7th

DRUG FORMULATION, SOLUBILITY & BIOAVAILABILITY SUMMIT

March 26-28, 2018 | Revere Hotel Boston Common | Boston, MA

The Latest Formulation Strategies and Predictive Technologies to Accelerate Manufacturing, Preclinical R&D, and Time to Market

DETAILED SCIENTIFIC STRATEGIES

- Apply 3D Printing to Accelerate Clinical Testing
- Map Crucial Steps to Ensure Availability of Reliable APIs
- Leverage Understanding of Self-Association to Enhance Formulation Performance
- Overcome the High Failure Rate of IVIVC
- Empirically Explore the Limitations of Predictive Tools
- Update Your Preformulation Skills for Continuous Manufacturing

PLUS: A FULL-DAY, INTERACTIVE SEMINAR DEVOTED TO ADVANCES IN DRUG DELIVERY! TOPICS INCLUDE:

- **Improving Developability of Ophthalmic Solutions**
- **Breakthroughs in Oral Biologics Delivery**
- **Adjusting Development Timelines for Long-Acting Injections**
- **Formulation Parameters to Ensure Subcutaneous Delivery Will Work**
- **Refining Targeted Delivery for Immuno-Oncology Therapeutics**

...and more!

Joachim Hoechel
Head, Clinical Pharmacology
BAYER

Rossitza Alargova
Director, Formulations
INFINITY PHARMACEUTICALS

Fady Ibrahim
Principal Scientist, Biopharmaceutics
PFIZER

Robert Saklatvala
Director, Basic Pharmaceutical Sciences
MERCK

Rakesh Dixit
Vice President, R&D, Global Head, Biologics Safety
MEDIMMUNE

Liping Zhou
Head, Formulation Development
RA PHARMACEUTICALS

Keith Horspool
Vice President, Pharmaceutics
BOEHRINGER INGELHEIM

Manuel Sanchez-Felix
Senior Fellow, Formulations
NOVARTIS

"Very focused group, great selection of topics and presentations, with useful information in discussions."
—*Manager,* ***APOTEX PHARMACEUTICALS***

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7th DRUG FORMULATION, SOLUBILITY & BIOAVAILABILITY SUMMIT

DEAR COLLEAGUE,

When over 80% of APIs in development are poorly water-soluble, drug companies must rely increasingly on new formulation and delivery strategies to maximize bioavailability. Recognizing the precise thresholds when an enabled formulation is necessary, as well as determining which method to use and how to predict and gauge its success, is an essential requirement for drug companies of all sizes.

ExL's **7th Drug Formulation, Solubility & Bioavailability** Summit provides you with an unmatched focus on the latest technologies and team skills that you need to gather and interpret first-in-human results and accelerate time-to-market. Featuring an all-new program built around audience requests, this year's agenda will empower you to:

- Achieve breakthroughs in **oral biologics delivery**
- Leverage your understanding of **self-association to enhance formulation performance**
- Design, interpret, and gauge the performance of the **next generation of predictive models**
- Refine your **formulation strategies** and selection methods
- Shorten the bridge from **preclinical to clinical data** gathering

Plus, for the first time, a full-day, intensive seminar focusing on breakthroughs in the design and selection of drug delivery methodologies!

I look forward to seeing you in Boston this spring!

Sincerely,

Matt Greenbaum

Production Team Leader
ExL Events

WHO SHOULD ATTEND?

- Formulation / Preformulation
- Pharmaceutical Development
- Preclinical Development
- Pharmacokinetics / Pharmacodynamics / PKDM / DMPK
- Solubility
- Pharmaceutics / Biopharmaceutics
- R&D / Process R&D
- Physicochemistry
- Solid State
- Drug Delivery
- Drug Discovery
- Analytical Development / Analytical Chemistry
- Pharmacometrics
- Manufacturing Technology / CMC
- Medicinal Chemistry
- Clinical Pharmacology
- Material Science
- Toxicology
- Chemical Engineering
- Correlation / Biocorrelation
- Modification

This event is also of interest to:

- Formulation Specialists
- Drug Delivery Specialists
- Excipient Manufacturers / Suppliers
- CROs

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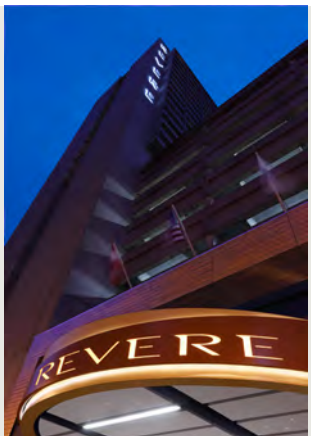
VENUE



Revere Hotel Boston Common

200 Stuart Street
Boston, MA 02116

To make reservations, please call 1-855-673-8373 and request the negotiated rate for ExL's **7th Bioavailability**. You may also make reservations online at http://bit.ly/2xnoHyN. The group rate is available until **March 5, 2018**. Please book your room early, as rooms available at this rate are limited.

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8:00 Registration and Continental Breakfast

8:45 INTRODUCTION FROM SEMINAR CHAIRPERSON

Joachim Hoechel, *Head, Clinical Pharmacology,* **BAYER**

9:00 ALTERNATIVES TO ORAL DOSING ROUTES

The U.S. market is atypical for focusing so heavily on oral drug delivery. A fuller examination of delivery methods used in international markets can help illuminate trends that can be duplicated for therapeutic success.

- Review materials science and polymer industry insights on new delivery options
- Explore case studies in dermal, ocular, nasal, microneedle patch, suppository, and other methods
- Analyze new biologics delivery modalities, such as cellular technologies and amorphous delivery

Meena Venugopal, *Vice President, Biopharmaceutics,* **ALVOGEN**

9:45 PANEL: ACHIEVE BREAKTHROUGHS IN ORAL BIOLOGICS DELIVERY

The challenges of oral biologic delivery include maintaining stability in the GI tract, ensuring adequate drug exposure over time, and keeping the drug intact before absorption. Special formulations are required to keep biologics from being degraded by enzymes.

- Encourage the industry to share data on oral biologics development more openly
- Review applications of oral peptides and insulins
- Extrapolate for dermatology and other non-oncology disease areas

MODERATOR: Rakesh Dixit, *Vice President, R&D, Global Head, Biologics Safety Assessment,* **MEDIMMUNE**

10:30 Networking Break

11:00 ENCAPSULATION AND RELEASE OF PEPTIDES AND BIOLOGICS AT HIGHER LOADINGS THAN W/O/W EMULSIONS FOR NANOPARTICLE AND DEPOT MICROPARTICLE DELIVERY

Encapsulation is often required to prevent premature clearance and to control the release of biologics. Advances in the field have been limited by the lack of encapsulation techniques that produce highly loaded constructs without burst release. Conventional W/O/W processing, limited to loadings of ~10%, can only be applied for highly potent drugs without requiring excessively large doses.

- Examine new, scalable encapsulation processes based on controlled rapid micromixing that enables loadings to 50 wt% active
- Apply new encapsulation processes to nanoparticle and depot microparticle formulations
- Learn how this approach can be applied for both parenteral and oral delivery

Robert Prud'homme, *Professor, Chemical and Biological Engineering,* **PRINCETON UNIVERSITY**

11:45 MAKE ADVANCES IN LONG-ACTING INJECTABLE DELIVERY OF PEPTIDES

Turning a daily injection into a weekly injection brings many benefits for patients, but it can be challenging to select the best formulation principles necessary for this. When dealing with an API that has unusually high solubility, the challenge is making sure it stays where it is needed and only releases into circulation gradually.

- Work through very narrow therapeutic index windows to avoid toxicity results
- Achieve very high dose requirements to maintain high proximate levels of API
- Explore the utility of delivery devices or API modifications to increase half-life

Liping Zhou, *Head of Formulation Development,* **RA PHARMACEUTICALS**

12:30 DEVELOP LONG-ACTING PARENTERAL AND DEPOT DELIVERY SYSTEMS AND MODELS TO DESIGN AND PREDICT SUCCESS IN THE CLINIC

There are several long-acting delivery systems for durations ranging from weeks to years, however each one may utilize a different technology. This presentation provides details around a model to design delivery systems with high probability of success.

- Model physical chemical properties of the drug and PK properties for desired duration
- Map the technology in the model by attributes of the drug to enable technology selection
- Explore the development pathway and challenges for selected technologies

Jaymin Shah, *Research Fellow, Pharmaceutical Sciences, Parenteral Development Centre of Emphasis,* **PFIZER**

1:15 Luncheon

2:15 SOLUBILITY AND FORMULATION APPROACHES FOR INJECTABLE DRUGS

Neera Jain, *Senior Director, CMC,* **SYROS PHARMACEUTICALS**

3:00 TARGETED TISSUE DELIVERY: DREAM OF THE DECADE

Current bio-therapeutics focus on the molecular targets expressed in cells/tumors. In spite of increased antigen expression on the targeted organ, less than 10% of the IV-administrated biologics can reach the diseased tissues. Tissue targeting using caveolae proteins can allow for specific delivery to organs of interest within minutes to hours.

- Focus on applications of caveolae technology to specifically deliver to lungs and kidneys
- Improve drug efficacy with novel targeting designs
- Review outcomes for fibrosis, COPD, infections, and tumors

Ruchi Gupta, *Scientist,* **MEDIMMUNE**

3:45 MAINTAIN NECESSARY FLEXIBILITY IN THE CLINICAL TESTING AND PRODUCTION OF SOLID DOSAGE TABLETS

First-in-human dose escalation studies feature a very different dose range, which may not be proportional to excipients and drug load. PK and consequently PD may be very different from one to the other, leading to major struggles when formulating better solid tablets.

- Dose ranges to be covered in typical FiH studies and strategies to explore the feasibility of solid dosage forms
- Address critical questions before embarking on expensive formulation endeavors
- Use supplementary investigations to identify the option space for optimized formulations

Joachim Hoechel, *Head, Clinical Pharmacology,* **BAYER**

4:30 Seminar Concludes

8:00 Registration and Continental Breakfast

9:00 CHAIRPERSON'S OPENING REMARKS
Keith Horspool, *Vice President, Pharmaceutics,* **BOEHRINGER INGELHEIM**

NEW SKILLS AND TECHNOLOGIES FOR DRUG DESIGN

9:15 PHARMA FORMULATION ASSUMPTIONS AND THE IMPORTANCE OF PATIENT INPUT TO ENABLE FORMULATION INNOVATION

The pharma industry has a number of unwritten rules that influence our formulation selection: A series of assumptions around patient formulation preference that hinder drug delivery innovation. These are very difficult to overturn but necessary to enable development of novel pharmaceuticals. This session discusses tools to overcome such biases.

- Analyze semi-quantitative patient formulation preference tools and new insights
- Discuss eHealth and learn start-up processes from Silicon Valley as tools to incorporate patient input
- Challenge widespread assumptions around patient preferences

Manuel Sanchez-Felix, *Senior Fellow, Formulations,* **NOVARTIS**

10:00 APPLY 3D PRINTING TECHNIQUES TO ACCELERATE CLINICAL TESTING AND REDUCE STABILITY TESTING REQUIREMENTS

For first-in-human tests, advancing to higher dose steps can sometimes leave you bound to dosage assumptions that are no longer in effect. 3D printing might be highly useful in such cases, allowing you to easily produce small batches of each formulation.

- Use 3D printing to streamline the efforts of stability testing and QC before administering to patients
- Quickly produce tablets that fit the needs of each successive drug cohort
- Implement existing 3D printing technology into clinical studies

10:45 Networking Break

11:15 LEVERAGE UNDERSTANDING OF SELF-ASSOCIATION TO ENHANCE FORMULATION PERFORMANCE

Analytical chemists can use signs of bio-partitioning and self-associating to help boost drug solubility and develop a drug product that keeps the capabilities and enhanced performance of its formulation. New screening tools for solubility can help recognize features that are an advantage for formulation and oral absorption.

- Use compounds that form complexes with others to make better drug products
- Bridge the gap between analytical chemistry and solubility research
- Recognize when outliers can be a problem or an advantage

Fady Ibrahim, *Principal Scientist,* **PFIZER**

12:00 PANEL: PROSPECTS OF VIRTUAL OR ULTRA-RAPID DEVELOPMENT USING A PLATFORM OF IN SILICO TECHNOLOGY

How close is the drug industry getting to a fully virtual development approach? Each company is trying to reduce costs and time, and may have more incentive than ever to try combining multiple predictive tools and tests.

- Weigh the latest advances in predictive analytics, stability, biorelevance, and in silico tools
- Approach methods to condense development times from research to clinic
- Gauge how far virtual product development is from reality

MODERATOR: **Keith Horspool,** *Vice President, Pharmaceutics,* **BOEHRINGER INGELHEIM**
Rossitza Alargova, *Director, Formulations,* **INFINITY PHARMACEUTICALS**
Eric Munson, *Professor, Pharmaceutical Technology,* **UNIVERSITY OF KENTUCKY**
Dedong Wu, *Senior Scientist,* **ASTRAZENECA**

12:45 Luncheon

	NEXT GENERATION MODELING	REFINING FORMULATION STRATEGY
1:45	**INTRODUCTION FROM TRACK CHAIR** **Manuel Sanchez-Felix,** *Senior Fellow, Formulations,* **NOVARTIS**	**INTRODUCTION FROM TRACK CHAIR**
2:00	**IDENTIFY THE CORRECT MODELS FOR SELECTING MULTIPLE FORMULATION OPTIONS** Many scientists use in vitro skin penetration studies, but are these truly relevant to clinical output? Beware of viewing models as a box to be checked without understanding their full significance to drug development. • Select the formulas that can lead into a composition when there are multiple options • Assess recent developments that are more predictable • Prioritize relevance of models for clinical output **Robert Saklatvala,** *Director, Basic Pharmaceutical Sciences,* **MERCK**	**GET LONG-TERM STABILITY ANSWERS IN THE SHORTEST TIME POSSIBLE** There is no substitute for real-time observation of solubility, but important steps toward anticipating stability answers are very much worth internalizing. The full breadth of accelerated stability programs should be made available to you. • Determine the utility of acid / base studies when judging stability • Review light / heat activation results • Spotlight when accelerated stability programs have proven the most reliable **Fenghe Qiu,** *Senior Research Fellow,* **BOEHRINGER INGELHEIM**

"Great examples of new formulation techniques."
—Senior Scientist, Biopharmaceutics, ***IPSEN***

"The sessions on amorphous solids were very helpful."
—Associate Director, Pharmaceutical Development, ***CUBIST PHARMACEUTICALS***

2:45

IN SILICO SOLID STATE MODELING IN DRUG SUBSTANCE FORM DEVELOPMENT

- Crystal structure prediction and polymorph energy landscape calculation for polymorph screening
- Virtual salt / cocrystal co-former screening for targeted salt / cocrystal selection and preparation
- Stabilization of an amorphous form through a predicted co-former interaction

Dedong Wu, *Senior Scientist,* **ASTRAZENECA**

NANOPARTICLE FORMULATIONS FOR ENHANCED BIOAVAILABILITY AND STABILITY

With over 40% of new drug candidates being poorly bioavailable, there is increased emphasis on being able to rapidly formulate drugs into bioavailable forms. A key problem is how to "downscale" bioavailability enhancement: Testing formulations at very small (mg) scales while ensuring the process and formulation will function at much larger scales. This presentation reviews nanoparticle formation processes based on rapid micromixing and controlled steric stabilization (Flash NanoPrecipitation).

- Contrast nanoparticle approaches to less stable formulations prepared by alternate hot melt extrusion or spray dried dispersion
- Analyze applicability of this technique for both hydrophilic and hydrophobic compounds
- Review low-cost global health implications of this unusually stable technique

Robert Prud'homme, *Professor, Chemical and Biological Engineering,* **PRINCETON UNIVERSITY**

3:30

PREDICTIVE ANALYTICS FOR AMORPHOUS SOLID DISPERSION STABILITY

Amorphous solid dispersions have enormous potential to increase the bioavailability of low solubility pharmaceuticals, but have the inherent risk that they may crystallize in the drug product. What can be done to avoid eliminating the bioavailability advantage?

- Provide a basic understanding of the mechanisms used to stabilize amorphous solid dispersions, including phase separation and molecular mobility
- Guide best practices for choosing polymers for stabilization
- Give case studies on how stability can be maintained, even at or above the glass transition

Eric Munson, *Professor, Pharmaceutical Technology,* **UNIVERSITY OF KENTUCKY**

IDENTIFY THE THRESHOLDS IN LOW-SOLUBILITY COMPOUNDS THAT MUST TRIGGER YOUR DEVELOPMENT OF ENABLED FORMULATIONS

What are the best strategies for balancing the efforts of multiple formulations, and the triggerpoints for choosing one formulation path over another? Not every low-solubility compound needs an enabled formulation, and you wouldn't have time to develop one for all of them anyway. How can you justify when they are and are not needed?

- Acknowledge the impact on timelines of your go / no-go decision on enabled formulations
- Predetermine circumstances where you would wait for first-in-human data before deciding
- Review the BCS classes of low-solubility compounds that did not need new formulation development

Rossitza Alargova, *Director, Formulations,* **INFINITY PHARMACEUTICALS**

4:15 **Networking Break**

4:45

DETERMINE IF FOOD EFFECTS CAN BE MEANINGFULLY PREDICTED

FDA and EMA don't think food effect science has advanced or that food effects can be adequately predicted. Are they correct? Under what circumstances can it be predicted, and when is it still useful?

- Use systemic exposure and oral absorption modeling for assessing food effects on your formulation
- Quantify interactions on oral bioavailability
- Recognize when drug exposure will be increased in the presence of proton pump inhibitors

Andy Zhu, *Scientist,* **TAKEDA**

ADAPT TO FORMULATION CHANGES WHEN APPROACHING FIRST-IN-HUMAN STUDIES

Though you may have an initial formulation in mind, the API formulation might change during scale-up in preclinical space. Formulations which work for early material may no longer be suitable tox studies, requiring that you redevelop them specifically for tox studies.

- Anticipate the need to redevelop formulations if the tox group wants to use much higher doses
- Be prepared for form changes after scale-up
- Screen for new formulations to increase exposure and enable the necessary doses

James Huckle, *Scientist, Basic Pharmaceutics, Oral Delivery Product and Process Development,* **AMGEN**

5:30

EMPIRICALLY EXPLORE THE LIMITATIONS OF PREDICTIVE TOOLS

Despite the promises of some groups, it is hard to determine which biomimetic media are actually predictive, and harder still to understand why some work and some don't. It is time to specifically explore the limitations of biomimetic media when they are not predictive of in vivo situations.

- Mechanistically work out why some models are or are not predictive
- Identify the physicochemical properties of drug substance in solution that determine whether or not it will be predictive
- Seek out unbiased opinions of the opportunities and limitations of different solution testing

Emilija Fredro-Kumbaradzi, *Manager, Biowaivers and Biocorrelations,* **APOTEX**

DETERMINE COMPOUND SUITABILITY FOR NANOPARTICLE FORMULATIONS

6:15 **Day One Concludes**

8:00 Continental Breakfast

9:00 CHAIRPERSON'S RECAP OF DAY ONE

Keith Horspool, *Vice President, Pharmaceutics,* **BOEHRINGER INGELHEIM**

MANAGING COMMON FORMULATION SETBACKS

9:15 SHORTEN THE BRIDGE FROM PRECLINICAL TO CLINICAL DATA GATHERING

A longstanding problem in the industry is the challenge of leaping into first-in-human trials. Under what circumstance can you use your preclinical data to predict performance in humans, and how can this accelerate overall development?

- Point out how preclinical PK results can influence clinical trial performance
- Discuss what it means to have the first wave of human data
- Evaluate special challenges of first-in-human data for oral drug delivery

Joachim Hoechel, *Head, Clinical Pharmacology,* **BAYER**

10:00 OVERCOME THE HIGH FAILURE RATE OF IVIVC

Lack of consistent, long-term planning can often cause IVIVC failure. Physiologically-based, clinically relevant dissolution and solubility data is a must in order to improve IVIVC results.

- Set the right input parameters for physiological models
- Rely on translational pharmaceutics to set up physiologically-based IVIVC relationships
- Find ways to support new data-gathering strategies even before a new guidance is published

Wen Lin, *Senior Investigator,* **NOVARTIS**

10:45 Networking Break

11:15 COMPARE ADVANTAGES AND DISADVANTAGES OF MULTIPLE OPTIONS FOR AMORPHOUS FORMULATION DEVELOPMENT

Karthik Nagapudi, *Senior Scientist,* **GENENTECH**

12:00 ENGINEER AMORPHOUS SOLID DISPERSIONS FOR DRUG DELIVERY

Advances in engineering amorphous solid dispersion for enhancing the oral bioavailability of drugs enable us to develop robust solid dispersion drug products. This presentation analyzes such approaches in depth.

- Combine modeling and experiments when engineering spray-dried dispersions
- Review characterization of amorphous dispersions
- Gain insight into microscopic origins and physics

Pavithra Sundararajan, *Assistant Principal Scientist, Preclinical Development,* **MERCK**

12:45 Luncheon

1:45 FOCUS ON THE PROCESS OF OPTIMIZATION WITHIN R&D

By thinking ahead in an R&D environment, you can better understand how to produce drugs at large scale and incorporate key concepts at a very early stage. This makes technology transfer and scale-up easier, and enables you to reduce costs in the long run.

- Solve how to get to final formulations as quickly as possible
- Use the latest applications of high-throughput screening
- Delve into case studies of process optimization

Gail Dempsey, *EOC and Director, Manufacturing Technologies,* **PIEDMONT ANIMAL HEALTH**

2:30 UPDATE YOUR PREFORMULATION SKILLS FOR CONTINUOUS MANUFACTURING

If you successfully find an orphan application for a new molecule, FDA will allow you to accelerate the molecule to market. But this requires the rapid development of multiple batches, in an industry constantly challenged at scaling-up production.

- Analyze the amount of room- and pod-based hardware necessary to avoid scaling up through continuous production
- Speed up early-phase development through simple tableting approaches that allow for production of clinical trial runs at size needed
- Refocus your team's energies onto drug product, formulation, and manufacturing, to allow for generating data much earlier than before

3:15 Conference Concludes

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