PharmaED RESOURCES, Inc.

Solubility & Bioavailability Summit 2015

New Strategies for Optimizing Bioavailability of Current and Future Drug Products

November 5-6, Racquet Club of Philadelphia, PA

Featured Speakers Include:

Yi Gao
Principal Scientist
Abbvie

Yuriy Abramov
Sr. Principal Scientist
Pfizer

Shawn Yin
Sr. Principal Scientist
Bristol-Myers Squibb

Sunny Bhardwaj
Sr. Scientist
Merck

Geeti Gangal
Principal Scientist
Novartis

With Comprehensive Coverage On:

- **Computational Approaches to Enhanced Solubility**
- **Novel In-Vitro Tools to Predict the Food Effect on Bioavailability**
- **Encapsulation and Controlled Release from Nanoparticles**
- **Implications of Drug/Polymer Interactions at Water/Crystal Interfaces**
- **Polymer Thin Films for the Delivery of Poorly Soluble Drugs**
- **Risk-Based Approaches in Early Product Design**
- **Formulation, Development and Stabilization of Spray-Dried Dispersions**
- **Stabilizing Supersaturated Systems Using Surfactants as Anti-Nucleation Agents**
- **New Approaches to the Interplay of Dissolution, Solubility and Permeability in Formulation Dev.**
- **Dosage Form Selection and Optimization in Early Clinical Trials**
- **Rational Formulation Approaches to Cost-Effective Product Development**
- **And Much More!**

A critical research agenda for today's pharmaceutical industry is achieving solubility and bioavailability of poorly soluble drug candidates. The challenges are not going away, and neither are your organization's demands. Pharma Ed's 3rd annual Solubility & Bioavailability Summit focuses on the innovative science required to overcome bioavailability/solubility challenges for API's in a wide range of pre-clinical, clinical, and manufacturing contexts.

Featuring Representation From:

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Thursday, November 5, 2015

7:45 *Complimentary Breakfast & Chairperson's Welcome and Opening Remarks*

Enhancing Solubility—Computational and Solid State Perturbation Approaches

8:15 **Computational Approaches to Guide Solubility Improvement of Pharmaceuticals: Some Challenges and Solutions**

Yuriy Abramov, Senior Principal Scientist, Pfizer Global Research & Development

An increasing trend towards low solubility is a major issue for drug development as formulation of low solubility compounds can be problematic. An overview of computational approaches that provide a rationale for solubility improvement of pharmaceuticals is presented. The topics considered include solvation vs. crystal packing contributions to solubility; coformer or solvent selection for cocrystallization or desolvation; and coformer selection for improved relative humidity stability.

8:55 **Intrinsic Solubility Enhancement through Compound Modification by In-Silico Solid State Perturbation Approach**

Dedong Wu, PhD, Senior Scientist, Product Development Unit, AstraZeneca R&D

More than half of drug candidates are poorly soluble in aqueous solutions. Often, enabling formulation techniques, including solid dispersions, lipid formulation and/or nanoparticles, are necessary for drug product development of these candidates. However, these enabling formulation approaches are usually time-consuming, cost-ineffective and risky. One of the most efficient ways to reduce burdens for pharmaceutical developments of drug candidates is to obtain compounds with better solubility. This presentation will introduce a new strategy by utilizing solid state perturbation method for molecule re-design in order to enhance compound solubility. We will present the concept of solid state perturbation, discuss the approach of systematically improving the intrinsic solubility of a compound by perturbing key interactions in its crystal structure, and discuss how to redesign a drug candidate to molecules similar to the original one but with significantly higher solubility. This innovative strategy for developing poorly soluble drug candidates will also demonstrate partnership between drug discovery and drug development.

9:35 *Networking Break*

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10:00 **Controlled Release Formulations in Drug Discovery: Early Investment for Better Products**

Sunny Bhardwaj, Senior Scientist, Merck

Controlled release (CR) dosage forms present an attractive drug delivery option owing to their ability to deliver a desired PK/PD profile and by that virtue, reduce adverse effects related to the exposure profile. Moreover, less frequent dosing has the potential to improve patient compliance. In view of the complexity of CR formulation development, proactive and early CR investment can increase the downstream probability of success and minimize development timelines. With the help of case studies, this presentation will highlight the importance of a cross-functional collaborative strategy to enable CR assessment and address PK/PD issues early in the development cycle of a drug candidate.

Critical Issues—In-Vitro Tools to Predict the Food Effect on Bioavailability

10:40 **Positive or Negative Food Effect—Predictions Using In-Vitro Tools**

Geeti Gangal, Principal Scientist, Novartis

Food can change the bioavailability of a drug and can influence the bioequivalence of the test and the reference products. It has been known that food effects on bioavailability have clinically significant consequences. And, the food effect can be either positive or negative. In practice, it is difficult to determine the exact mechanism by which food changes the bioavailability of a drug product without performing mechanistic studies. Also, the food effect can be dose dependent as well. Various in-vitro tools available to make food effect predictions early on and their applications will be discussed.

11:20 **Case Studies Of In-Vitro Methods For Bio-Relevant Analysis Of Both Small Molecules And Proteins**

CASE STUDY

Jon Mole, Executive VP, Sirius Analytical Inc.

There is a need across industry for automated in-vitro tools that can provide insights into the behavior of new drugs and complex enabling formulations under bio-relevant conditions, to reduce development time and mitigate the need for expensive in-vivo studies. This presentation will focus on case studies using novel instrumentation for dissolution, solubility, precipitation studies under simulated bio-relevant conditions, including:

* Robust, automated bio-relevant dissolution & solubility measurements

With many orally administered drugs now requiring solubility enhancement, formulators need ways to characterize supersaturation and precipitation. Sirius inForm measures solubility using the CheqSol method; new assays report the extent and duration of supersaturation, precipitation rates and excipient gain factors.

Uniquely, concentrations are calculated from measured pH, which eliminates interference by suspended solids.

*Sirius Scissor—a new in-vitro tool for subcutaneous injection site simulation
Subcutaneous (SC) injection is becoming an increasingly common route for the administration of biopharmaceuticals. Historically, there has been no reliable in vitro method that can be used to anticipate the in vivo performance of a biopharmaceutical formulation intended for SC injection, or an animal model that can predict in vivo outcomes such as bioavailability in humans. Scissor (Subcutaneous Injection Site SimulatOR) addresses this need and models environmental changes that a biopharmaceutical may experience as it transitions from conditions of a drug product formulation to the homeostatic state of the hypodermis following SC injection.

12:00 *Lunch Sponsored By:*

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Conference Keynote— A New Screen for Physical Stability Risks in Spray Dried Dispersions

1:15 KEYNOTE

Studying Early Phase Separation Warning Signs for Spray Dried Disperse Materials

Shawn Yin, Senior Principal Scientist, Bristol-Myers Squibb

Recently, we have developed a system containing screening techniques capable of assessing the physical stability risks of spray dried disperse (SDD) materials. The objective of this screen is to give formulators a warning when phase separation and crystallization of the dispersion may be likely. Better understanding of phase separation risk should impact choice of API loading in the dispersion and polymer selection. Ultimately, a more complete understanding of the phase separation and crystallization risk should enhance our ability to assess the API crystallization risk of SDD materials during product stability and performance evaluation studies and product storage as well. The physical characterization techniques in this screen include powder X-ray diffraction (PXRD); isothermal calorimetry (TAM); differential scanning calorinetry (DSC); Fourier transform infrared spectroscopy (FT-IR); solid state Nuclear Magnetic Resonance (ssNMR); and other common pharmaceutical physical characterization techniques. Illustrated by case study examples in this presentation, studying SDD materials phase separation sign and crystallization risk fills gaps in our understanding of SDD material physical stability risk, and enables the development of robust SDD materials.

1:55 CASE STUDY

Formulation and Development of a Spray-Dried Amorphous Dispersion for Bioavailability Enhancement—Recent Case Studies

Stephanie Buchanan, Senior Research Chemist, Bend Research

Recent studies suggest that up to 75% of new chemical entities currently under development exhibit low aqueous solubility. Enabling technologies may be required to achieve adequate exposure for efficiency. Amorphous solid dispersions can provide a supersaturated concentration of drug in the gastrointestinal environment, which often translates to rapid absorption and improved bioavailability. Spray drying is a well-understood, effective method of producing amorphous solid dispersions.

Spray-dried amorphous dispersions (SDDs) represent a versatile and scalable technology with a proven track record for increasing bioavailability. There is a large selection of applicable excipients for formulation optimization, and aqueous solubility may be enhanced across a wide range of compound properties. The SDD is amenable to manufacture into solid dosage forms such as tablets, capsules, and controlled-release dosage forms. This presentation will focus on considerations in the formulation and processing of spray-dried dispersions, including stability assessment and in vitro performance. Case studies will be used to demonstrate key aspects of manufacturability, stability and performance.

2:35 *Afternoon Networking Break*

3:00

The Role of Surfactants as Anti-Nucleation Agents to Stabilize Supersaturated Systems

James D. Ormes, Associate Principal Scientist, Discovery Pharmaceutical Sciences, Merck

Recent advances in the pharmaceutical literature have emphasized an important distinction between the impact of solubility and supersaturation on the chemical potential of a solute in an aqueous system, even at the same nominal solution concentration. These advances have eloquently demonstrated how flux across a membrane is driven thermodynamically, not by solubility, but rather by the solute activity. In light of these findings, the importance of supersaturated formulations, such as amorphous solid dispersions, cannot be understated. An emphasis on maximizing chemical potential in solution, to drive membrane flux, necessitates supersaturation. However, with the enhanced chemical potential to drive membrane flux comes the need to stabilize supersaturated formulations from an enhanced driving force for crystallization.

As formulation scientists attempt to stabilize supersaturated systems, and delay onset of crystallization,

the importance of re-evaluating the role of excipients, bio-relevant dissolution media components, and endogneous fluids, from an anti-nucleation perspective, must be emphasized. The role of polymers as anti-nucleation agents has been studied extensively. However, the role of surfactants, which have long played a role in the pharmaceutical industry as solubilizing additives, as anti-nucleation agents, warrants fresh evaluation. This talk hopes to highlight the role of surfactants as anti-nucleation agents from numerous perspectives including incorporation as formulation excipients, bio-relevant media components and intestinal fluid contents.

3:40 **Addressing Drug Delivery Challenges Early: Enhanced Formulation Decision-making Within First-in-Human Trials**

Kieran Crowley, Senior Director, Translational Pharmaceutics, Quotient Clinical

A Translational Pharmaceutics® platform integrates formulation development, GMP manufacture and clinical testing capabilities so that drug product manufacture occurs in real-time immediately prior to dosing, in healthy volunteers or patients. Each manufacture is therefore conducted in response to emerging clinical data and under a flexible clinical protocol permits within-trial dose and formulation adjustments, or switches to alternate dosage forms. Such within- protocol flexibility is being increasingly applied to first-in-human clinical trials, not just to ensure effective dose escalation, but also to enable selection of optimum formulation technologies to overcome challenging drug properties. This approach obviates the need for multiple clinical studies and therefore delivers significant benefits to the development team.

This presentation will cover formulation development applications and case studies, including de-risking formulation selection decisions for poorly soluble compounds, and successfully transitioning from fit-for-purpose liquid formulations to solid oral dosage forms for POC clinical trials.

Panel Discussion

4:20 **Reducing Time-to-Market: How Do We Accelerate the Development of Challenging Compounds?**

Participants:
Beth Sarsfield, Ph.D., Senior Partner, Pharma Product Solutions, LLC
Sunny Bhardwaj, Senior Scientist, Merck
Geeti Gangal, Principal Scientist, Novartis
Yuriy Abramov, Senior Principal Scientist, Pfizer
Shawn Yin, Senior Principal Scientist, BMS

5:00 *End of Day One*

Friday, November 6, 2015

7:45 *Complimentary Breakfast*

8:15 **Risk-Based Approaches in Early Product Design**

Beth Sarsfield, Ph.D., Senior Partner, Pharma Product Solutions, LLC

Integrated risk-based approaches to drug development, including early product design, are necessary to facilitate early decision-making and speed-to-market, while limiting increasingly expensive research costs and assuring that the right products pass best-of-class clinical profiles and regulatory hurdles. The risks associated with a strong development plan must optimize the risks and benefits to the whole discovery, development, and manufacturing timeline. Early product design has its own risks that can strongly affect the remaining timeline. Thus, preclinical, clinical, drug substance development, and formulation design need to be integrated to balance risks, with special attention given to timing, cost, and the possibility of clinical, regulatory and market success.

Selection of an early product design strategy starts with data developed during the discovery stage, including solubility and permeability. Early drug substance property and formulation strategies that improve these parameters and assure that the Phase I clinical trials are successful, come with a different set of risks than testing the drug as-is. Costs and timing are also affected by the strategies, with faster timing and lower early development costs sometimes resulting in increased total cost during late development. In this presentation drug substance properties, early product design strategies, related risks and risk mitigation programs, and examples of the success and failures of different strategies, will be discussed.

8:55 **Rational, Expedited and Cost Effective Product Development; Is It Possible?**

Chonghui Gu, Head of CMC, Senior Director, Agios

With a precision medicine approach, more and more new therapeutics are developed under breakthrough therapy pathways which significantly shortens the clinical development timeline and may place CMC on critical path for product approval. It is therefore a requirement to have a rational and expedited approach to develop products with high quality and a robust manufacture process. In this talk, approaches to efficiently develop oral solid drug product of small molecules using biopharmaceutical modeling, rational formulation selection and automation will be discussed.

9:35 *Mid-Morning Networking Break*

Research Spotlight— Drug-Polymer Interactions at Water-Crystal Interfaces; and Drug Delivery Using Polymer Thin Films Contexts

10:00

Drug–Polymer Interactions at Water–Crystal Interfaces and Implications for Crystallization Inhibition: Molecular Dynamics Simulations of Amphiphilic Block Copolymer Interactions with Tolazamide Crystals

Yi Gao, Principal Scientist, AbbVie

A diblock copolymer, poly(ethylene glycol)-block-poly(-lactic acid) (PEG-b-PLA), modulates the crystal growth of tolazamide (TLZ), resulting in a crystal morphology change from needles to plates in aqueous media. To understand this crystal surface drug–polymer interaction, we conducted molecular dynamics simulations on crystal surfaces of TLZ in water containing PEG-b-PLA. A 130-ns simulation of the polymer in a large water box was run before initiating 50 ns simulations with each of the crystal surfaces. The simulations demonstrated differentiated drug–polymer interactions that are consistent with experimental studies. Interaction of PEG-b-PLA with the (001) face occurred more rapidly (&10 ns) and strongly (total interaction energy of –121.1 kJ/mol/monomer) than that with the (010) face (#35 ns, –85.4 kJ/mol/monomer). There was little interaction with the (100) face. Hydrophobic and van der Waals (VDW) interactions were the dominant forces, accounting for more than 90% of total interaction energies. It suggests that polymers capable of forming strong hydrophobic and VDW interactions might be more effective in inhibiting crystallization of poorly water-soluble and hydrophobic drugs in aqueous media (such as gastrointestinal fluid) than those with hydrogen-bonding capacities. Such in-depth analysis and understanding facilitate the rational selection of polymers in designing supersaturation-based enabling formulations.

10:40

ElectroNanospray™ platform as a formulation screening and development tool for solubility-challenged APIs.

Robert Hoerr, Co-Founder and Chief Scientific Officer, Nanocopoeia, LLC.

Delivery of poorly water-soluble drugs is a continuing challenge to formulators seeking to maximize an API's therapeutic potential. Stabilizing excipients are invariably required, whether the API is blended with the polymer in an amorphous dispersion, produced with hot melt extrusion or solvent spray drying, or in submicron powders, such as milling to produce nanocrystals. Cone-jet mode electrospray is an emerging process that produces amorphous solid dispersions in the form of nanoscale powders. The resulting API intermediate rapidly disperses to achieve supersaturated concentrations in biorelevant fluids. The practical application of electrospray for pharmaceutical purposes lagged other processing innovations of the past several decades due to the fundamental scale limitations imposed by capillary spray nozzles. This hurdle has been overcome by a novel multi-jet nozzle design. The latest generation ElectroNanospray™ platform incorporates manifold arrays of multi-jet nozzles capable of continuous operation. Nanopowders are produced in a single step under ambient conditions and collected on a variety of substrates for further incorporation into standard dose forms. Formulations can be optimized quickly at small scale and translated to multi-nozzle production for larger yields. The flexibility of the system will be demonstrated through several case studies involving solubility-challenged APIs and various polymeric excipients, contrasting their physical characterization and functional performance.

11:20

Polymer Thin Films for the Delivery of Poorly Water Soluble Drugs

Rajesh N. Davé, Distinguished Professor, Department of Chemical, Biological and Pharmaceutical Engineering, NJIT

While polymer thin films have garnered significant attention for their patient compliance and cost-effective scale-up, recent studies have shown that they are also an ideal platform for poorly water-soluble drug delivery. In contrast to popular belief that they are only suitable for very low dosage and must be formed using drug solutions, our work has shown that this form is ideally suited to delivery of very poorly water-soluble drugs. By incorporating drug in form of engineered nano and micro sized particles, the drug dissolution rate is enhanced by preserving the high surface area through uniform particle dispersion and size/form control. The robustness of this approach is demonstrated using multiple BCS Class II drugs where the drug as a stable suspension or in dry micronized powder form may be mixed with film-forming polymeric solutions and then caste as films and dried to form stabilized drug nano or micro composite structures. It is shown that the film matrix may be designed to impart desired functionality to the final product. Examples are included to show film formed using nanosuspensions produced from wet stirred media milling (WSMM), liquid-antisolvent precipitation, melt-emulsion solid particle formation, as well as dry jet milled powders. Overall, the films exhibited very good mechanical properties, improved drug content uniformity, and achieved fast drug dissolution. These results set the foundation for continuously operating process development of films containing nanoparticles, specifically, for poorly water-soluble drugs, for various drug delivery applications.

12:00

Complimentary Lunch

Formulation Development

1:15 CASE STUDY

Experimental Methods to Study Interplay of Dissolution, Solubility and Permeability in Formulation Development

Konstantin Tsinman, Ph.D., Director, Science and Research, Pion, Inc.

Development strategy for insoluble compounds requires not only measurements of the solubility enhancement from formulations but also the assessment for the effect formulations having on permeability. An introduced dissolution-permeability (μFLUX) measurement platform allows simultaneous monitoring for both effects enabling in vitro setup for early in vivo predictive formulations testing.

Ability to measure concentration of free (solubilized) drug in situ is critically necessary in formulation research because any off-line solution handling can disturb quasi-stable (kinetic) phase that low soluble compounds often form in the presence of excipients. Case studies involving two different detection techniques based on fiber-optic UV measurements and potentiometric free drug sensors (FDS) will be presented. These case studies will highlight:

- Combining dissolution and permeability assays for better formulation design, understanding the food effect on bioavailability and more realistic IVIVC;
- Studying if solubility enhancement in the bio-relevant media leads to the same gain in the absorption and bioavailability;
- Real time concentration monitoring of free drug in the presence of lipid passed formulations, nanoparticles and binding proteins;
- Monitoring in real time the free API fraction released from nanoparticles and predicting absorption enhancement from nanoparticle formulations;
- Developing a predictive in vitro method to monitor powder/formulation dissolution and concomitant precipitation processes in dynamically changing bio-relevant media.

1:55

Novel Approach of IV Formulation Development of Solithromycin, a Fourth Generation Macrolide Antibiotic

Sara Wu, Director of Drug Product Development, Cempra Pharmaceuticals

Solithromycin is a 4th generation macrolide, the first fluoroketolide antibiotic. The Phase III clinical trials using the oral dosage and IV-oral switch of solithromycin have been completed for treating Community Acquired Bacterial Pneumonia. The challenges faced during the intravenous formulation development of solithromycin will be presented. Solithromycin has good solubilities at pHs below 5 (≥20 mg/ml). As pH increases to neutrality, the solubility of solithromycin gradually decreases to approximately 0.4 mg/ml. The goal of the IV development program was to establish a formulation that can deliver 400 mg of solithromycin in 250 ml infusion solution (1.6 mg/ml of the drug in the infusion solution). The challenges were to define a suitable pH, suitable buffers and buffer capacity that allow a sufficiently high solubility to provide the needed dose and more importantly to minimize the infusion related local intolerance. The local intolerance is hypothesized to be caused by precipitation of the drug at physiological pH conditions. Using the in-vitro dynamic precipitation model in Professor Yalkowsky's lab, solithromycin aqueous solutions with numerous combinations of various buffers at various pHs were examined for the level of dynamic precipitation. Selected formulations based on the results from the in-vitro model were tested in the rabbit ear vein irritation model. Several formulations were further tested in phase I clinical studies. In considerations of the in-vitro, in vivo and phase I clinical results, a solithromycin IV formulation containing three amino acids (L-Histidine, L-Glutamic acid and L-Aspartic acid) at pH 4.5 was selected for the IV to oral Phase III clinical trial, which finished treatment very recently

2:35 *Afternoon Networking Break*

2:50 CASE STUDY

Lipid Multiparticulates as a Versatile and Novel Vehicle for Solubilization and Bioavailability Enhancement, Immediate and Modified Release

Eduardo Jule, Senior Manager, Formulation and Pharmaceutical Development, Capsugel

Lipid multiparticulates (LMP) constitute a novel drug delivery platform that combines the well-established benefits of lipid-based formulations with the functionality of non-monolithic formats. Made from GRAS materials, LMPs are solid matrices that can be tailored to accommodate a variety of drugs, from poorly- to water-soluble compounds, and formulated to release through an equally wide range of mechanisms including solubilization/emulsification/digestion and erosion/diffusion, and achieve immediate or modified release. Other benefits include taste and odor masking, and the flexibility to accommodate to multiple dosage forms, from capsules or sprinkle capsules to stick packs and sachets, all of which will be evidenced through a commercial case study. Within another internally sponsored development program, LMPs were compared head to head against different technologies and shown to increase the solubilization, and enhance the bioavailability of a poorly soluble compound both in vitro and in vivo.

Research Spotlight—Encapsulation and Controlled Release through Nanoparticles

3:30 **Encapsulation and Controlled Release of Therapeutics from Nanoparticles**

Brian K. Wilson and Robert K. Prud'homme, Princeton University, Department of Chemical and Biological Engineering

Nanoparticles have received substantial attention as delivery vehicles for therapeutics, yet many drugs have undesirable solubility profiles resulting in low drug loading, poor encapsulation efficiency and burst release profiles in nanoparticle formulations. Flash NanoPrecipitation (FNP) provides a platform for preparing block copolymer stabilized nanoparticles of hydrophobic materials. Converting therapeutics into hydrophobic prodrugs allows the use of FNP to synthesize nanoparticles with high drug loading and nearly complete encapsulation by altering the solubility profile of the therapeutic. The controlled release profile of active therapeutic can then be tuned by adjusting the rate of prodrug degradation through prodrug chemistry and excipient formulation. Adding lipid excipients into the nanoparticle formulation increases the rate of prodrug degradation, allowing tunable release rates from a single prodrug chemistry.

4:10 ***Close of Program***

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