January 26-28, 2015 | Hilton Boston Logan Airport | Boston, MA

**4th DRUG FORMULATION & BIOAVAILABILITY**

*Breakthrough Techniques in Optimizing the Screening, Delivery, Solubility, and Stability of Drugs and Biologics to Enhance Product Life Cycles*

**Distinguished Speaker Faculty Includes:**

- **Michael Ausborn**
  Site Head, Pharma Research & Early Development
  F. HOFFMAN – LA ROCHE

- **Mehran Yazdanian**
  Director, Global R&D, Branded Products
  TEVA

- **Keith Horspool**
  VP, Pharmaceutical Development
  BOEHRINGER-INGELHEIM

- **Evan Thackaberry**
  Therapeutic Area Leader, Safety Assessment
  GENENTECH

- **Riccardo Panicucci**
  Global Head, Chemical & Pharma Profiling
  NOVARTIS

- **Liping Zhou**
  Senior Scientist, CMC & Engineering
  IPSEN

*TO REGISTER* Call 866-207-6528 or visit www.exlpharma.com/bioavailability
DEAR COLLEAGUE,

The biopharma industry, facing unprecedented regulatory and patent-life pressure, is leaning harder than ever on its formulation teams in order to accelerate time-to-market, expand product life cycles, and maximize revenue. Longstanding challenges to drug solubility are still causing development slowdowns, with 90% of APIs and 40% of drugs at market believed to be poorly-soluble. Only by employing the most innovative new formulation and delivery technologies, and accurately matching each type of molecule to its optimal design and delivery method, can you make significant progress against this challenge.

And amidst these ever-present problems, you are now facing new regulatory hurdles, particularly regarding FDA’s position on the development of pediatric formulations for all new drug candidates.

That is why you cannot afford to miss ExL Pharma’s 4th Drug Formulation & Bioavailability conference. Built specifically around feedback from YOU - our audience - the 2015 conference features an all-new program that targets your greatest and most immediate formulation, solubility, permeability, and bioavailability challenges.

Across 3 full days, and featuring more than 6 hours of unparalleled networking, 4 unique program tracks, 2 in-depth interactive workshops, and over 200 of the industry’s most distinguished drug formulation, preformulation, and delivery experts, your attendance will prepare you to:

- Develop action plans when real human data is lacking
- Explore the potential for solid-state chemistry as the next breakthrough in drug design
- Select the optimal technologies for advancing drug candidates and maintaining a robust pipeline
- Transition your formulators from small-molecule work to peptides and biologics
- Improve your modeling & simulation tactics for enabled formulations
- Successfully redesign previously-unworkable drugs on a molecular level
- Set priorities and risks in salt and polymorph screening
- Adapt to new scientific and regulatory challenges in the development of pediatric formulations

I look forward to welcoming you to Boston alongside the leaders of the biopharma industry so we can set next practice together!

Sincerely,
Matt Greenbaum
Matt Greenbaum
Senior Conference Producer
ExL Pharma
mgreenbaum@exlpharma.com

WHO SHOULD ATTEND:
Pharmaceutical and biotech executives responsible for:
- Pharmaceutical development
- Preclinical development
- Formulation
- Preformulation
- Medicinal / Analytical / Solid-State Chemistry
- Physicochemistry
- Pharmaceutics
- Pharmacokinetics / DMPK
- Drug Delivery
- Drug Discovery
- Material Science
- Life-Cycle / Portfolio Management
- Toxicology
- Chemical Engineering
- Process R&D

THIS PROGRAM WOULD ALSO BE OF INTEREST TO:
- Solubility / Formulation Characterization service providers
- Drug Delivery specialists
- API manufacturers / providers
- CROs
- CMOs

“Very good examples provided. Great explanations to questions raised!”
- Associate Director, Pharmaceutical Sciences, TAKEDA

SPONSORSHIP & EXHIBITING OPPORTUNITIES

Do you want to spread the word about your organization’s solutions and services to potential clients who will be attending this event? Take advantage of the opportunity to exhibit, underwrite an educational session, host a networking event, or distribute promotional items to attendees. ExL Pharma will work closely with you to customize a package that will suit all of your needs.

To learn more about these opportunities, please contact:
Jeffrey Friedman
Business Development Manager,
917-258-5163, jfriedman@exlpharma.com

HOTEL INFORMATION

Hilton Boston Logan Airport
One Hotel Drive
Boston, MA 02128

To make reservations, please call 1-800-445-8667 and request the negotiated rate for ExL’s 4th Drug Formulation & Bioavailability Conference. You may also make reservations using the following weblink:
The group rates are available until January 5, 2015.

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WELCOME TO BIO EAST!

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8:30  Registration and Continental Breakfast for Morning Workshop Participants

9:00  MORNING WORKSHOP:
The Industry’s Technical and Regulatory Path Forward for Pediatric Formulations
   ➢ Overview of FDA preferences for the developmental timeline of pediatric versions of all new drugs and the need for greater regulatory clarity
   ➢ Brainstorm the development of more discriminating methods than the hundred-person profile
   ➢ Isolate the formulations, ingredients, excipients, and sugars linked to pediatric products that represent the greatest analytical challenge
   ➢ Understand acceptable levels of degradation of pediatric products
   ➢ Extrapolation from adult products to pediatrics – when does it work and when doesn’t it?
   ➢ Determine the best data submission packages for your PIP and pediatric strategy to different regulatory agencies
   ➢ Reorient your development cycle around these additional formulation needs
   
   Manuel Sanchez-Felix, Senior Fellow, Formulation, NOVARTIS
   Elizabeth Galella, Research Scientist, BRISTOL-MYERS SQUIBB
   Madhavi Srikoti, Research Scientist, BRISTOL-MYERS SQUIBB

12:00  Luncheon for AM Workshop Participants; Registration for Afternoon Workshop

1:00  AFTERNOON WORKSHOP:
Selecting Methodologies, Priorities, and Risks in Salt and Polymorph Screening
   ➢ Target the screening techniques that give you the highest confidence in form stability and solubility
   ➢ Employ different crystallization methods to give the clearest understanding of the compound’s purity profile
   ➢ Understand the full scope of relationships between crystallization and screening methods – pros and cons of each
   ➢ Maximize form stability during scale-up through exploring different solvents, ratios, and procedures
   ➢ Ensure you maintain the same API ratio in cocrystals during production scale-up – compare and contrast different methods
   ➢ Instill new habits of mind for cocrystal screening based on understanding our system, the importance of proper crystallization, and avoiding impractical techniques i.e. Grinding, melting
   ➢ Set best practice on screening and bioavailability testing based on your company’s acceptability criteria
   ➢ Measure amorphous content and particle size during and after scale-up of salts to test characterization and solubility
   ➢ Differentiate between essential elements of molecular and formulation screening
   ➢ Determine the ideal material for further stability and solubility steps based on the amount of crystal in your sample
   ➢ Focus patenting strategy on platform technology in cases where you are partnering with other companies on co-developed molecules
   ➢ Predetermine cases where the formulation is so instrumental to function that you must patent both molecule and formulation

   Marianne Langston, Senior Scientist, Chemical Development, TAKEDA
   Brian Chekal, Senior Principal Scientist, Crystallization Process Development, PFIZER

4:00  End of Workshop Day

“Informative and thought-provoking. Great panel discussions!”
- President, AMLYX PHARMACEUTICALS

“A very well-organized event!”
- Scientist, DMPK, LEXICON PHARMACEUTICALS

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7:45  Registration Opens & Continental Breakfast

8:45  Chairperson’s Day One Welcome and Opening Remarks

9:00  KEYNOTE: Future Trends in Drug Formulation: Agnostic Modality
   - Consider a broader focus beyond pill formulations
   - Expand delivery tools in early discovery to design molecules for various administration routes
   - Brainstorm minimally-invasive delivery of poorly permeable drugs
   - Design delivery systems to support better patient adherence
   Robert Saklatvala, Director, Basic Pharmaceutical Sciences, MERCK

9:45  KEYNOTE: An Action Plan for the Lack of Real Human Data
   - Gain insight into formulation methods through awareness of failures as much as successes
   - Grasp the significance of the knowledge gap between preclinical and clinical AUC and CMAX data
   - Reorient knowledge-sharing towards the correlation of specific methodologies with human outcomes
   - Examine the threats to formulation timelines and budgets when different suppliers of the same API yield slightly different purity profiles, processing, performance, and bioequivalence result
   Dongmei Qiang, Senior Principal Scientist; Manager, External Collaborations, BOEHRINGER-INGELHEIM

10:30  KEYNOTE: Selecting Technologies that Overcome Solubility Challenges and Advance Drug Delivery and Pipeline Robustness
   Michael Ausborn, Site Head, Pharma Research & Early Development, Basel, F. HOFFMAN-LA ROCHE

10:45  Networking & Refreshment Break

11:45  PANEL: “Think Outside the Tablet”: Examine and Explain the Slowdown in New Formulation Approaches
   - Understand the limiting scientific explanations behind why no novel widespread formulation approaches have been adopted since solid dispersion technology
   - Identify what the industry is missing through an excessive focus on oral administration
   - Examine the prospects for achievable new drug targeting and device techniques for parenteral delivery that would not require new formulations
   Moderator: Mehran Yazdanian, Director, Global R&D, Branded Products, TEVA
   Speaker to be determined, AbbVie

12:45  Luncheon
3:15  **Latest Challenges in Simulating Supersaturation**  
- Overview of the enhancements made to enable supersaturated formulations  
- Select the best methods for predicting how long supersaturated conditions will be sustained  
- Estimate how much supersaturation impacts overall formulation performance  
- Design in-vitro models best capable of predicting and assessing supersaturations  
  
  **Chris Towler, Principal Scientist, NOVARTIS**

4:00  **Networking & Refreshment Break**

4:30  **Dosing and Dispersability Studies to Model Supersaturation**  
- Look into excipient options that would allow you to predict or maintain supersaturation and prevent rapid precipitation  
- Identify the trends in compound crystalline structure most associated with rapid nucleus formation, alignment, and precipitation  
- Properly dose your amorphous solid dispersions for animal studies  
- Gauge the likelihood of maintaining an amorphous state while in oversaturated solution  
  
  **Mengwei Hu, Development Fellow, Basic Pharmaceutical Sciences, MERCK**

4:30  **Novel Automated Analysis Methods for Biorelevant Dissolution**  
- In vitro methods show how APIs and formulations behave in presence of simulated gastric and intestinal pH and biorelevant media (FaSSIF and FeSSIF); the quest for IVIVC  
- In vivo predictive dissolution methodology; biphasic dissolution to model GI dissolution and absorption  
- Monitoring precipitation from supersaturated solutions and studying the effect of precipitation inhibitors  
  
  **John Comer, CSO, SIRIUS ANALYTICAL**

5:15  **Avoid Underpredicting Exposures through Better Modeling of Enabled Formulations**  
  
  **Manuel Sanchez-Felix, Senior Fellow, Formulation, NOVARTIS**

5:15  **CASE STUDY: Addressing pH-Dependent Absorption**  
  
  **Michael Perlman, Senior Scientist II, Pharmaceutical Profiling, MILLENNIUM PHARMACEUTICALS**

5:15  **Stepwise Approach to Preformulation and Formulation Development to Maximize Success**  
  
  **Paul Sabo, Senior Technician, PDS Formulation Development, PATHEON**

6:00  **End of Day One**

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"**Fascinating mix of industry researchers and technologies.**"  
- Director of Pharmacy Nanotechnology, CONCORDIA UNIVERSITY OF WISCONSIN SCHOOL OF PHARMACY

"**Great presentations - clear and knowledgeable.**"  
- VP, Product Development R&D, CORERX

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11:00 KEYNOTE: Oral Delivery for Biologics: Formulations and Device-Based Strategies

- Though IV delivery of standard biologics gives 100% bioavailability, oral formulations can sometimes deliver better results or an improved clearance rate.
- Survey the different approaches industry is taking towards oral biologic formulations, through new technical tools and cross-company partnerships.
- Identify why some oral formulations fail and carry those lessons forward into the next generation of biologics.
- Transcend standard formulation challenges through device-based consumable oral delivery methods.

Riccardo Panicucci, Global Head of Chemical & Pharmaceutical Profiling, NOVARTIS

11:45 In Situ Concentration Monitoring as a Measurement Tool within In Vivo Predictive Dissolution Systems

- Recognize the greater need for analyzing realtime free drug concentration.
- Identify the challenges to in-situ monitoring presented by bio-relevant simulated fluids and complex foods containing dissolution media.
- Deploy in-situ measurement tools to reduce mechanical complexity of pumping-based sampling systems and provide a very high density of realtime concentration data.
- Gain insight into drug and formulation behavior via combining the dual-chamber dissolution-permeability setup with the ability to monitor concentration in both compartments.

Konstantin Tsinman, Director, Science & Research, PION

12:30 Luncheon

1:30 Crystallization Screening Options: A New Approach to Cocrystals

- Develop new methods for studying polar interactions that do not focus on stacking efforts.
- Explore the likelihood of prior cocrystal failures due to compounds "hiding" the part of the molecule that would tend to associate with water and impact solubility.
- Assess the benefit of matching polar moieties with less hydrophilic portions of cocrystals.

John Morrison, Senior Research Investigator, Discovery Pharmaceutics, BRISTOL-MYERS SQUIBB

2:15 WRAP-UP PLENARY DISCUSSION: Enable Breakthroughs in Manufacturing and Drug Design through Rational Formulations

- Improve understanding of why certain technologies make formulations more effective.
- Recognize the limits of empirical approaches and substitute rational formulation methods when determining the feasibility of new technologies.
- Build an understanding of molecular features and molar design into formulations in a manner that empirical techniques cannot equal.

Evan Thackaberry, Therapeutic Area Leader, Safety Assessment, GENENTECH

3:00 Conference Concludes