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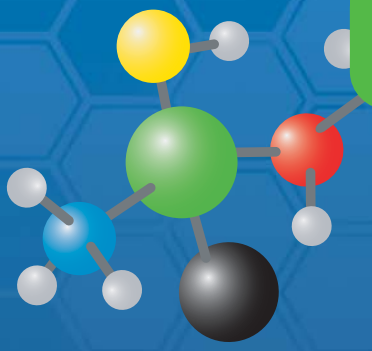

8th Annual

PCSF

Polymorphism & Crystallization Scientific Forum™

Improving Solubility, Increasing Bioavailability and Improving Drug Development

Philadelphia, PA • October 26-28, 2009

Learn Best Practice Strategies On How To

- Predict **crystal nucleation** from the amorphous state
- Understand and rationalize **co-crystal discovery, solubility and selection**
- Discover the **roles and significances of materials science and engineering** in modern drug development
- Determine the interface between **drug substance and drug product** in materials sciences and crystallization
- Evaluate **polymorphism and crystallinity determination** in discovery
- Identify when to **effectively use hydrates** in pharmaceutical development
- Decipher new strategies for polymorphism as a tool for **life cycle extension**

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Scientific Forum Chairman:

Harry G. Brittain PhD, FRSC, Institute Director, **Center for Pharmaceutical Physics**

Hear from Leading Polymorphism & Crystallization Experts Including:

Naír Rodríguez-Hornedo, PhD, Associate Professor of Pharmaceutical Sciences, The College of Pharmacy, **The University of Michigan**

Eric J. Munson, PhD, Professor, Department of Pharmaceutical Chemistry, **University of Kansas**

M. Sherry Ku, PhD, Senior Director, Pharmaceutical Development, **Wyeth Research**

Keith R. Horspool, PhD, Senior Director, Materials Science and Oral Products, **Pfizer Inc.**

Harry G. Brittain, PhD, FRSC, Chief Executive Officer, **Center for Pharmaceutical Physics**

Changquan Calvin Sun, PhD, Assistant Professor, Department of Pharmaceutics, College of Pharmacy, **University of Minnesota**

Dedong Wu, PhD, Senior Scientist, Pharmaceutical and Analytical R&D, **AstraZeneca**

Duk Soon Choi, PhD, Research Leader, **Hoffmann La Roche**

Michael McNevin, PhD, Senior Research Chemist, **Merck Research Laboratories**

Yun Alelyunas, PhD, Principal Scientist I, Head of Physical Properties Team, **AstraZeneca**

Fred Vogt, PhD, Manager, Analytical Sciences, Chemical Development, **GlaxoSmithKline**

Gregory Stephenson, PhD, Research Advisor, Preformulations, **Eli Lilly & Company**

Xiaoming (Sean) Chen, PhD, Drug Product Development & Manufacturing, **OSI Pharmaceuticals, Inc**

Richard Varsolona, Crystal Engineering Technology, **Wyeth**

Elena Kostik, PhD, Principal Scientist, **Synta Pharmaceuticals Inc**

www.polymorphismforum.com

8th Annual

PCSF Polymorphism & Crystallization Scientific Forum™

Philadelphia, PA • October 26-28, 2009

Dear Colleagues,

As the U.S.'s leading scientific forum on Polymorphism and Crystallization, this year's event will provide cutting edge information to identify practices and scientific processes that increase efficiency of design, preparation and selection processes for polymorphs and salts in drug development. With the goal of improving solubility and increasing bioavailability of salts at the forefront of every session, we have gathered a unique array of the industry's most renowned pharmaceutical, biotech and academic thought leaders to share the latest scientific advancements through interactive and engaging formats.

You will hear over 17 in-depth sessions and case study examples including:

- Practical uses of amorphous API's
- Physical stability of salts of weak bases in the solid state
- Improvement of solid state chemical stability through form selection
- Salt and polymorph selection strategy based on the Biopharmaceutical Classification System (BCS) for early pharmaceutical development
- Modulation of the solubility and dissolution rate of crystalline substances: The effect of polymorphic/solvatomorphic identity and particle size
- The role of XRPD in accelerating pharmaceutical phase identification and selection
- The continuing evolution of solid-state NMR in pharmaceutical analysis

Additionally, benefit from industry presentations from AstraZeneca, Merck, Pfizer, Wyeth, Hoffmann La Roche, GlaxoSmithKline, Eli Lilly, OSI Pharmaceuticals and many more pharmaceutical, biotech and academic experts. This conference promises to be a networking and discussion-filled event leaving you with new ideas and solutions to help you overcome your Polymorphism and Crystallization issues and challenges.

We look forward to seeing you in Philadelphia in October!

S T Curtis

Simon Curtis
Conference Director, Pharma IQ
simon.curtis@iqpc.com

P.S. Don't miss the highly interactive and informative pre-conference workshops! See page 5 for details

Who Will You Meet At The Conference?

Chief Scientific Officers, Vice Presidents, Directors, Heads, Scientists, Chemists, Research Leaders/Fellows/Advisors and Academics specializing in:

- Analytical Chemistry/Sciences
- Solid-state Chemistry
- Process Chemistry
- Physical Chemistry
- Organic Chemistry
- Chemical Engineering
- Chemical Development
- Physical Properties
- Pharmaceutical Development
- Pre-formulation
- Formulation
- Discovery Chemistry
- Drug Delivery
- Materials Science
- Pharmaceutics
- Physiochemistry
- Solid State
- Process R&D

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Sponsorships and Exhibits are excellent opportunities for your company to showcase its products and services to high-level, targeted decision makers attending **The 8th Polymorphism & Crystallization Scientific Forum.** Pharma IQ and the IQPC help companies like yours achieve sales, marketing, and branding objectives by setting aside a limited number of event sponsorships and exhibit spaces – all of which are custom-tailored to help your company create a platform to maximize its exposure at the event.

For sponsorship opportunities, please contact Mario Matulich at 212-885-2719 or sponsorship@iqpc.com

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- Naír Rodríguez-Hornedo, PhD, Associate Professor of Pharmaceutical Sciences, The College of Pharmacy, The University of Michigan
- Yun Alelyunas, PhD, Principal Scientist I, Head of Physical Properties Team, AstraZeneca
- Fred Vogt, Manager, Analytical Sciences, GlaxoSmithKline
- Andre Raw, PhD, Office of Generic Drugs, Center for Drug Evaluation and Research (CDER), FDA
- Changquan Calvin Sun, PhD, Assistant Professor, Department of Pharmaceutics, College of Pharmacy, University of Minnesota
- Scott Smith, PhD, Director, Physical Chemistry, Allergan

Main Conference Day 1

Tuesday, October 27, 2009

8:00 **Registration and Coffee**

8:45 **Welcome Address and Chairperson's Opening Remarks**
Harry G. Brittain, PhD, FRSC, Chief Executive Officer, **Center for Pharmaceutical Physics**

Novel Solubility Enhancement Techniques and Practices

9:00 **Opening Keynote Presentation: Understanding and Rationalizing Co-Crystal Discovery, Solubility and Selection**
Co-Crystals offer the advantage of generating solid forms of active pharmaceutical ingredients (APIs) with other molecular components and produce materials with strikingly different and advantageous properties. Much of the research in this field has focused on the application of supramolecular chemistry concepts to the design of co-crystals while co-crystal formation and co-crystal structure-property relationships are not well understood. Understanding how co-crystal solubility is affected by co-crystal components and solution chemistry is essential to (1) engineer co-crystals with customized solubility and (2) streamline co-crystal discovery and selection. This talk will present approaches that are valuable to predict co-crystal-solution phase behavior and guide co-crystal selection without the time and material consuming requirements of traditional methods.
- Identifying effective co-crystal synthesis by solution mediated processes
- Understanding why the same solvent can lead to no co-crystal or to co-crystal
- Discussing mechanisms by which co-crystal solubility is enhanced
- Examining co-crystal structure-solubility relationships
- Displaying thermodynamic indicators of co-crystal solubility and stability

Naír Rodríguez-Hornedo, PhD, Associate Professor of Pharmaceutical Sciences, The College of Pharmacy, **The University of Michigan**

9:45 **Modulation of the Solubility and Dissolution Rate of Crystalline Substances: Effect of Polymorphic/ Solvatomorphic Identity and Particle Size**
- Outlining the structural aspects of polymorphism and solvatomorphism, and the resulting effects on the thermodynamic and kinetic properties of solids
- Discussing the most appropriate techniques for the study of organic crystalline polymorphism and solvatomorphism
- Summarizing of the theory relating particle size and dissolution rate of crystalline solids
- Examining methodology and tools, through the use of case studies, for evaluating the effect of solid-state characteristics on dissolution rate and solubility

Harry G. Brittain, PhD, FRSC, Institute Director, **Center for Pharmaceutical Physics**

10:30 **Morning Networking Break**

11:15 **Understanding When to Effectively Use Hydrates in Pharmaceutical Development**
- Understanding the importance of hydrates in Pharmaceutical Development
- Discussing different types of hydrates
- Examining physical/chemical analysis of hydrates
- Estimating the relative stability among polymorphs and hydrates
- Processing issues with hydrates

Dedong Wu, PhD, Senior Scientist, Pharmaceutical and Analytical R&D, **AstraZeneca**

12:00 **Polymorph Control and Crystal Engineering for Improvement of API Mechanical Properties**
- Discussing phase relationships of Polymorphs, solvates and hydrate
- Addressing solvent base morphology modifications
- Examining impurity base morphology modifications
- Identifying morphology modification and PSD control with in-line wet milling techniques and PAT technology

Richard Varsolona, Crystal Engineering Technology, **Wyeth**

12:45 **Networking Luncheon**

Characterization and Identification of Drug Forms

1:45 **Predicating Crystal Nucleation from the Amorphous State**
- Understanding the physics of crystal nucleation
- Identifying sites for nucleus formation
- Determining the amorphous state most (or least) likely for recrystallization
- Relating crystallization to thermodynamic parameters such as Tg
- Comparing amorphous dispersions and solid solutions for amorphous form stabilization

Eric J. Munson, PhD, Professor, Department of Pharmaceutical Chemistry, **University of Kansas**

2:30 **Practical Uses of Amorphous API's: Features and Stability**
- Discussing and understanding where amorphous materials fit in drug development
- Evaluating the advantages and disadvantages of amorphous materials
- Weighing up the pros and cons of stabilization of amorphous solids in dispersions
- Identifying practical properties required for development
- Screening for solid dispersions – Uncovering novel tools and techniques
- Displaying case study examples of developing practical solid dispersions

Duk Soon Choi, PhD, Research Leader, **Hoffmann La Roche**

3:15 **Afternoon Networking Break**

4:00 **Interactive Roundtable Best Practice Discussions**
After a jam-packed day of big picture keynotes, panel discussions, case studies, and presentations, the 8th Polymorphism & Crystallization Scientific Forum gives you the chance to meet and brainstorm with small groups of your peers during our interactive roundtable discussions. This is a great opportunity to make valuable contacts from your area of interest, and to deep-dive into the tricky details that you may missed in the course of the day's sessions. **MUST ATTEND!**
Round Tables include:
- Identification and quantitation of forms
- Developing an Integrated approach to solid state development
- Chiral co-crystals
- Strategies for patenting co-crystals

*** Delegates are encouraged to bring their own data or study results or submit them earlier to simon.curtis@iqpc.com*

4:45 **Physical Stability of Salts of Weak Bases in the Solid State**
- Understanding the ability to prepare and isolate a salt form of a drug substance in its solid state, and the stability of that salt form
- Discussing ionic equilibria of acidic and basic substances
- Examining utility of salt-form ionic equilibria in the design of salt-selection studies
- Understanding why the identification of a salt form of an API becomes essential if the characteristics of the free acid or free base are not found to be acceptable
- Affecting salt preparation by the simple mixing of equimolar amounts of ibuprofen and the pharmaceutically acceptable bases deduced to have appropriate pKA values

Gregory Stephenson, PhD, Research Advisor, Preformulations, **Eli Lilly & Company**

5:30 **Improvement of Solid State Chemical Stability Through Form Selection**
- Describing why solid state chemical stability has a significant impact on the quality, safety, and shelf life of drug substances and drug products
- Examining poor stability issues which could be due to molecular properties and/or solid state characteristics
- Improvingsolid state chemical stability by changing solid state characteristics such as crystal packing, Crystallinity, and hygroscopicity through selecting a different polymorph, salt form, or co-crystals
- Examining mechanisms of solid state chemical reactions
- Uncovering solid state characteristics and chemical stability
- Characterizing form selection and improvement of stability

Xiaoming (Sean) Chen, PhD, Drug Product Development & Manufacturing, **OSI Pharmaceuticals, Inc.**

6:15 **Chairman's Closing Remarks and End of Day One**

Main Conference Day 2

Wednesday, October 28, 2009

8:00 **Registration and Coffee**

8:45 **Welcome Address and Chairperson's Opening Remarks**

Characterization and Identification of Drug Forms

9:00 **Salt and Polymorph Selection Strategy Based on the Biopharmaceutical Classification System (BCS) for Early Pharmaceutical Development**

- Providing an overview of Wyeth's drug substance form selection process
- Conveying examples for the integration of form selection with toxicology (TOX) formulation development and pharmacokinetic (PK) assessment
- Outlining rationale for early solid-form selection
- Discussing pre-selection: First evaluation of a solid-state API
- Examining potential advantages with salt and polymorph form selection

M. Sherry Ku, PhD, Senior Director, Pharmaceutical Development, **Wyeth Research**

9:45 **Sharing Best Practices for Polymorphism and Crystallinity Determination in Discovery**

- Understanding and discussing discovery needs for Polymorphism and Crystallinity determination
- Surveying of a project's need for the determination
- Differing needs of discovery vs. development
- Examining observations in solubility determination relating to polymorphism
- Evaluating observation in preclinical toxicology studies relating to Crystallinity
- Summarizing potential techniques suitable for discovery phase

Yun Alelyunas, PhD, Principal Scientist I, Head of Physical Properties Team, **AstraZeneca**

10:30 **Morning Networking Break**

11:15 **The Roles and Significances of Materials Science and Engineering in Modern Drug Development**

Discussing the concept of Materials Science Tetrahedron and its roles in guiding characterization and design of new products or materials

- Identifying the relationship between structure and mechanical properties of crystals
- Optimizing powder compaction properties of drugs by crystal engineering
- Engineering crystals by co-crystallization
- Fundamentals in powder compaction

Changquan Calvin Sun, PhD, Assistant Professor, Department of Pharmaceutics, College of Pharmacy, **University of Minnesota**

12:00 **Current Capabilities in Technologies to Effectively Analyze Impurities in Crystal Forms**

- Identifying and evaluating solid forms and formulations of drug candidates including salt, hydrate and solvate selection and polymorph discovery and evaluation
- Discussing novel tools for the removal of impurities from the final product and generation of thermodynamically stable crystal forms
- Explaining isolation and recrystallization of forms in the thermodynamically most stable polymorph
- Evaluating novel HT technologies to drug product and drug development
- Displaying the power of high throughput systems to discover knowledge that enables pharmaceutical scientists to make more informed and better decisions about product development choices
- Describing the application of novel high throughput physical–chemical technologies to the pharmaceutical discovery and development process

***Speaker and sponsorship opportunities available. Please contact Simon.Curtis@iqpc.com for more information**

12:45 **Networking Luncheon**

Advancing Practices to Increase the Speed of Drug Development

1:45 **Materials Sciences and Particle Engineering: The Interface between Drug Substance and Drug Product**

Particle engineering is a cornerstone of a Pfizer technology strategy aimed at designing drug substance (DS) crystallization/isolation processes which maintain the traditional deliverables of yield, purity, process efficiency combined with a focus on controlling physical properties to create final DSs with rational properties for drug product (DP) design. The ultimate goal is to develop fully integrated DS and DP design to facilitate the progression of projects by either simplifying DP processing (e.g., direct compression vs wet granulation of tablets) or by enabling more sophisticated drug delivery systems (e.g., inhalation).

- Utilizing materials science capabilities to optimize the relationship between the drug substance form, its formation, and formulation
- Discussing particle engineering technologies (e.g. sonocrystallization) to control physical attributes of drug substances
- Evaluating high throughput and science of scale approaches to accelerate form and formulation selection
- Assessing the benefits of integrating of Drug Substance and Drug Product Design to facilitate development programs

Keith R. Horspool, PhD, Senior Director, Materials Science and Oral Products, **Pfizer Inc.**

2:30 **The Role of XRPD in Accelerating Pharmaceutical Phase Identification and Selection**

- Understanding the importance of rapid and early phase selection
- Identifying and analyzing new HT tools and techniques and useful phases of a drug substance, and reduce the risk of failure in drug development
- Detailing fast and economical methods for the identification and evaluation of crystalline phases of drug substances, including neutral API, salts, co-crystals, and hydrates, solvates and polymorphs
- Evaluating the merit of high throughput XRPD as one of the main analytical techniques used for rapid analysis of new pharmaceutical solid
- Discussing tools for managing the large volume of data that is generated

Michael McNevin, PhD, Senior Research Chemist, **Merck Research Laboratories**

3:15 **Afternoon Networking Break**

3:45 **The Continuing Evolution of Solid-state NMR in Pharmaceutical Analysis**

- Highlighting the role of solid-state NMR (SSNMR) as part of an integrated analytical strategy for chemical and pharmaceutical development
- Examining recent advances in the application of SSNMR, including investigations of weak solvates, solid solutions, inclusions, and other phenomena that can occur during API crystallization
- Illustrating the characterization of API and excipient phases in drug product and formulations, including low-dose products, with SSNMR and Raman spectroscopy
- Evaluating detailed structural analysis of polymorphs, salts and co-crystals, including crystal structure solution with SSNMR, powder x-ray diffraction, and computational methods
- Structural characterization of complex systems, including amorphous dispersions, variable hydrates and mixed co-crystal-salt phases

Fred Vogt, PhD, Manager, Analytical Sciences, Chemical Development, **GlaxoSmithKline**

4:30 **The Appearance of New Polymorph During the Development Work Preceding Process Lock**

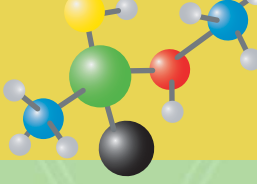
- Discussing optimization of crystallization procedure and range finding experiments
- Describing how a new form overwhelms the previously produced in various procedures, but very "slowly" travels from lab to lab
- Addressing the Challenge: In a limited time find conditions to restore production of thermodynamically stable form, and transfer these conditions to the pilot plant
- Reviewing alternative ways to obtain the stable form, which result in undesirable crystal habit

Elena Kostik, PhD, Principal Scientist, **Synta Pharmaceuticals Inc**

5:15 **End of Conference & Chairperson's Closing Remarks**

Pre-Conference Workshops

Monday, October 26, 2009



A 8:45am – 11:30am *(Registration 8:30am)*

Polymorphism as a Tool for Life Cycle Extension

Extension of propriety protection of drug substances demands intensive search for additional salts and solid-state forms that may secure the market for the originator for additional years beyond normal patent life. This workshop will address both business and scientific issues and solutions regarding polymorphism as a tool for lifecycle extension.

What will be covered:

- Polymorphism should be seen as an opportunity and not a hindrance in the drug substance development
- Changing properties of the drug substance rather than changing formulation
- Using the different properties of the different solid forms to extent life cycle
- Identifying better IP positions in the current environment than formulation patents

***Speaker and sponsorship opportunities available. Please contact Simon.Curtis@iqpc.com for more information**

B 12:00pm – 3:00pm *(Registration 11:30am, Lunch included)*

Understanding the Polymorphism and Crystallization Behavior of Pharmaceuticals

Polymorphism is the phenomenon where a compound can form different crystal structures. It is very important in many areas of industries, and people are aware of the presence of polymorphisms and the properties of the different polymorphs. Different crystalline structures have different physical properties, which can change the use of a compound. The physical properties that may differ from one polymorph to another include: solubility, density, melting point and even color. This workshop will discuss polymorphism of pharmaceuticals with an emphasis on a good understanding of polymorphism in drug development.

What will be covered:

- Introduction to the relevance of polymorphism
- Thermodynamics of polymorphism
- Characterization of polymorphs by various techniques
- Process development based on a good understanding of polymorphism
- Process analytical techniques for the desired polymorph
- Relevant industrial case studies

About your workshop Leaders:
Robert Wenslow, PhD, Associate Scientific Director, **Merck Manufacturing Division**
Yanfeng Zhang, PhD, Senior Research Chemist, **Merck Research Laboratories**
George Zhou, PhD, Principal scientist, **Merck Manufacturing Division**

C 3:30pm – 6:00pm *(Registration 3:00pm)*

Amorphous Dispersions: Modes of Failure, Experimental Characterization, and Stability

This workshop will briefly outline our current understanding of amorphous solid dispersions. Failure modes of single phase amorphous solid dispersions will be discussed in an interactive setting. An overview of available techniques used to detect failure will be highlighted. The attendees are encouraged to scrutinize the utility and liability of each technique and offer their own techniques. Time permitting, physical stability risk assessment will be discussed.

What will be covered:

- Failure modes of dispersions including amorphous-amorphous phase separation & crystallization
- Kinetics and thermodynamics of amorphous solid dispersions
- Characterization of amorphous dispersions
- Physical stability risk assessment

Workshop Leader: Patrick J. Marsac, Ph.D. Phase Definition & Materials Science, **Merck & Co., Inc**

Registration Information

Qualified Pharmaceutical Organizations	Register by August 7, 2009	Register by August 21, 2009	Register by September, 4, 2009	Register by October, 2, 2009	Standard Price
Conference Only	**(Save $400)** $1,199	**(Save $300)** $1,299	**(Save $200)** $1,399	**(Save $100)** $1,499	$1,599
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Workshop Only	$549 each	$549 each	$549 each	$549 each	$549 each

Academic	Standard Price
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Workshop Only	$549 each

Others	Register by September, 4, 2009	Register by October, 2, 2009	Standard Price
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*All access pass includes conference + all workshops.

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