD
Associate Engineering Advisor, Eli Lilly
Rajan Patel
CEO and Founder, iO Life Science
Dirk Schapeler
VP, Digital Health, Bayer

1:00 pm
Networking Lunch & Partnering Meetings

2:00 pm
Presentations by:
Sheauyu Teddy Hsu, PhD, MBA
Managing Director, Adepthera, LLC
Alex Wasson
CEO, Cinti Medical
Bryce Beverlin II, PhD
Founder and CEO, Quench Medical
Abhita Batra, MBA
CEO, Otomagnetics
Vadim Yuzhakov, PhD
CEO, AdminMed

www.theconferenceforum.org
2:40 pm
How Do We Overcome the Barriers of Getting New Technologies Evaluated and Brought in Earlier in Product Development?
Pharma companies often face challenges when it comes to working with external drug delivery technologies as a result of cost and resources. Because pharma’s primary focus is developing molecules, developing drug delivery strategies doesn’t always get worked into the pipeline early enough. This panel will delve into the following:
• How can we get drug delivery technologies earlier in the pipeline development of molecules?
• How can we lower the upfront risks?
• What are the workarounds?
Moderator:
Ann Daugherty, PhD
Senior Manager, Drug Delivery, Genentech
Panelists:
Nima Akhavein
Associate Fellow and Scientific Leader, GSK
Jason Olbrich, PhD
Principal Engineer, Final Product Technologies, Amgen
Andrew Ratz
Senior Director, Delivery, Device & Connected Solutions, Eli Lilly

3:25 pm
End of Day Two